

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:

Judge Dan Aaron Polster

*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).*

**AMENDED RESPONSES AND OBJECTIONS OF DEFENDANTS CEPHALON, INC.,
TEVA PHARMACEUTICALS USA, INC., ACTAVIS LLC, ACTAVIS
PHARMA, INC., AND WATSON LABORATORIES, INC. TO PLAINTIFFS'
CORRECTED SECOND 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' Corrected Second 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.

PLAINTIFFS TRIAL
EXHIBIT
P-04929_00001

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 One 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 “Opioid Products” to the extent it incorporates the defined term “Opioid,” for the reasons stated above with respect to that defined term.

7. 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, and not proportional to the needs of the case.

8. 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.

9. 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.

10. 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.

11. 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.

12. 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.

13. 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 Complaints.

14. 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.

15. 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.

16. The Teva Defendants object to the definition of “Identify” when used with respect to persons, on the ground 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.

17. The Teva Defendants object to the “Instructions” of the Interrogatories as covering the time period “one year prior to the launch of each relevant Opioid Product 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 No. 2 (Dkt. No. 693).

18. 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. 16:

Identify with specificity all facts, documents and data that You plan to rely on in Your defense in this case, including any contention by You that: (a) that the statements at issue were not false or misleading; (b) that You did not direct, control, or make the statements; (c) that Your representations did not cause increase prescribing, use, abuse, misuse or injuries from Opioids; (d) that Your Opioids were not the source of the harms described in the Complaint or experienced by the Jurisdictions; (e) that Your conduct did not cause injury to a public right, as opposed to an individual injury; (f) that the public nuisance described in the Complaint was reasonable or not substantial; and (g) the Jurisdictions were aware or on notice of or failed to mitigate Your conduct and violations of law, as described in the Complaint.

AMENDED RESPONSE TO INTERROGATORY NO. 16:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 16 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. 16 on the ground that it is overly broad and unduly burdensome because it encompasses “all facts, documents and data that [Teva Defendants] plan to rely on in [their] defense,” which may be unknown to the Teva Defendants at this time and will depend in whole or in part on which claims (if any) remain after

dispositive motions are decided and what arguments and evidence Plaintiffs present in their case in chief. The Teva Defendants further object to Interrogatory No. 16 as not reasonably limited as to time or scope. The Teva Defendants further object that the contentions set forth in parts (a) through (g) are vague and ambiguous, including as to the purported “statements,” “representations,” and “conduct” alleged against the Teva Defendants. The Teva Defendants further object to Interrogatory No. 16 on the ground that it is a premature contention interrogatory. The Teva Defendants further object to Interrogatory No. 16 on the ground that the Track One Complaints do not identify or allege any specific false statements by the Teva Defendants. The Teva Defendants further object to Interrogatory No. 16 on the ground that the information sought is not relevant to the claims in the Complaints and is therefore not proportional to the needs of the Track One cases.

Subject to and without waiver of the foregoing objections, the Teva Defendants state that among other facts, documents, and data upon which they may rely are the FDA-approved Full Prescribing Information (“FPI”); Risk Evaluation and Mitigation Strategy (“REMS”), RiskMAPS, and risk mitigation plans applicable to their Schedule II opioid products and their various components; and forthcoming expert reports and testimony in their defense of this case. The Teva Defendants state that, to the extent that this Interrogatory calls for information regarding alleged statements or representations by the Teva Defendants that Plaintiffs claim are actionable, Plaintiffs have not identified any such statements and the Teva Defendants are thus unable to respond to them. The Teva Defendants further state that, to the extent this Interrogatory calls for information relating to sources of harm experienced by the Jurisdictions, injury to the Jurisdictions, or the Jurisdictions’ response to allegations in the Complaint, Plaintiffs have acknowledged multiple intervening, supervening, and/or superseding causes between the Teva Defendants’ conduct and

any of the Jurisdictions' injuries alleged in the Complaints in Plaintiffs' own documents and through the testimony of Plaintiffs' own witnesses, and the Teva Defendants intend to rely on facts, documents, and data associated with them.

INTERROGATORY NO. 17:

Identify all prescriptions of Opioids in the Jurisdictions that were medically unnecessary or inappropriate, including the criteria applied to identify such prescriptions.

RESPONSE TO INTERROGATORY NO. 17:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 17 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. 17 as not reasonably limited as to time or scope. The Teva Defendants further object to Interrogatory No. 17 on the ground that Plaintiffs request the Teva Defendants to develop Plaintiffs' affirmative case. The Teva Defendants further object to Interrogatory No. 17 on the ground that it is a premature contention interrogatory. The Teva Defendants further object to Interrogatory No. 17 on the ground that the information sought is not relevant to the claims in the Complaints and is therefore not proportional to the needs of the Track One cases.

Subject to and without waiver of the foregoing objections, the Teva Defendants state that they are not aware of any medically unnecessary or inappropriate prescriptions of their Schedule II opioid products in the jurisdictions at issue, and Plaintiffs, who have the burden of proof, have identified none. Prescribing decisions are the result of medical judgments that depend on the

various facts and circumstances of any given patient. Answering further, the Teva Defendants will produce prescription data from IQVIA Holdings, Inc. f/k/a IMS Heath for their Schedule II opioid products.

INTERROGATORY NO. 18:

Identify with specificity all facts, documents and data that concern any statements made or disseminated by Your employees or agents to Prescribers, patients, and payors in the Jurisdictions that the Complaint identifies as misrepresentations, including that: (a) Opioids are not addictive, the risk of addiction is low, pain patients will not become addicted to Opioids, and that Your Opioids are steady state or less addictive or safer than other Opioids; (b) patients may experience pseudoaddiction; (c) the use of risk mitigation strategies (including but not limited to risk assessment instruments, patient education and contracts, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, and pill counts) can help to reduce, assess, or manage the risk of addiction; (d) Prescribers can titrate doses of Opioids to achieve pain relief or that there is no ceiling dose for Opioids, or failed to disclose the risks of addiction, abuse, and overdose increase at higher doses; (e) patients on Opioids long-term can be tapered from Opioids without disclosing the risks of withdrawal, or that Your Opioids cause less severe or no withdrawal symptoms; (f) Opioids improve patients' function and quality of life or reduce Chronic Pain; (g) abuse-deterrent formulations prevent or reduce abuse, addiction, or misuse of Opioids, cannot be tampered with or defeated, and did not disclose the risk of oral abuse or transition to heroin; and (h) Opioids are safer than nonsteroidal anti-inflammatory drugs (or "NSAIDs") or discussing the risks of NSAIDs. Include in your response the names of all individuals and entities involved in such activities, the individuals or entities to which the activities were directed, and the dates of such activities.

RESPONSE TO INTERROGATORY NO. 18:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 18 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. 18 on the ground that it is overly broad and unduly burdensome because it encompasses “all facts, documents and data that concern any statements made or disseminated by Your employees or agents to Prescribers, patients, and payors in the Jurisdictions that the Complaint identifies as misrepresentations,” which may be unknown to the Teva Defendants at this time. The Teva Defendants further object to Interrogatory No. 18 as not reasonably limited as to time or scope. The Teva Defendants further object to Interrogatory No. 18 on the ground that Plaintiffs request the Teva Defendants to develop Plaintiffs’ affirmative case. The Teva Defendants further object to Interrogatory No. 18 on the ground that it is a compound interrogatory and that subparts (a) through (h) exceed Plaintiffs’ allotted number of interrogatories per CMO 1 such that a response is not required. The Teva Defendants further object to Interrogatory No. 18 on the ground that the information sought is not relevant to the claims in the Complaints and is therefore not proportional to the needs of the Track One cases.

Subject to and without waiver of the foregoing objections, the Teva Defendants state that they do not promote and have never promoted their generic opioid products. With respect to their branded opioid products, the Teva Defendants’ policy and practice is to promote only consistent

with the applicable FDA-approved labels. The Teva Defendants are not aware of any statements made or disseminated to any prescriber, patient, or payor in the jurisdictions at issue as set forth in Interrogatory No. 18, and Plaintiffs, who have the burden of proof, have identified none.

INTERROGATORY NO. 19:

Identify all Documents related to or reflecting any and every Communication, including but not limited to meetings, telephone calls, and correspondence, with any Ohio or federal legislator, agency, lobbyists, governmental body or medicals association with respect to: (1) the coverage of Opioids, including the coverage of abuse-deterrent formulations; (2) the obligation to prescribe Opioids, including the Pain Patient’s Bill of Rights, or limitations on prescribing, Opioids; (3) Pain as a Fifth Vital Sign; (4) patient satisfaction standards with respect to the treatment of pain; (5) the scheduling of Opioids; (6) warnings or indications for Your Opioids or Opioids generally; (7) the quota for Your Opioids. Include in Your response the names of all individuals and entities involved in such Communications, the individuals or entities to which the Communications were directed, and the dates of such Communications.

AMENDED RESPONSE TO INTERROGATORY NO. 19:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 19 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. 19 on the ground that it is overly broad and unduly burdensome because it encompasses “any and every Communication, including but not limited to meetings, telephone calls, and correspondence, with any Ohio or

federal legislator, agency, lobbyists, governmental body or medicals [sic] association,” which may be unknown to the Teva Defendants at this time. The Teva Defendants further object to Interrogatory No. 19 as not reasonably limited as to time or scope. The Teva Defendants further object that the contentions set forth in parts (1) through (7) are overly broad, unduly burdensome, vague, and ambiguous. The Teva Defendants further object to Interrogatory No. 19 on the ground that it is a compound interrogatory and that subparts (1) through (7) exceed Plaintiffs’ allotted number of interrogatories per CMO 1 such that a response is not required. The Teva Defendants further object to Interrogatory No. 19 on the ground that the information sought is not relevant to the claims in the Complaints and is therefore not proportional to the needs of the Track One cases.

Subject to and without waiver of the foregoing objections, and pursuant to Federal Rule of Civil Procedure 33(d), the Teva Defendants refer Plaintiffs to documents that the Teva Defendants have already produced in this litigation. Those documents contain the information responsive to Interrogatory No. 19 and the burden of ascertaining the requested information from those documents is the same for both parties.

Subject to and without waiver of the foregoing objections, the Teva Defendants further state that they have routinely communicated with the FDA regarding various topics, including the labeled warnings and indications for the Teva Defendants’ opioid products. These communications, which are stored in the Teva Defendants’ SAGE database, have been produced at TEVA_MDL_A_00033947–TEVA_MDL_A_00320996, TEVA_MDL_A_00419131–TEVA_MDL_A_00454746, and TEVA_MDL_A_00565064–TEVA_MDL_A_00566138, and TEVA_MDL_A_00568762–TEVA_MDL_A_00570134.

The Teva Defendants further state that they had various communications with the FDA and federal legislators relating to abuse-deterrent opioids, including 1) various communications with

the FDA regarding the Teva Defendants' application and FDA's approval of an abuse-deterrent opioid, Vantrela ER, 2) various communications with members of Congress regarding the Teva Defendants' support of the Curb Opioid Misuse and Advancing Technology (COMBAT) Act, and 3) submission of a letter to the FDA Division of Dockets and Management regarding FDA's Draft Guidance for Industry on Abuse-Deterrent Opioids Evaluation and Labeling: Availability, which was produced at TEVA_MDL_A_01088619.

The Teva Defendants further state that they have routinely communicated with the DEA regarding the Teva Defendants' quota for Schedule II substances, including opioid products. Documents containing such communications can be found at TEVA_MDL_A_13733966 – TEVA_MDL_A_13738181.

The Teva Defendants further state that, after a reasonable search, they are unable to identify any communications with legislators, agencies, governmental bodies, or medical associations in Ohio with respect to the subject matter of this Interrogatory. The Teva Defendants further state that, after a reasonable search, they are unable to identify any communications with federal legislators, agencies, lobbyists, governmental bodies or medical associations related to the obligation to prescribe Opioids, including the Pain Patient's Bill of Rights, or limitations on prescribing, Opioids; Pain as a Fifth Vital Sign; or patient satisfaction standards with respect to the treatment of pain.

INTERROGATORY NO. 20:

Identify all Documents related to or reflecting any and every Communication, including but not limited to meetings, telephone calls, and correspondence, with any entity, whether public or private, that set formularies for, insured, paid or processed health care claims with respect to: the coverage, formulary status, authorization requirements, pricing, or discounts of Your Opioids by payors in or covering Ohio consumers. Include in Your response the names of all individuals

and entities involved in such Communications, the individuals or entities to which the Communications were directed, and the dates of such Communications.

AMENDED RESPONSE TO INTERROGATORY NO. 20:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 20 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. 20 on the ground that it is overly broad and unduly burdensome because it encompasses “any and every Communication, including but not limited to meetings, telephone calls, and correspondence, with any entity, whether public or private, that set formularies,” which may be unknown to the Teva Defendants at this time. The Teva Defendants further object to Interrogatory No. 20 as not reasonably limited as to time or scope. The Teva Defendants further object to Interrogatory No. 20 to the extent it seeks documents that are publicly available and/or equally available to Plaintiffs as to the Teva Defendants. The Teva Defendants further object to Interrogatory No. 20 on the ground that the information sought is not relevant to the claims in the Complaints and is therefore not proportional to the needs of the Track One cases.

Subject to and without waiver of the foregoing objections, the Teva Defendants state that, based on a reasonable investigation, the Teva Defendants’ communications responsive to Interrogatory No. 20 are not stored in a central location; however, documents containing information responsive to Interrogatory 20 have been produced in this litigation. The Teva

Defendants believe that documents containing the information responsive to Interrogatory No. 20 are likely to be found in the custodial files of Deborah Bearer, Chuck DeWildt, Doug Boothe, and Nathalie Leitch. Pursuant to Federal Rule of Civil Procedure 33(d), the Teva Defendants refer Plaintiffs to those documents, which contain the information responsive to Interrogatory No. 20, and state that the burden of ascertaining the requested information from those documents is the same for both parties.

INTERROGATORY NO. 21:

Identify with specificity all facts, documents and data that concern or relate to when and how You became aware of excessive or improper prescribing or use of Opioids, and the incidence of addiction, diversion, misuse, abuse, and overdose in the Jurisdictions and nationally, and state the dates on which You became aware of such facts and the source of such facts.

AMENDED RESPONSE TO INTERROGATORY NO. 21:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 21 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. 21 on the ground that it is overly broad and unduly burdensome because it encompasses “all facts, documents and data that concern or relate to when and how [Teva Defendants] became aware” of various issues, which may be unknown to the Teva Defendants at this time. The Teva Defendants further object to Interrogatory No. 21 as not reasonably limited as to time or scope. The Teva Defendants further object to Interrogatory No. 21 on the ground that the term “aware” is vague, ambiguous, and overly

broad to the extent it purports to encompass information that the Teva Defendants did not control or sponsor. The Teva Defendants further object to Interrogatory No. 21 on the ground that it is premature at this stage in the litigation. The Teva Defendants further object to Interrogatory No. 21 on the ground that the information sought is not relevant to the claims in the Complaints and is therefore not proportional to the needs of the Track One cases.

Subject to and without waiver of the foregoing objections, the Teva Defendants state that information and warnings are reflected in the FDA-approved FPI, REMS, and RiskMAPs for their Schedule II opioid products. The Teva Defendants have at all times engaged in appropriate surveillance activities through, among other things, risk management programs implemented with oversight and approval of the FDA and suspicious order monitoring programs implemented in accordance with directives of the DEA and under the DEA's supervision. Numerous documents relating to these efforts have been produced in this litigation, including the ACTIQ® and FENTORA® RiskMAPs, which have been produced at TEVA_CHI_00028341 and TEVA_CHI_0049296, as well as quarterly reports submitted to the FDA that discuss issues related to misuse and diversion of Fentora, which have been produced at:

- TEVA_MDL_A_10313692;
- TEVA_MDL_A_10315736;
- TEVA_MDL_A_10316841;
- TEVA_MDL_A_10422175;
- TEVA_MDL_A_10497915;
- TEVA_MDL_A_10502990;
- TEVA_MDL_A_10510166;
- TEVA_MDL_A_10552587;

- TEVA_MDL_A_10552668;
- TEVA_MDL_A_10562042;
- TEVA_MDL_A_10568672;
- TEVA_MDL_A_10598611;
- TEVA_MDL_A_00652142;
- TEVA_MDL_A_10621200;
- TEVA_MDL_A_10635646;
- TEVA_MDL_A_10641276;
- TEVA_MDL_A_10645019;
- TEVA_MDL_A_10657239; and
- TEVA_MDL_A_10666318.

Additional documents related to the Teva Defendants' surveillance efforts, such as documents relating to Cephalon's Fentanyl Product Safety Group, and documents relating to the issues described in Interrogatory 21 have been produced in the course of this litigation. Pursuant to Federal Rule of Civil Procedure 33(d), the Teva Defendants refer Plaintiffs to those documents, which contain the information responsive to Interrogatory No. 21, and state that the burden of ascertaining the requested information from those documents is the same for both parties.

INTERROGATORY NO. 22:

Do You contend that there were intervening or supervening or superseding causes between Your conduct and any of the Jurisdictions' injuries alleged in the Second Amended Complaint? If so, please identify each such intervening or supervening or superseding cause, including but not limited to the name and address of any individual who You contend is such a cause, how that

person or entity acted as such a cause, and each and every fact that supports Your contention that each such individual or entity is such a cause.

RESPONSE TO INTERROGATORY NO. 22:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants further object to Interrogatory No. 22 as not reasonably limited as to time or scope. The Teva Defendants further object to Interrogatory No. 22 on the ground that it is a premature contention interrogatory. The Teva Defendants further object to Interrogatory No. 22 on the ground that it prematurely calls for expert testimony. The Teva Defendants further object to Interrogatory No. 22 to the extent that it implies that the Teva Defendants' conduct caused any of the jurisdictions' injuries alleged in the Complaints. The Teva Defendants further object to Interrogatory No. 22 on the ground that the information sought is not relevant to the claims in the Complaints and is therefore not proportional to the needs of the Track One cases.

Subject to and without waiver of the foregoing objections, the Teva Defendants state that Plaintiffs have acknowledged multiple intervening, supervening, and/or superseding causes between the Teva Defendants' conduct and any of the jurisdictions' injuries alleged in the Complaints in Plaintiffs' own documents and through the testimony of Plaintiffs' own witnesses.

INTERROGATORY NO. 23:

Do You contend that no prescriber, patient, payor or consumer in or affecting any of the Jurisdictions was influenced by Your marketing of Opioids? If so, state in detail the basis of that contention, all factual support therefore, the purpose of Your marketing of Opioids, and each and every reason You continued to market Opioids despite such lack of influence. If You do not so contend, identify those prescribers, patients, payors or consumers in or affecting the Jurisdictions who were influenced by Your marketing.

RESPONSE TO INTERROGATORY NO. 23:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 23 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. 23 on the ground that the term “influence” is vague, ambiguous, and overly broad to the extent it purports to encompass behavior or actions taken by a third party. The Teva Defendants further object to Interrogatory No. 23 as not reasonably limited as to time or scope. The Teva Defendants further object to Interrogatory No. 23 on the ground that Plaintiffs request Teva Defendants to develop Plaintiffs’ affirmative case. The Teva Defendants further object to Interrogatory No. 23 on the ground that it is a premature contention interrogatory with respect to matters as to which Plaintiffs have the burden of proof. The Teva Defendants further object to Interrogatory No. 23 on the ground that it prematurely calls for expert testimony. The Teva Defendants further object to Interrogatory No. 23 on the ground that the information sought is not relevant to the claims in the Complaints and is therefore not proportional to the needs of the Track One cases.

INTERROGATORY NO. 24:

Identify all Prescribers to whom You ceased Marketing Your Opioids because Your Marketing was not having an impact.

RESPONSE TO INTERROGATORY NO. 24:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 24 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. 24 on the ground that it is premature at this stage in the litigation. The Teva Defendants further object to Interrogatory No. 24 on the ground that the phrase “having an impact” is vague and ambiguous. The Teva Defendants further object to Interrogatory No. 28 to the extent that the scope is not limited to the jurisdictions at issue. The Teva Defendants further object to Interrogatory No. 24 on the ground that the information sought is not relevant to the claims in the Complaints and is therefore not proportional to the needs of the Track One cases.

Subject to and without waiver of the foregoing objections, the Teva Defendants state they do not detail or otherwise promote their generic opioid products to prescribers, have not actively promoted ACTIQ® since September 2006, and no longer promote FENTORA®. Promotion is entirely legal and appropriate and can be an important vehicle for communicating FDA-approved risk and benefit information about prescription drugs. According to the Teva Defendants’ policies, when the Teva Defendants promoted their branded opioid products, they did so only when it was reasonable to believe that the prescriber’s practice included patients that could be treated with a product for an on-label indication and, based upon the nature of the prescriber’s practice, it was likely that he or she would treat the on-label condition. To the extent that Interrogatory No. 24 is intended to suggest that the Teva Defendants fraudulently marketed to persuade prescribers to write medically unnecessary or inappropriate prescriptions, the Teva Defendants expressly deny

that suggestion and state that Plaintiffs have failed to identify any such medically unnecessary or inappropriate prescriptions.

INTERROGATORY NO. 25:

Identify and provide salary and bonus information for all of Your former or current Employees who were or are engaged in Marketing to Prescribers or ensuring compliance with applicable laws, policies, and procedures in the Jurisdictions, including all Employees who (1) developed, implemented, reported on, or supervised Marketing Activities that included or targeted Prescribers in the Jurisdictions; (2) gave, assisted, or supervised speaking programs, CME, or other promotional events, programs, or meetings conducted in the Jurisdictions or attended by Prescribers from the Jurisdiction; (3) were responsible for ensuring compliance with state and federal laws and regulations regarding the Marketing of Opioids, any settlement, corporate integrity, consent judgment, or plea agreement and/or the compliance with laws and regulations related to preventing diversion of controlled substances. Include in your response the titles and dates of employment for all such individuals.

AMENDED RESPONSE TO INTERROGATORY NO. 25:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 25 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. 25 as not reasonably limited as to time or scope. The Teva Defendants object to Interrogatory No. 25 on the ground that it is vague, ambiguous, and overly broad because it requires the identification of “all of [Teva

Defendants'] former or current Employees who were or are engaged in Marketing to Prescribers or ensuring compliance with applicable laws, policies, and procedures in the Jurisdictions," regardless of whether these individuals were involved with marketing of the products at issue. The Teva Defendants further object to Interrogatory No. 25 on the ground that the information sought is not relevant to the claims in the Complaints and is therefore not proportional to the needs of the Track One cases.

Subject to and without waiver to the foregoing objections, the Teva Defendants state that they did not promote generic opioid products, and marketed only pricing and availability of generic opioids. The Teva Defendants further state that the compensation paid to employees within the Teva Marketing and DEA Compliance Departments varied by time, role, and region. Employees of the Teva Marketing and DEA Compliance Departments received base salary commensurate with each employee's position and seniority. These employees were further eligible for incentive compensation through at various times, the Cephalon Performance Incentive Plan, the Cephalon Management Incentive Compensation Program, and the Teva Bonus Program. These programs set general parameters for employees' eligibility for incentive compensation and permitted eligible employees to receive merit-based incentive compensation based on their performance evaluations, which included a number of factors that were set by the employee's supervisor. Certain of these factors that were set by certain supervisors may, at times, have included sales or revenue goals for specific products within that employee's portfolio. In addition, around 2009 as part of the Management Incentive Compensation Program, the Cephalon Marketing Department apportioned 10% of potential incentive compensation with fulfilling objectives that required employees to attend Compliance training and adhere to Compliance-related policies. These Documents that

describe the parameters of certain incentive compensation plans for employees within the Teva Marketing and DEA Compliance Departments can be found at

- TEVA_MDL_A_00552245;
- TEVA_MDL_A_06883373;
- TEVA_MDL_A_06659213;
- TEVA_MDL_A_06660597;
- TEVA_MDL_A_06663269; and
- TEVA_MDL_A_09622006.

Employees within the Teva-Acquired Actavis Marketing and DEA Compliance Departments received base salary and were eligible for incentive compensation, but the compensation paid to these employees varied by time, role, and region. Generally, the incentive compensation component for these employees was based on both individual performance and the performance of the company. Each employee's individual performance was measured by a number of factors and was not tied to sales of particular products or revenue generated from the employee's function. Certain employees of the Teva-Acquired Actavis Entities, including employees in their Marketing and DEA Compliance Departments, also were eligible for long-term incentive compensation. Documents that describe the parameters of certain of the Teva-Acquired Actavis Entities' incentive compensation plans that the Teva Defendants understand to apply to these employees can be found at:

- Acquired_Actavis_01169588;
- Acquired_Actavis_01169598;
- Acquired_Actavis_01169602;
- Acquired_Actavis_01170714;

- Acquired_Actavis_01170734;
- Acquired_Actavis_01183766;
- Acquired_Actavis_01865511; and
- Acquired_Actavis_01865066.

Numerous additional documents in the Teva Defendants' document productions include individual performance evaluations, discussions of compensation, and other information responsive to Interrogatory No. 25, but these documents are not centrally located in the Teva Defendants' document productions. Pursuant to Federal Rule of Civil Procedure 33(d), the Teva Defendants refer Plaintiffs to these documents. The burden of ascertaining the requested information from those documents is the same for both parties.

INTERROGATORY NO. 26:

Identify all Scientific Research and any other data or information on which You relied to make or cause to be made Marketing statements described in the Complaint, including: (1) improvement in patient function and/or quality of life while on Opioids; (2) the risk and/or prevalence of addiction, abuse, misuse, or diversion of Opioids, including, but not limited to, after OxyContin's 2010 reformulation; (3) the use of risk mitigation strategies (including but not limited to risk assessment instruments, patient education and contracts, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, and pill counts) to reduce, assess, or manage the risk of addiction; (4) the concept of pseudoaddiction; (5) that withdrawal symptoms could be managed or prevented while discontinuing Opioids; (6) the safety or risks of increasing patients' dose; and (7) safety or efficacy comparisons of Opioids to other pain treatments, including NSAIDs, or Your Opioids versus other Opioids. Include in Your response the identification of any Scientific Research that Your sales representatives

provided or described, or were authorized to provide or describe, to Prescribers or payors, and the time period during which such Research was used.

AMENDED RESPONSE TO INTERROGATORY NO. 26:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 26 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. 26 as not reasonably limited as to time or scope. The Teva Defendants further object to Interrogatory No. 26 to the extent that it is duplicative of information requested in Interrogatory No. 2. The Teva Defendants further object to Interrogatory No. 26 on the ground that it is a compound interrogatory and that subparts (1) through (7) exceed Plaintiffs’ allotted number of interrogatories per CMO 1 such that a response is not required. The Teva Defendants further object to Interrogatory No. 26 on the ground that the information sought is not relevant to the claims in the Complaints and is therefore not proportional to the needs of the Track One cases.

Subject to and without waiver of the foregoing objections, the Teva Defendants state that the information about the clinical studies the Teva Defendants relied on in making promotional statements regarding ACTIQ® and FENTORA® are included in the NDA files that the Teva Defendants have produced to Plaintiffs. Answering further, a list of sources cited in the Teva Defendants’ submissions of ACTIQ® and FENTORA® marketing materials to the FDA Center for Drug Evaluation and Research (formerly the Division of Drug Marketing, Advertising and

Communications) for FDA's approval is attached as Appendix B. The documents in which these sources are cited have been produced in this litigation. To the extent that additional marketing materials contain citations to sources that are not included in Appendix B, pursuant to Federal Rule of Civil Procedure 33(d), the Teva Defendants refer Plaintiffs to those documents, which contain the information responsive to Interrogatory No. 26, and state that the burden of ascertaining the requested information from those documents is the same for both parties.

The Teva Defendants further 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®, and that the Teva Defendants did not promote any generic opioids products.

INTERROGATORY NO. 27:

State with specificity, each year by year, for the Jurisdictions, the State of Ohio, and nationally, respectively, all transactional-level cost and expense data relating to sales (including staffing), promotional, marketing, advertising, and educational expenditures for each of your Opioids. For each transaction, identify the type of promotional, marketing and advertising expenditure incurred (e.g., journal advertising, conferences, continuing education, speakers, copayment coupons, reprints, etc.). For each transaction, identify whether it was undertaken for, or allocated to, a specific drug, a combination of drugs, or corporate imaging. To the extent a transaction was allocated in whole or part to one or more of your Opioids, identify the product(s) and the amounts allocated.

RESPONSE TO INTERROGATORY NO. 27:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 27 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. 27 as not reasonably limited as to time or scope. The Teva Defendants further object to Interrogatory No. 27 on the ground that the information sought is not relevant to the claims in the Complaints and is therefore not proportional to the needs of the Track One cases.

Subject to and without waiver of the foregoing objections, the Teva Defendants will produce non-privileged documents containing information determined to be responsive to this Interrogatory to the extent that they are within the Teva Defendants’ possession, custody, and control, and can be located through a reasonable search.

INTERROGATORY NO. 28:

Provide distribution, readership, viewership, and attendance information for your Marketing Activities (by year), including the total number of website views and website views associated with the Jurisdictions, distribution of each publication attributed to You in the Complaint or any other publication You developed concerning Opioids, and attendance or viewership for each CME or other program offered in or to the Jurisdiction. Provide such numbers for the Jurisdictions or, if not available, nationally.

RESPONSE TO INTERROGATORY NO. 28:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 28 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. 28 as not reasonably limited as to time or scope. The Teva Defendants further object to Interrogatory No. 28 on the ground that it is vague, ambiguous, and overly broad because it requires information about “distribution, readership, viewership, and attendance information for [Teva’s] Marketing Activities,” regardless of whether these “Marketing Activities” involved the products at issue. The Teva Defendants further object to Interrogatory No. 28 to the extent it seeks documents and information that are not available to the Teva Defendants and may be in the possession of third parties. The Teva Defendants further object to Interrogatory No. 28 to the extent that it seeks documents and information that are publicly available and/or equally available to Plaintiffs as to the Teva Defendants. The Teva Defendants further object to Interrogatory No. 28 to the extent that the scope is not limited to the jurisdictions at issue. The Teva Defendants further object to Interrogatory No. 28 on the ground that the information sought is not relevant to the claims in the Complaints and is therefore not proportional to the needs of the Track One cases.

Subject to and without waiver of the foregoing objections, the Teva Defendants will produce non-privileged documents containing information determined to be responsive to this Interrogatory to the extent that they are within the Teva Defendants’ possession, custody, and control, and can be located through a reasonable search.

INTERROGATORY NO. 29:

Specify the number of and revenue from prescriptions of each of Your Opioids, nationally, in the State of Ohio, and in the Jurisdictions, in each year. Include in your response how many of those prescriptions and what proportion of that revenue was for medically necessary or appropriate prescriptions.

RESPONSE TO INTERROGATORY NO. 29:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 29 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. 29 as not reasonably limited as to time or scope. The Teva Defendants further object to Interrogatory No. 29 to the extent that it is duplicative of information requested in Request for Production No. 3. The Teva Defendants further object to Interrogatory No. 29 to the extent that the scope is not limited to the jurisdictions at issue. The Teva Defendants further object to Interrogatory No. 29 on the ground that the information sought is not relevant to the claims in the Complaints and is therefore not proportional to the needs of the Track One cases.

Subject to and without waiver of the foregoing objections, the Teva Defendants will produce non-privileged documents containing information determined to be responsive to this Interrogatory to the extent that they are within the Teva Defendants’ possession, custody, and control, and can be located through a reasonable search.

INTERROGATORY NO. 30:

Identify all individuals and entities You have interviewed or from whom You have obtained testimony or from whom You have obtained or attempted to obtain Documents, Communications, or other information that tends to support, contradict, concern, or relate to the allegations in the Complaint or Your defenses. Include in your response a description of the Documents, Communication, or information obtained from such individuals or entities.

RESPONSE TO INTERROGATORY NO. 30:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 30 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 because it encompasses "all individuals and entities" the Teva Defendants have interviewed or obtained testimony or documents from that "relate to the allegations in the Complaint or [the Teva Defendants'] defenses" no matter how tangential the relation to the claims and/or defenses. The Teva Defendants further object to Interrogatory No. 30 as not reasonably limited as to time or scope. The Teva Defendants further object to Interrogatory No. 30 on the ground that Plaintiffs request the Teva Defendants to develop Plaintiffs' affirmative case. The Teva Defendants further object to Interrogatory No. 30 to the extent that it seeks the production of documents and communications protected by the attorney-client privilege and/or work product doctrines. The Teva Defendants further object to Interrogatory No. 30 on the ground that the information sought is not relevant to the claims in the Complaints and is therefore not proportional to the needs of the Track One cases.

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. Answering further, the Teva Defendants state that they have and/or will obtain testimony from certain witnesses identified by Plaintiffs in connection with fact and Rule 30(b)(6) depositions.

INTERROGATORY NO. 31:

Identify all vendors (including but not limited to public relations firms, lobbyists, analysts who reviewed or analyzed data regarding potential abuse or diversion of Opioids) You have retained for purposes relating to Opioids; and identify for each vendor, the purpose for which each

vendor was retained, each project or undertaking on which each vendor worked; the remuneration provided; and the reasons for termination of their retention, if applicable.

RESPONSE TO INTERROGATORY NO. 31:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 31 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. 31 as not reasonably limited as to time or scope. The Teva Defendants further object to Interrogatory No. 31 as vague, ambiguous, and overly broad to the extent it seeks information from “vendors” that are outside of the Teva Defendants’ control. The Teva Defendants further object to Interrogatory No. 31 on the ground that the information sought is not relevant to the claims in the Complaints and is therefore not proportional to the needs of the Track One cases.

Subject to and without waiver of the foregoing objections, the Teva Defendants will produce non-privileged documents containing information determined to be responsive to this Interrogatory to the extent that they are within the Teva Defendants’ possession, custody, and control, and can be located through a reasonable search.

Dated: March 4, 2019

Respectfully submitted,

/s/ Steven A. Reed
Steven A. Reed
Rebecca Hillyer
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street

Philadelphia, PA 19103-2921
Phone: (215) 963-5000
Fax: (215) 963-5001
Email: steven.reed@morganlewis.com
Email: rebecca.hillyer@morganlewis.com

Wendy West Feinstein
MORGAN, LEWIS & BOCKIUS LLP
One Oxford Centre, 32nd Fl.
Pittsburgh, PA 15219-6401
Phone: (412) 560-7455
Fax: (412) 560-7001
Email: wendy.feinstein@morganlewis.com

*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:

Liaison Counsel for Plaintiffs:

Peter Henry Weinberger
SPANGENBERG SHIBLEY & LIBER LLP
1001 Lakeside Avenue East, Suite 1700
Cleveland, OH 44114-1149
(216) 696-3232
pweinberger@spanglaw.com

Steven J. Skikos
SKIKOS CRAWFORD SKIKOS & JOSEPH
One Sansome Street, Suite 2830
San Francisco, CA 94104
(415) 546-7300
sskikos@skikoscrawford.com

Troy A. Rafferty
LEVIN PAPANTONIO THOMAS MITCHELL RAFFERTY & PROCTOR PA
316 S. Baylen Street, Suite 600
Pensacola, FL 32502
(805) 435-7000
trafferty@levinlaw.com

Liaison Counsel for Defendants:

Mark Cheffo, Esq.
Quinn Emanuel
51 Madison Avenue
New York, NY 10010
markcheffo@quinnemanuel.com

Carol Rendon, Esq.
Baker Hostetler
Key Tower, 127 Public Square
Cleveland, OH 44114
crendon@bakerlaw.com

Enu Mainigi, Esq.
Williams & Connolly

725 Twelfth Street, NW.
Washington, DC 20005
emainigi@wc.com

Shannon McClure, Esq.
ReedSmith
Three Logan Square
1717 Arch Street, Suite 3100
Philadelphia, PA 19103
smcclure@reedsmith.com

Geoffrey E. Hobart, Esq.
Covington & Burling
One CityCenter
850 Tenth Street, NW.
Washington, DC 20001
ghobart@cov.com

Kaspar Stoffelmayr, Esq.
Bartlit Beck
54 West Hubbard Street, Ste 300
Chicago, IL 60654
Kaspar.stoffelmayr@bartlit-beck.com

Tina Tabacchi, Esq.
Jones Day
77 West Wacker Drive
Chicago, IL 60601
tmtabacchi@jonesday.com

Tyler Tarney, Esq.
Gordon & Rees
41 S. High Street, Suite 2495
Columbus, OH 43215
ttarney@grsm.com

/s/ Wendy West Feinstein
Wendy West Feinstein

APPENDIX A

Name	Title	Subject Matter
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

Name	Title	Subject Matter
Chuck DeWildt	Former Teva Pharmaceuticals Vice President, Regional Payers	Sales training
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
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
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
Susan Larijani	Teva Pharmaceuticals Senior Director, Medical Information	Medical information requests

Name	Title	Subject Matter
Nathalie Leitch	Teva Senior Vice President	Generic opioid products
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
David Myers	Teva Pharmaceuticals Senior Manager, Product Marketing	Marketing issues
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
Tom Napoli	Former Actavis Associate Director, Controlled Substance Compliance	DEA compliance
Arvind Narayana	Former Teva Pharmaceuticals Senior Global Medical Director	Research and development

Name	Title	Subject Matter
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
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 practice
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
Jamie Warner	Teva Pharmaceuticals Vice President, Global Labeling and Brand Management	Product labeling

Name	Title	Subject Matter
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

APPENDIX B

<p>ACTIQ and FENTORA REMS Education Program. Available at: http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM264065.pdf. Accessed October 7, 2011.</p>
<p>Ahles T, Ruckdeschel J, Blanchard E. Cancer-related pain. I. Prevalence in an outpatient setting as a function of stage of disease and type of cancer. <i>J Psychosom Res.</i>1984;28:115-119.</p>
<p>American Academy of Pain Medicine, American Pain Society, American Society of Addiction Medicine. Definitions related to the use of opioids for the treatment of pain. Available at: http://opi.areastematicas.com/generalidades/definicionesopiaceos.AAPM.pdf. Accessed October 24, 2011.</p>
<p>American Pain Foundation, Pain Notebook.</p>
<p>American Pain Foundation. Breakthrough pain survey: executive summary. Prepared December 14, 2009. Available at: http://www.painfoundation.org/learn/pain-conditions/btcp/survey-executivesummary.pdf. Accessed February 18, 2011</p>
<p>American Pain Society. Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain. 5th ed. Glenview, Ill: American Pain Society;2003.</p>
<p>American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition-Text Revision. Washington, DC: American Psychiatric Association;2000:198-199.</p>
<p>American Society of Anesthesiologists. Comparing the duration of action of opioids, sedatives and reversal agents. Available at: http://www.asahq.org/clinical/toolkit/CS&20Hand1.doc. Accessed February 12, 2011.</p>
<p>Ashburn MA, Slevin KA, Messina J, Xie F. The efficacy and safety of fentanyl buccal tablet compared with immediate-release oxycodone for the management of breakthrough pain in opioid-tolerant patients with chronic pain. <i>Anesth Analg.</i> 2011;112:693–702.</p>
<p>Assessment of Cancer Pain. International Association for the Study of Pain Web site. Available at:http://www.iasp-pain.org/AM/Template.cfm?Section=Home&Template=/CM/ContentDisplay.cfm&ContentID=7187. Accessed March 31, 2010.</p>
<p>Beck AT, Epstein N, Brown G, Steer RA. An inventory for measuring clinical anxiety: psychometric properties. <i>J Consult Clin Psychol.</i> 1988;56(6):893-897.</p>
<p>Beck AT, Ward CH, Mendelson M, Mock J, Erbaugh J. An inventory for measuring depression. <i>Arch Gen Psychiatry.</i> 1961;4:561-571.</p>
<p>Becker N, Bondegaard Thomsen A, Olsen AK, Sjogren P, Bech O, Eriksen J. Pain epidemiology and health related quality of life in chronic non-malignant pain patients referred to a Danish multidisciplinary pain center. <i>Pain.</i> 1997;73:393-400.</p>

Bennett D, Burton A. Consensus panel recommendations for the assessment and management of breakthrough pain, PART 1 ASSESSMENT. P&T. 2005;30(5):296-301. (This article was supported by an educational grant from Cephalon, Inc.)
Bennett D, Burton AW, Fishman S, et al. Consensus panel recommendations for the assessment and management of breakthrough pain, PART II MANAGEMENT. P&T. 2005;30:354-361.
Bennett D, Burton AW, Fishman S, et al. Consensus panel recommendations for the assessment and management of breakthrough pain. Part I—assessment. Pharmacol Ther. 2005;30:296-301.
Bennett D, Burton AW, Fishman S, et al. Consensus panel recommendations for the assessment and management of breakthrough pain. Part II—management. Pharm Ther. 2005;30:354–361.
Bolen J. Taking back your turf: understanding the role of law in medical decision making in opioid management (part I-overview). J Opioid Manag. 2005;1(3):125-130.
Boyes B, Meyer J. A comprehensive assessment of pain clinicians perceptions and knowledge of breakthrough pain. Poster presented at PAINWeek 2010. September 8–11, 2010;Las Vegas, NV.
BreivikH, ChernyN, CollettB, et al. Cancer-related pain: a pan-European survey of prevalence, treatment, and patient attitudes. Ann Oncol. 2009;20(8):1420-1433.
Brennan F, Carr DB, Cousins M. Pain management: a fundamental human right. Anesth Analg. 2007;105(1):205-221.
Brescia FJ, Adler D, Gray G, et al. Hospitalized advanced cancerpatients: a profile. J Pain Symptom Manage.1990;5:221-227.
Brown RL, Leonard T, Saunders LA, Papisoulitotis O. The prevalence and detection of substance use disorders among inpatients ages 18 to 49: an opportunity for prevention. Prev Med. 1998;27(1):101-110.
Brown RL, Rounds LA. Conjoint screening questionnaires for alcohol and other drug abuse: criterion validity in a primary care practice. Wis Med J. 1985;94(3):136-140.
Butler SF, Budman SH, Fernandez K, Jamison RN. Validation of a screener and opioid assessment measure for patients with chronic pain. Pain. 2004;112(1-2):65-75.
Caraceni A, Martini C, Zecca E, Portenoy RK, for the Working Group of an IASP Task Force on Cancer Pain. Breakthrough pain characteristics and syndromes in patients with cancer pain: an international survey. Palliat Med. 2004;18:177-183.
Caraceni A, Martini C, Zecca E. Breakthrough pain characteristics and syndromes in patients with cancer pain; an international survey. Palliat Med. 2004;(3)18:177-183.
Christine JM, Simmonds M, Patt R, et al. Dose-titration, multicenter study of oral transmucosal fentanyl citrate for the treatment of breakthrough pain in cancer patients using transdermal fentanyl for persistent pain. J Clin Oncol. 1998;16:3238-3245.
Christo PJ. Anesthesiol Clin North America. 2003;21(4):699-713.

Coombs RB, Jarry JL, Santhiapillai AC, et al. The SISAP: a new screening instrument for identifying potential opioid abusers in the management of chronic nonmalignant pain in general medical practice. <i>Pain Res Manage.</i> 1996;1(3):155-162.
Coluzzi PH, Schwartzberg L, Conroy JD, et al. Breakthrough cancer pain: a randomized trial comparing oral transmucosal fentanyl citrate (OTFC) and morphine sulfate immediate release (MSIR). <i>Pain.</i> 2001;91(1-2):123-130.
Compton P. <i>Pain Manag Nurs.</i> 2007;8(4):166-172.
Cone EJ, Heit HA, Caplan YH, Gourlay D. Evidence of morphine metabolism to hydromorphone in pain patients chronically treated with morphine. <i>J Anal Toxicol.</i> 2006;30(1):1-5.
Darwish M et al. Absolute and relative bioavailability of fentanyl buccal tablet and oral transmucosal fentanyl citrate. <i>J ClinPharmacol.</i> 2007;47(3):343-350.
Darwish M, et al. Single-dose and steady-state pharmacokinetics of fentanyl buccal tablet in healthy volunteers. <i>J Clin Pharmacol.</i> 2007;47(1):56-63.
Darwish M, Kirby M, Jiang JG, et al. Bioequivalence following buccal and sublingual placement of fentanyl buccal tablet 400 mcg in healthy subjects. <i>Clin Drug Invest.</i> 2008;28:1-7.
Darwish M, Kirby M, Robertson P Jr, Hellriegel E, Jiang JG. Comparison or Equivalent Doses of Fentanyl Buccal Tablets and Arteriovenous Differences in Fentanyl Pharmacokinetics <i>Clin Pharmacokinet</i> 2006;45(8): 843-850
Darwish M, Kirby M, Robertson P Jr, Hellriegel E, Jiang JG. Single-dose and steady-state pharmacokinetics of fentanyl buccal tablet in healthy volunteers. <i>J Clin Pharmacol.</i> 2007;47:56-63.
Darwish M, Kirby M, Robertson P Jr, Tracewell W, Jiang JG. Absolute and relative bioavailability of fentanyl buccal tablet and oral transmucosal fentanyl. <i>J Clin Pharmacol.</i> 2007;47:343-350.
Darwish M, Kirby M, Robertson P Jr, Tracewell W, Jiang JG. Comparative bioavailability of the novel fentanyl effervescent buccal tablet formulation: an open-label crossover study. Poster presented at: American Pain Society Annual Meeting;May 3-6, 2006;San Antonio, Tex.
Darwish M, Kirby M, Robertson P Jr, Tracewell W, Jiang JG. Pharmacokinetic properties of fentanyl effervescent buccal tablets: a phase I, open-label, crossover study of single-dose 100, 200, 400, and 800 ug in healthy adult volunteers. <i>Clin Ther.</i> 2006;28:707-714.
Dhingra LK, Passik SD. Smoking and aberrant behavior in chronic pain patients. <i>Practical Pain Manage.</i> September 2007.
Donovan M, Dillon P. Incidence and characteristics of pain in a sample of hospitalized cancer patients. <i>Cancer Nurs.</i> 1987;10:85-92.
Douglass AB. Pain. In.: Rakel RE, Bope ET, eds. <i>Conn's Current Therapy</i> 2005. 57th ed. Philadelphia, PA: WB Saunders;2005:1-5.

Droney J, Riley J. Recent advances in the use of opioids for cancer pain. <i>J Pain Res.</i> 2009;2:135-155.
Drug Abuse Warning Network. 2009: Selected tables of national estimates of drug-related emergency department visits. Rockville, MD: Center for Behavioral Health Statistics and Quality, SAMHSA, 2010.
Dunbar SA, Katz NP. Chronic opioid therapy for nonmalignant pain in patients with a history of substance abuse: report of 20 cases. <i>J Pain Symptom Manage.</i> 1996;11(3):163-171.
Durfee S, Messina J, Khankari R. Fentanyl effervescent buccal tablets: enhanced buccal absorption. <i>Am J Drug Deliv.</i> 2006;4(1):1-5.
Dworkin RH, Turk DC, Farrar JT, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. <i>Pain.</i> 2005;113:9-19.
Emerging solutions in pain tool kit. Emerging Solutions in Pain Web site. http://www.emergingsolutionsinpain.com/index.php?option=com_content&task=view&id=85&Itemid=97 , Accessed April 8, 2008.
Eriator I. Narcotics analgesics for chronic pain management. <i>Curr Rev Pain.</i> 1998;2:193-200.
Farrar JT, Cleary J, Rauck R, et al. Oral transmucosal fentanyl citrate: randomized, double-blinded, placebo-controlled trial for treatment of breakthrough pain in cancer patients. <i>J Natl Cancer Inst.</i> 1998; 90:611-616.
Farrar JT, Berlin JA, Strom BL. Clinically important changes in acute pain outcome measures: A validation study. <i>Pain Symptom Manage.</i> 2003;25:406-411.
FDA. Approved Risk Evaluation and Mitigation Strategies (REMS). Available at: http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm . Accessed August 25, 2011.
FDA. Background on opioid REMS. Available at: http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm187975.htm . Accessed August 25, 2011.
Federation of State Medical Boards of the United States, Inc. Web site. http://www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf . Accessed May 12, 2009.
Federation of State Medical Boards of the United States, Inc. Web site. http://www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf . Accessed October 20, 2010.
Fielin DA, Reid MC, O'Connor PG. Outpatient management of patients with alcohol problems. <i>Ann Intern Med.</i> 2000;133(10):815-827.
Fine G, Narayana A, Passik SD. Treatment of breakthrough pain with fentanyl buccal tablet in opioid-tolerant patients with chronic pain: appropriate patient selection and management. <i>Pain Med.</i> 2010;11:1024-1036.
Fine P, Portenoy RK. Opioid analgesia. New York, NY: McGraw Hill;2004.

Fine P. Managing cancer related breakthrough pain with Fentora. Pain Medicine News. September/October 200
Fine P. Managing cancer related breakthrough pain with Fentora. Pain Medicine News. September/October 2007.
Fine G, Narayana A, Passik SD. Treatment of breakthrough pain with fentanyl buccal tablet in opioid-tolerant patients with chronic pain: appropriate patient selection and management. Pain Med. 2010;11(7):1024-1036.
First MB, ed. Diagnostic and Statistical Manual of Mental Disorders – Text Revision (DSM-IV-TR). 4th ed. Washington, DC: American Psychiatric Association;2000.
Fishbain DA. Pharmacotherapeutic management of breakthrough pain in patients with chronic persistent pain. Am J Manag Care. 2008;14(5 Suppl 1):S123-S128.
Fishman SM, Badman TB, Edwards A, Borsook D. The opioid contract in the management of chronic pain. J Pain Symptom Manage. 1999;18(1):27-37.
Fishman SM, Kreis PG. The opioid contract. Clin J Pain. 2002;18(4)(sup;):S70-S75.
Fleming MF, et al. J Pain. 2007;8(7):573-582.
Fortner BV, Okon TA, Portenoy RK. A survey of pain-related hospitalizations, emergency department visits, and physician office visits reported by cancer patients with and without history of breakthrough pain. J Pain.2002;3:38-44.
Glajchen M. Chronic pain: treatment barriers and strategies for clinical practice. K Am Board Fam Pract. 2001;14(3):211-18.
Gourlay DL, Heit HA, Almahrezi . Universal precautions in pain medicine: a rational approach to the treatment of chronic pain. Pain Med. 2005;6(2):107-112.
Gourlay DL, Heit HA, Caplan YH. Urine drug testing in pain medicine: dispelling the myths and designing strategies. California Academy of Family Practice;August 2004.
Gourlay DL, Heit HA. Pain and addiction: managing risk through comprehensive care. J Addict Dis. In press.
Heit HA, Gourlay, Douglas L. Buprenorphine: New tricks with an old molecule for pain management. Clin J Pain. 2008;24:93-97.
Heit HA, Gourlay, Douglas L. Urine drug testing in pain medicine. J Pain and Symptom Management. 2004;27(3):260-267.
Heit HA. Addiction, physical dependence, and tolerance: precise definitions to help clinicians evaluate and treat the patient with chronic pain. J Pain Palliative Care Pharmacother.2003;17(1):15-29.
Heit HA. Personal communication. January 26, 2011.
Ives TJ, Chelminski PR, Hammett-Stabler CA, et al. Predictors of opioid misuse in patients with chronic pain: a prospective cohort study. BMC Health Serv Res. 2006;6:46.

Jamison RN, Kauffman J, Katz NP. Characteristics of methadone maintenance patients with chronic pain. <i>J Pain Symptom Manage</i> . 2000;19(1):53-62.
Jamison RN, Stetson BA, Parris WC. The relationship between cigarette smoking and chronic low back pain. <i>Addict Behav</i> . 1991;16(3-4):103-110.
Joranson DE, et al. Drug crime is a source of abused pain medications in the United States. <i>J Pain Symptom Manage</i> . 2005;30:299-301.
Katz N, Fanciullo GJ. <i>Clin J Pain</i> . 2002;18(4)(suppl):S76-S82.
Kendler KS, Bulik CM, Silberg J, Hetterma JM, Myers J, Precott CA. Childhood sexual abuse and adult psychiatric and substance abuse disorders in women: an epidemiological and cotwin control analysis. <i>Arch Gen Psychiatry</i> . 2000;57(10):953-959.
Lister B. Dilemmas in the treatment of chronic pain. <i>Am J Med</i> . 1996;101(1A):S25-S55.
Manchikanti L, Cash KA, Damron KS, Manchukonda R, Pampati V, McManus CD. Controlled substances abuse and illicit drug use in chronic pain patients: an evaluation of multiple variables. <i>Pain Physician</i> . 2006;9(3):215-225.
Manchikanti L. National drug control policy and prescription drug abuse: facts and fallacies. <i>Pain Physician</i> . 2007;10(3):399-424.
Marcus DA. Tips for managing chronic pain: implementing the latest guidelines. <i>Postgrad Med</i> . 2003;113(4):49-60.
Margarit C, Julia J, Lopez R, et al. Breakthrough cancer pain — still a challenge. <i>J Pain Research</i> . 2012;5:559-566.
Mercadante S, Maddaloni S, Roccella S, Salvaggio L. Predictive factors in advanced cancer pain treated only by analgesics. <i>Pain</i> . 1992;50:151-155.
Mercadante S;Radbruch L, Caraceni A, et al. Episodic (Breakthrough Pain), Consensus conference of an expert working group of the European Association for Palliative Care. <i>American Cancer Society</i> , 2002.832-839.
Miser A, Dothage J, Wesley R, Miser J. The prevalence of pain in a pediatric and young adult cancer population. <i>Pain</i> .1987;29:73-83.
National Center for Health Statistics. QuickStats: number of poisoning deaths involving opioid analgesics and other drugs or substances — United States, 1999–2007. <i>MMWR</i> . 2010;59(No. 32):1026.
National Comprehensive Cancer Network. NCCN Guidelines Version 1.2013. Adult Cancer Pain.
National Pharmaceutical Council, Inc. Pain: current understanding of assessment, management, and treatments (monograph). Available at: www.npcnow.org/resources/PDFs/painmonograph.pdf . Accessed March 18, 2008.
National Pharmaceutical Council, Inc. Web sit. http://npcentral.net/ce/pain/pain.pdf . Accessed March 29, 2009.

National Pharmaceutical Council, Inc. Web site. http://www.npcnow.org/App_Themes/Public/pdf/Issues/pub_related_research/pub_quality_care/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf . Accessed October 13, 2010.
National Pharmaceutical Council, Inc. Pain: current understanding of assessment, management, and treatments. Available at: www.npcnow.org/App_Themes/Public/pdf/Issues/pub_related_research/pub_quality_care/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf . Accessed April 12, 2012.
Oster M, Vizel M, Turgeon M. Pain of terminal cancer patients. <i>Arch Intern Med.</i> 1978;138:1801-1802
Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center. Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation. 2nd ed. http://www.medsch.wisc.edu/painpolicy/eguide2003/index/eguide2003.pdf . Updated February 2004. Accessed April 4, 2008.
Parkes CM. Home or hospital? Terminal care as seen by surviving spouses. <i>J Research Coll Gen Pract.</i> 1978;28:19-30.
Passik SD, Kirsh KL, Donaghy KB, Portenoy RK. Pain and aberrant drug-related behaviors in medically ill patients with and without histories of substance abuse. <i>Clin J Pain.</i> 2006;22(2):173-181.
Passik SD, Kirsh KL, Whitcomb L, et al. Monitoring outcomes during long-term opioid therapy for noncancer pain: results with the Pain Assessment and Documentation Tool. <i>J Opioid Manag.</i> 2005;1(5):257-266.
Passik SD, Kirsh KL. Managing Pain in patients with aberrant drug-taking behaviors. <i>J Support Oncol.</i> 2005;3(1):83-86.
Passik SD, Portenoy RK. Substance abuse illness in palliative care. In: Berger AM, Portenoy RK, Weissman DE, eds. <i>Principles and Practice of Supportive Oncology.</i> Philadelphia, PA: Lippincott-Raven Publishers;1998:513-529.
Passik SD, Weinreb HJ. Managing chronic nonmalignant pain: overcoming obstacles to the use of opioids. <i>Adv. Ther.</i> 2000;17(2):70-83.
Pather SI, Siebert JM, Hontz J, Khankari R, Gupte SV, Kumbale R. Enhanced buccal delivery of fentanyl using OraVescent drug delivery system. <i>Drug Deliv Tech</i> 2001;1:54-57.
Payne R, Coluzzi P, Hart L, et al. Long-term safety of oral transmucosal fentanyl citrate for breakthrough cancer pain. <i>J Pain Symptom Manage.</i> 2001;22(1):575-583.
Payne TJ, Stetson B, Stevens VM, Johnson CA, Penzien DB, Van Dorsten B. The impact of cigarette smoking on headache activity in headache patients. <i>Headache.</i> 1991;31(5):329-332.
Peabody FW. The care of the patient. <i>JAMA.</i> 1927;88(12):877-882.
Plante, GE, Vanlittallie TB. Opioids for cancer pain;the challenge of optimizing treatment. <i>Metabolism,</i> 2010;59(Suppl 1):S47-S52

Pletcher MJ, Kertesz SG, Sidney S, Kiefe CI, Hulley SB. Incidence and antecedents of nonmedical prescription opioid use in four US communities. The Coronary Artery Risk Development in Young Adults (CARDIA) prospective cohort study. <i>Drug Alcohol Depend.</i> 2006;85:171-176.
Portenoy RK, Bennett DS, Rauck R, et al. Prevalence and characteristics of breakthrough pain in opioid-treated patients with chronic noncancer pain. <i>J Pain.</i> 2006;7:583-591.
Portenoy RK, Hagen NA. Breakthrough pain: definition, throughout the prevalence and characteristics. <i>Pain.</i> 1990;41(3):273-281. presentation.
Portenoy RK, Messina J, Fang X, et al. Fentanyl buccal tablet (FBT) for relief of breakthrough pain in opioid-treated patients with chronic low back pain: a randomized, placebo-controlled study. <i>Current Medical Research and Opinion</i> 23(1): 223-233, 2007.
Portenoy RK, Payne D, Jacobsen P. Breakthrough pain: characteristics and impact in patients with cancer pain. <i>Pain.</i> 1999;81:129-134.
Portenoy RK, Payne R, Coluzzi P, et al. Oral transmucosal fentanyl citrate (OTFC) for the treatment of breakthrough pain in cancer patients: a controlled dose titration study. <i>Pain.</i> 1999;79:303-312.
Portenoy RK, Taylor D, Messina J, Tremmel L. A randomized, placebo-controlled study of fentanyl buccal tablet for breakthrough pain in opioid-treated patients with cancer. <i>Clin J Pain.</i> 2006;22:805-811.
Portenoy RK. Opioid therapy for chronic nonmalignant pain: a review of the critical issues. <i>J Pain Symptom Manage.</i> 1996;11(4):203-217.
Portenoy RK. Opioid therapy for chronic nonmalignant pain: clinician's perspective. <i>J Law Medicine Ethics.</i> 1996;24(4):296-309.
Portenoy RK, Hagen NA. Breakthrough pain: definition, prevalence and characteristics. <i>Pain.</i> 1990;41(3):273-281.
Portenoy RK, Payne D, Jacobsen P. Breakthrough pain: characteristics and impact in patients with cancer pain. <i>Pain.</i> 1999;81:129-134.
Portenoy RK, Taylor D, Messina J, Tremmel L. A randomized, placebo-controlled study of fentanyl buccal tablet for breakthrough pain in opioid-treated patients with cancer. <i>Clin J Pain.</i> 2006;22:805-811.
Porter SE, Hanley EN Jr. The musculoskeletal effects of smoking. <i>J Am Acad Orthop Surg.</i> 2001;9(1):9-17.
Potter JS, Hennessey G, Borrow JA, Greenfield SF, Weiss RD. Substance abuse histories in patients seeking treatment for controlled-release oxycodone dependence. <i>Drug Alcohol Depend.</i> 2004;76(2):213-215.
Potter M, Schafer S, Gonzalez-Mendez E, et al. Opioids for chronic nonmalignant pain: attitudes and practices of primary care physicians in the UCSF/Stanford Collaborative Research Network. <i>J Fam Pract.</i> 2001;50(2):145-151.
Prommer E, Ficek B. Fentanyl transmucosal tablets: current status in the management of cancer-related breakthrough pain. <i>Patient Prefer Adherence.</i> 2012;6:465-475.

Rhiner M, Palos G, Termini M. Managing breakthrough pain;A clinical review with three case studies using oral transmucosal fentanyl citrate. Clin J Oncol Nurs. 2004;507-512.
Risk Evaluation and Mitigation Strategies: the experts answer questions from health-system pharmacists. ASHP Advantage eNewsletter. Winter 2010.
Rohsenow DJ, Colby SM, Martin RA, Monti PM, et al. Nicotine and other substance interaction expectancies questionnaire: relationship of expectancies to substance abuse. Addict Behav. 2005;3(4):629-641.
Sakai S, Van Doren S. The REMS in practice: recent trends. Regulatory Focus. July 2010:19-23.
SAMHSA, US DHHS. Results from the 2009 National Survey on Drug Use and Health: National Findings. Rockville, MD;US DHHS: 2009. NHSDA Series: H38A, DHHS Publication No. SMA 10-4586.
Savage SR, Joranson DE, Covington EC, Schnoll SH, Heit HA, Gilson AM. Definitions related to the medical use of opioids: evolution towards universal agreement. J Pain Symptom Manage. 2003;26(1):655-657.
Savage SR. J Pain Symptom Manage. 1996;11:274-286.
Savage SR. Long-term opioid therapy: assessment of consequences and risks. J Pain Symptom Manage. 1996;11:274-286.
Schnoll SH, Finch J. Medical education for pain and addiction: making progress toward answering a need. J Law Med Ethics. 1994;22(3):252-256.
Simmonds MA. Management of breakthrough pain due to cancer. Oncology. 1999;13:1103–1108.
Simon S. Opioids and treatment of chronic pain: understanding pain patterns and the role for rapid-onset opioids. MedGenMed. 2005;7:54.
Slatkin NE et al. Fentanyl buccal tablet for relief of breakthrough pain in opioid-tolerant patients with cancer-related chronic pain. J Support Oncol. 2007;5(7):327-334.
Slatkin NE, Xie F, Messina J, Segal TJ. Fentanyl buccal tablet for relief of breakthrough pain in opioid tolerant patients with cancer- chronic pain: a double-blind, randomized, placebo-controlled study. J Support Oncol. 2007;5:327-334.
Stanley TH. Fentanyl. J Pain Symptom Manage. 2005;29(5 Suppl):S67-S71.
Sternbach RA. Survey of pain in the United States: the Nuprin pain report. Clin J Pain. 1986;2:49-53.
Stewart WF, Ricci JA, Chee E, Morganstein D, Lipton R. Lost productive time and cost due to common pain conditions in the US workforce. JAMA 2003;290(18):2443-2454.
Strasser F, Walker P, Bruera E. Palliative pain management: when both pain and suffering hurt. J Palliat Care. 2005;21(2):69-79.

<p>Streisand JB, Varvel JR, Stanski DR, et al. Absorption and bioavailability of oral transmucosal fentanyl citrate. <i>Anesthesiology</i>. 1991;75:223-229.</p>
<p>Substance Abuse and Mental Health Services Administration (SAMHSA), US Department of Health and Human Services (DHHS). Results from the 2002 National Survey on Drug Use and Health: National Findings. Rockville, MD: US DHHS;2003. NHSDA Series H-22, DHHS Publication No. SMA 03-3836.</p>
<p>Svendsen K, Andersen S, Arnason S, et al. Breakthrough pain in malignant and non-malignant diseases: a review of prevalence, characteristics and mechanisms. <i>Eur J Pain</i>. 2005;9:195–206.</p>
<p>Taylor D, Portenoy RK, Messina J, Tremmel L. A randomized, placebo-controlled study of fentanyl buccal tablet for relief of breakthrough pain in opioid-treated patients with cancer. <i>Clin J Pain</i>. 2006;22(9):805-811.</p>
<p>The Pinnacle Group Study: Exploring the BTP Communication Gap Among Patients & Physicians;2006.</p>
<p>Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Access Web site. Attachment 1: list of TIRF medicines available only through the TIRF REMS Access Program. Available at: https://www.TIRFREMSAccess.com/TirfUI/remis/pdf/medication-list-short.pdf. Accessed July 11, 2013.</p>
<p>Tsuang MT, Lyons MJ, Eisen SA, et al. Genetic influences in DSM-II-R drug abuse and dependence: a study of 3,372 twin pairs. <i>Am J Med Genet</i>. 1996;67(5):473-477.</p>
<p>Tsuang MT, Lyons MJ, Meyer JM, et al. Co-occurrence of abuse of different drugs in men: the role of drug-specific and shared vulnerabilities. <i>Arch Gen Psychiatry</i>. 1998;55(11):967-972.</p>
<p>US FDA Website. Available at: http://www.fda.gov/Drugs/DrugSafety/InformationDrugClass/ucm251735.htm. Accessed July 9, 2012.</p>
<p>US Food and Drug Administration. Orange Book. Available at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Accessed August 7, 2013.</p>
<p>Walsh D, Rybicki L. Symptom clustering in advanced cancer. <i>Support Care Cancer</i>. 2006;14:831–836.</p>
<p>Warner M, Chen LH, Makuc DM. Increase in fatal poisonings involving opioid analgesics in the United States, 1999–2006. NCHS data brief, no. 22. Hyattsville, MD: US DHHS, CDC, National Center for Health Statistics;2009. DHHS;2003. NHSDA Series H-22, DHHS Publication No. SMA 03-3836.</p>
<p>Weaver M, Schnoll S. Abuse liability in opioois therapy for pain treatment in patients with an addiction history. <i>Clin J Pain</i>. 2002;18(4)(suppl):S62-S69.</p>
<p>Webster LR, Webster RM. Predicting aberrant behaviors in opioid-treated patients: preliminary validation of the Opioid Risk Tool. <i>Pain Med</i>. 2005;6(6):432-442.</p>
<p>Webster LR. Breakthrough pain in the management of chronic persistent pain syndromes. <i>Am J Manag Care</i>. 2008;14(5 Suppl 1):S116-S122.</p>

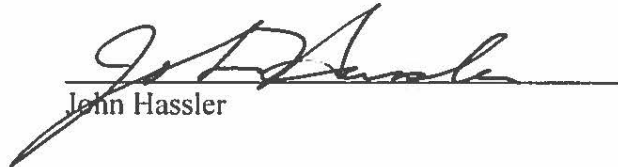
<p>Weick J, Tremmel L, Messina J, Portenoy RK. Fentanyl effervescent buccal tablets for relief of breakthrough pain in opioid-treated patients with cancer: a randomized, placebo-controlled study. Poster presented at: American Society of Clinical Oncology 42nd Annual Meeting; June 2-6, 2006; Atlanta, GA.</p>
<p>Weinstein SM et al. Cancer, 2009; published online April 16, 2009.</p>
<p>Weinstein SM, Laux LF, Thornby JL, et al. Medical students' attitudes toward pain and the use of opioid analgesics: implications for changing medical school curriculum. South Med J. 2000;93(5):472-478.</p>
<p>Weinstein, Sharon M, Messina, J, Xie, F Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients With Chronic Cancer Pain: A Long-term, Open-Label Safety Study. Cancer 2009.</p>
<p>Weissman DE, Haddox JD. Opioid pseudoaddiction – an iatrogenic syndrome. Pain. 1989;36(3):363-366.</p>
<p>Wiedemer NL, Harden PS, Arndt IO, Gallagher RM. The opioid renewal clinic: a primary care, managed approach to opioid therapy in chronic pain patients at risk for substance abuse. Pain Med. 2007;8(7):573-584.</p>
<p>Yunus MB, Arsian S, Aldag JC. Relationship between fibromyalgia features and smoking. Scand J. Rheumatol. 2002;31(5):301-305.</p>
<p>Zeppetella G, O'Doherty CA, Collins S. Prevalence and characteristics of breakthrough pain in cancer patients admitted to a hospice. J Pain Symptom Manage. 2000;20:87-90.</p>
<p>Zeppetella G, O'Doherty CA, Collins S. Prevalence and characteristics of breakthrough pain in cancer patients admitted to a hospice. J Pain Symptom Manage. 2000;20:87-92.</p>
<p>Zeppetella G. Breakthrough pain in cancer patients. Clin Oncol. 2011;23:393-398.</p>

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 Amended Responses and Objections of Defendants Cephalon, Inc., Teva Pharmaceuticals USA, Inc., Actavis LLC, Actavis Pharma, Inc., and Watson Laboratories, Inc. to Plaintiffs' Second 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