IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel.,
MIKE HUNTER,
ATTORNEY GENERAL OF OKLAHOMA,

Plaintiff,

vs.

(1) PURDUE PHARMA L.P.;
(2) PURDUE PHARMA, INC.;
(3) THE PURDUE FREDERICK COMPANY,
(4) TEVA PHARMACEUTICALS USA, INC.;
(5) CEPHALON, INC.;
(6) JOHNSON & JOHNSON;
(7) JANSSEN PHARMACEUTICALS, INC,
(8) ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS;
(9) JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.;
(10) ALLERGAN, PLC, f/k/a ACTAVIS PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.;
(11) WATSON LABORATORIES, INC.;
(12) ACTAVIS LLC; and
(13) ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.,

Defendants.

For Judge Balkman's Consideration

Case No. CJ-2017-816
Honorable Thad Balkman

William C. Hetherington
Special Discovery Master

DEFENDANTS TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, AND ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.'S MOTION FOR SUMMARY JUDGMENT AND BRIEF IN SUPPORT

DOCUMENTS SEALED PER COURT ORDER DATED APRIL 16, 2018 THAD BALKMAN DISTRICT JUDGE

—CONFIDENTIAL—
TO BE FILED ONLY UNDER SEAL

Part E

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EXHIBIT 19

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Cephalon, Inc
c/o CIMA Labs
41 Moores Road
Frazer, PA 19355

Attention: Carol S. Marchione
Senior Director, Regulatory Affairs

Dear Ms. Marchione:

Please refer to your New Drug Application (NDA) dated August 31, 2005, received August 31, 2005, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for FENTORA (fentanyl buccal tablet), 100 mcg, 200 mcg, 400 mcg, 600 mcg, and 800 mcg.

We acknowledge receipt of your submissions dated September 9, January 5, 6, 20, February 22, 24, March 2, 13, 24, 29, April 7 (2), 24, May 11, 23, 26 (2), June 2, 5, 16 (2), 21, 23, 26 (2), 27, 29 (2), July 25 and September 7, 12, 18, and 19, 2006.

The July 25, 2006, submission constituted a complete response to our June 29, 2006 action letter.

This new drug application provides for the use of FENTORA for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text, Medication Guide and the components of your Risk Minimization Action Plan (RiskMAP). Marketing of this drug product and related activities are to be in accordance with the substance and procedures of all FDA regulations.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the Medication Guide, immediate container [blister] and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Your FENTORA RiskMAP is an important part of the post marketing risk management for fentanyl buccal tablet. The primary goals of your RiskMAP are to minimize the use of FENTORA by opioid nontolerant individuals, minimize misuse of FENTORA, and minimize unintended (accidental) exposure to FENTORA.

Your RiskMAP must include the following components:

1. Implementation of a program and distribution of materials to educate prescribers, pharmacies, nurses, and patients about the risks and benefits of FENTORA.

2. Implementation of a reporting and data collection system for safety surveillance.

3. Implementation of a plan to monitor, evaluate, and determine the incidence of use of FENTORA by opioid nontolerant individuals, misuse of FENTORA, and unintended (accidental) exposure to FENTORA.

The FENTORA RiskMAP submitted on August 31, 2005 and finalized in your submission dated September 19, 2006, and as described in the attached document, adequately addresses each of these requirements. This plan includes ongoing assessment and periodic reporting to FDA of the operation of the program and needed revisions, if any. Any change to the program must be discussed with FDA prior to its institution and is subject to FDA's determination that the required components are still present. We expect your continued cooperation to resolve any problems regarding the FENTORA RiskMAP that may be identified following approval of this application.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-947**." Approval of this submission by FDA is not required before the labeling is used.

The proprietary name for this product and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring submission of your pediatric studies for ages 0 to 17 years until June 28, 2011.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for the treatment of the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain in pediatric patients ages 0 to 17 years.

   Final Report Submission: September 25, 2011

Submit final study reports to this NDA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitment(s) must be clearly designated "**Required Pediatric Study Commitments**".

Under 21 CFR Part 208, we have determined that this product poses a serious and significant public health concern requiring the distribution of a Medication Guide. Fentanyl buccal tablet is a product for which patient labeling could help prevent serious adverse effects and inform the patient of serious risks relative to benefit that could affect their decisions to use, or continue to use, the product. Therefore, a Medication Guide is necessary for safe and effective use of this product and FDA hereby approves the enclosed Medication Guide submitted on July 25, 2006. Please note that:

1. This Medication Guide must be reprinted at the end of the package insert (21 CFR 201.57(f)(2));

2. You are responsible for ensuring that this Medication Guide is available for distribution to every patient who is dispensed a prescription for this product (21 CFR 208);

3. The final printed Medication Guide distributed to patients must conform to all conditions described in 21 CFR 208.20, including a minimum of 10 point text; and

4. You are responsible for ensuring that the label of each container or package includes a prominent and conspicuous instruction to authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed, and states how the Medication Guide is provided (e.g., affixed on the container, provided with the product, etc.).

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Amendable Road
Beltsville, MD 20705-1266

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence to support that claim.

Please submit one market package (that does not contain any active drug) of the drug product when it is available.

We acknowledge your amendment dated June 27, 2006, that you will the change the tablet color of all strengths to white before marketing and that the manufacturing process for all strengths will be the same as that which is currently used for the 200-mcg tablets.

We acknowledge that you will provide three months of accelerated and long-term stability data for at least one lot of each strength within six months from the date of NDA approval.

We acknowledge, based on your submission dated June 26, 2006, that you will to reduce the specification for (b) (4) impurity in active drug substance from (b) (4) to NMT (b) (4) by the end of December 2006 and update this in your first NDA Annual Report.

Your product is approved with a shelf-life of 24 months.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kimberly Compton, Regulatory Project Manager, at (301) 796-1191.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures

Package Insert
Medication Guide
Blister and Carton Labels
Summary of RiskMAP

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Bob Rappaport
9/25/2006 05:28:02 PM

EXHIBIT 20

Initial REMS approval: 12/2011

Most recent modification: 08/2017

TRANSMUCOSAL IMMEDIATE RELEASE FENTANYL (TIRF) RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOALS

The goals of the TIRF REMS Access program are to mitigate the risk of misuse, abuse, addiction, overdose and serious complications due to medication errors by:

1. Prescribing and dispensing TIRF medicines only to appropriate patients, which includes use only in opioid-tolerant patients.
2. Preventing inappropriate conversion between TIRF medicines.
3. Preventing accidental exposure to children and others for whom it was not prescribed.
4. Educating prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose of TIRF medicines.

II. REMS ELEMENTS

A. Medication Guide

The product-specific TIRF Medication Guide will be dispensed with each TIRF prescription in accordance with 21 CFR 208.24.

The Medication Guides for TIRF medicines are part of the TIRF REMS Access program and will be available on the TIRF REMS Access website (www.TIRFREMSaccess.com).

B. Elements to Assure Safe Use

1. Healthcare providers who prescribe TIRF medicines for outpatient use are specially certified.

a. TIRF sponsors will ensure that healthcare providers who prescribe TIRF medicines for **outpatient** use are specially certified.

b. To become certified to prescribe TIRF medicines, prescribers will be required to enroll in the TIRF REMS Access program. Prescribers must complete the following requirements to be enrolled:

i. Review the TIRF REMS Access education materials (*TIRF REMS Access Education Program*), including the Full Prescribing Information (FPI) for each TIRF medicine, and successfully complete the Knowledge Assessment (*Knowledge Assessment).*

ii. Complete and sign the *Prescriber Enrollment Form.* In signing the *Prescriber Enrollment Form*, each prescriber is required to acknowledge the following:

a) I have reviewed the TIRF REMS Access Education Program, and I have completed the Knowledge Assessment. I understand the responsible use conditions for TIRF medicines and the risks and benefits of chronic opioid therapy.

b) I understand that TIRF medicines can be abused and that this risk should be considered when prescribing or dispensing TIRF medicines in situations

where I am concerned about an increased risk of misuse, abuse, or overdose, whether accidental or intentional.

c) I understand that TIRF medicines are indicated only for the management of breakthrough pain in cancer patients 18 years of age or older (Actiq and its generic equivalents are approved for 16 years of age and older), who are already receiving, and who are tolerant to, around-the-clock opioid therapy for their underlying persistent cancer pain.

d) I understand that TIRF medicines are contraindicated for use in opioid non-tolerant patients, and know that fatal overdose can occur at any dose.

e) I understand that TIRF medicines must not be used to treat acute or postoperative pain, including headache/migraine, dental pain, or acute pain in the emergency department.

f) I understand that converting patients from one TIRF medicine to a different TIRF medicine must not be done on a microgram-per-microgram basis. I understand that TIRF medicines are not interchangeable with each other, regardless of route of administration, and that conversion may result in fatal overdose, unless conversion is done in accordance with labeled product-specific conversion recommendations (refer to the list of currently approved TIRF products located on the TIRF REMS Access website at www.TIRFREMSaccess.com/TirfUI/rems/products.action. Note, a branded TIRF medicine and its specific generic product(s) are interchangeable.

g) I understand that the initial starting dose for TIRF medicines for all patients is the lowest dose, unless individual product labels provide product-specific conversion recommendations, and I understand that patients must be titrated individually.

h) I will provide a Medication Guide for the TIRF medicine that I intend to prescribe to my patient or their caregiver and review it with them. If I convert my patient to a different TIRF medicine, the Medication Guide for the new TIRF medicine will be provided to, and reviewed with, my patient or their caregiver.

i) I will complete and sign a TIRF REMS Access *Patient-Prescriber Agreement Form* with each new patient, before writing the patient's first prescription for a TIRF medicine, and **renew the agreement every two (2) years.**

j) I will provide a completed, signed copy of the *Patient-Prescriber Agreement Form* to the patient and retain a copy for my records. I will also provide a completed, signed copy to the TIRF REMS Access program (through the TIRF REMS Access website or by fax) within ten (10) working days.

k) At all follow-up visits, I agree to assess the patient for appropriateness of the dose of the TIRF medicine, and for signs of misuse and abuse.

l) I understand that TIRF medicines are only available through the TIRF REMS Access program. I understand and agree to comply with the TIRF REMS

Access program requirements for prescribers.

m) I understand that I must re-enroll in the TIRF REMS Access program and successfully complete the enrollment requirements every two (2) years.

In signing the *Patient-Prescriber Agreement Form*, the prescriber documents the following:

1) I understand that TIRF medicines are indicated only for the management of breakthrough pain in cancer patients 18 years of age or older (Actiq and its generic equivalents are approved for 16 years of age and older), who are already receiving, and who are tolerant to, around-the-clock opioid therapy for their underlying persistent cancer pain.

2) I understand that TIRF medicines are contraindicated for use in opioid non-tolerant patients, and know that fatal overdose can occur at any dose.

3) I understand that TIRF medicines are not for use in the management of acute or postoperative pain, including headache/migraine, dental pain, or acute pain in the emergency department.

4) I understand that patients considered opioid-tolerant are those who are taking, for one week or longer, at least: 60 mg oral morphine/day; 25 micrograms transdermal fentanyl/hour; 30 mg oral oxycodone/day; 8 mg oral hydromorphone/day; 25 mg oral oxymorphone/day; 60 mg oral hydrocodone/day; or an equianalgesic dose of another opioid daily.

5) I have provided to, and reviewed with, my patient or their caregiver the Medication Guide for the TIRF medicine I intend to prescribe.

6) If I change my patient to a different TIRF medicine, I will provide the Medication Guide for the new TIRF medicine to my patient or my patient's caregiver, and I will review it with them.

7) I understand that if I change my patient to a different TIRF medicine, the initial dose of that TIRF medicine for all patients is the lowest dose, unless individual product labels provide product-specific conversion recommendations.

8) I have counseled my patient or their caregiver about the risks, benefits, and appropriate use of TIRF medicines including communication of the following safety messages:

   A. If you stop taking your around-the-clock pain medicine, you must stop taking your TIRF medicine.

   B. NEVER share your TIRF medicine.

   C. Giving a TIRF medicine to someone for whom it has not

been prescribed can result in a fatal overdose.

D. TIRF medicines can be fatal to a child; used and unused dosage units must be safely stored out of the reach of children living in or likely to visit the home and disposed of in accordance with the specific disposal instructions detailed in the product's Medication Guide.

I will ensure that the patient and/or caregiver understand that, in signing the *Patient-Prescriber Agreement Form*, they document the following:

1) My prescriber has given me a copy of the Medication Guide for the TIRF medicine I have been prescribed, and has reviewed it with me.

2) I understand that TIRF medicines should only be taken by patients who are regularly using another opioid, around-the-clock, for constant pain. If I am not taking around-the-clock opioid pain medicine, my prescriber and I have discussed the risks of only taking TIRF medicines.

3) I understand that if I stop taking another opioid pain medicine that I have been taking regularly, around-the-clock, for my constant pain, then I must also stop taking my TIRF medicine.

4) I understand how I should take this TIRF medicine, including how much I can take, and how often I can take it. If my prescriber prescribes a different TIRF medicine for me, I will ensure I understand how to take the new TIRF medicine.

5) I understand that any TIRF medicine can cause serious side effects, including life-threatening breathing problems which can lead to death, especially if I do not take my TIRF medicine exactly as my prescriber has directed me to take it.

6) I agree to contact my prescriber if my TIRF medicine does not relieve my pain. I will not change the dose of my TIRF medicine myself or take it more often than my prescriber has directed.

7) I agree that I will never give my TIRF medicine to anyone else, even if they have the same symptoms, since it may harm them or even cause death.

8) I will store my TIRF medicine in a safe place, out of reach of children and teenagers because accidental use by a child, or anyone for whom it was not prescribed, is a medical emergency and can cause death.

9) I have been instructed on how to properly dispose of my partially used or unneeded TIRF medicine remaining from my prescription, and will dispose of my TIRF medicine as soon as I no longer need it.

10) I understand that selling or giving away my TIRF medicine is against the law.

11) I have asked my prescriber all the questions I have about my TIRF medicine. If I have any additional questions or concerns in the future about my treatment with my TIRF medicine, I will contact my prescriber.

12) I have reviewed the "Patient Privacy Notice for the TIRF REMS Access Program" and I agree to its terms and conditions which allow my healthcare providers to share my health information, as defined in that document, with the makers of TIRF medicines (TIRF Sponsors) and their agents and contractors for the limited purpose of managing the TIRF REMS Access program.

c. Prescribers are required to re-enroll every two (2) years. Additionally, prescribers must re-counsel their patients and complete a new Patient-Prescriber Agreement Form every two (2) years.

d. TIRF Sponsors will:

i. Ensure that prescriber enrollment can successfully be completed via the TIRF REMS Access website, or by mailing or faxing the forms.

ii. Ensure that, as part of the enrollment process, the following materials that are part of the TIRF REMS Access program are available to prescribers. These materials are appended:

- *TIRF REMS Access Prescriber Program Overview*
- *TIRF REMS Access Education Program*
- *Knowledge Assessment*
- *Prescriber Enrollment Form*
- *Patient-Prescriber Agreement Form*
- *TIRF REMS Access Patient and Caregiver Overview*
- *Frequently Asked Questions (FAQs)*
- *TIRF REMS Access Website*

iii. Ensure that prescribers have successfully completed the Knowledge Assessment, and ensure that enrollment forms are complete before activating a prescriber's enrollment in the TIRF REMS Access program.

iv. Ensure that prescribers are notified when they are successfully enrolled in the TIRF REMS Access program, and therefore, are certified to prescribe TIRF medicines.

v. Monitor education and enrollment requirements for prescribers and may inactivate non-compliant prescribers. Upon initial activation, prescribers remain active until inactivation occurs or expiration of the enrollment period.

vi. Ensure that prior to the first availability of the TIRF REMS Access program/website, *Dear Healthcare Provider Letters* will be sent. The target audience for the letters will include pain management specialists (comprised of anesthesiologists, physical medicine and rehabilitation physicians), primary care

physicians, oncologists, oncology nurse practitioners who treat breakthrough pain in patients with cancer, and other appropriately licensed healthcare professionals who prescribe TIRF medicines. The letter will include information on the risks associated with the use of TIRF medicines and will explain to healthcare providers that if they wish to treat patients using TIRF medicines, they must enroll in the TIRF REMS Access program. The letters will be available on the TIRF REMS Access website for 1 year from the date of the mailing.

The *Dear Healthcare Provider Letter* is part of the TIRF REMS Access program and is appended.

2. **TIRF medicines will only be dispensed by pharmacies that are specially certified.**

   a. TIRF Sponsors will ensure that TIRF medicines will only be dispensed by certified pharmacies. To become certified to dispense TIRF medicines, each pharmacy must be enrolled in the TIRF REMS Access program.

   b. Each pharmacy will be required to designate an authorized pharmacy representative (chain and closed system outpatient pharmacies) or authorized pharmacist (independent outpatient and inpatient pharmacies) to complete enrollment on behalf of the pharmacy(s).

   c. For the purposes of this REMS, there are different requirements for :

      - **Outpatient Pharmacies**

        i. **Chain Outpatient Pharmacy:** Retail, mail order or institutional outpatient pharmacies having a chain headquarters that is responsible for ensuring enrollment and training of the pharmacy staff of all associated outpatient pharmacies. The chain headquarters will enroll multiple locations (i.e., chain stores) in the TIRF REMS Access program.

        ii. **Independent Outpatient Pharmacy:** Retail, mail order, or institutional outpatient pharmacies having an authorized pharmacy representative that is responsible for ensuring enrollment and training of the pharmacy staff within an individual outpatient pharmacy. Each store will individually enroll in the TIRF REMS Access program as a single pharmacy location.

        iii. **Closed System Outpatient Pharmacy:** Institutional or mail order outpatient pharmacies that use a pharmacy management system that does not support the process of electronically transmitting the validation and claim information currently required by the TIRF REMS Access program.

      - **Inpatient pharmacies** (e.g., hospitals, in-hospital hospices, and long-term care facilities that dispense for inpatient use)

   d. ***Chain and Independent Outpatient Pharmacy(s):***

      The authorized pharmacist/pharmacy representative must complete the following requirements to enroll their **chain or independent outpatient pharmacy:**

      i. Review the TIRF REMS Access Education Program (*TIRF REMS Access Education Program)* and successfully complete the *Knowledge Assessment.*

ii. Ensure the pharmacy enables its pharmacy management system to support communication with the TIRF REMS Access program system, using established telecommunication standards, and runs the standardized validation test transaction to validate the system enhancements.

iii. Complete and sign the *Independent Outpatient Pharmacy Enrollment Form* or the *Chain Outpatient Pharmacy Enrollment Form* for groups of associated pharmacies. In signing the *Independent Outpatient Pharmacy Enrollment Form or Chain Outpatient Pharmacy Enrollment Form,* the authorized pharmacist is required to acknowledge the following:

a) I have reviewed the TIRF REMS Access Education Program, and I have completed the Knowledge Assessment. I understand the risks and benefits associated with TIRF medicines and the requirements of the TIRF REMS Access program for pharmacies.

b) I will ensure that all pharmacy staff who participate in dispensing TIRF medicines are educated on the risks associated with TIRF medicines and the requirements of the TIRF REMS Access program, as described in the *TIRF REMS Access Education Program.* This training should be documented and is subject to audit.

c) I understand that converting patients from one TIRF medicine to a different TIRF medicine must not be done on a microgram-per-microgram basis. I understand that TIRF medicines are not interchangeable with each other, regardless of route of administration, and that conversion may result in fatal overdose, unless conversion is done in accordance with labeled product-specific conversion recommendations (refer to the list of currently approved TIRF products located on the TIRF REMS Access website at www.TIRFREMSaccess.com/TirfUI/rems/products.action. Note, a branded TIRF medicine and its specific generic product(s) are interchangeable.

d) I understand that TIRF medicines are contraindicated for use in opioid non-tolerant patients.

e) I understand that the initial starting dose of TIRF medicines for all patients is the lowest dose, unless individual product labels provide product-specific conversion recommendations, and I understand that patients must be titrated individually.

f) I understand the importance of discussing the risks and benefits of TIRF medicines with patients and their caregivers, and in particular the importance of taking the drug as prescribed, not sharing with others, and proper disposal.

g) I understand that the product-specific Medication Guide must be given to the patient or their caregiver each time a TIRF medicine is dispensed.

h) I understand that TIRF medicines will not be dispensed without verifying through our pharmacy management system that the prescriber and pharmacy are enrolled and active, and that the patient has not been inactivated in the program.

i) I understand that ALL TIRF medicine prescriptions, regardless of the method

of payment, must be processed through our pharmacy management system.

j) I understand that all dispensing locations must be enrolled in the TIRF REMS Access program to dispense TIRF medicines.

k) I understand that TIRF medicines can only be obtained from wholesalers/distributors that are enrolled in the TIRF REMS Access program.

l) I understand that our pharmacy will not sell, loan or transfer any TIRF medicine inventory to any other pharmacy, institution, distributor, or prescriber.

m) I understand that our pharmacy must re-enroll in the TIRF REMS Access program and successfully complete the enrollment requirements every two (2) years.

n) I understand that TIRF medicines are only available through the TIRF REMS Access program. I understand that the pharmacy must comply with the TIRF REMS Access program requirements for outpatient pharmacies.

o) I understand that differences in pharmacy software may affect automation capabilities for adjudicating prescriptions through the TIRF REMS Access program without an insurance claim (i.e.: cash claim). If insurance is not used, pharmacy staff must manually enter the REMS Cash BIN #014780 or the designated chain pharmacy cash bin in order for the transaction to be properly adjudicated through the TIRF REMS Access program.

Note: The *'or the designated chain pharmacy cash bin'* language will not be included in the attestation on the Independent Outpatient Pharmacy Enrollment Form

e. ***Closed System Outpatient Pharmacies:***

The authorized pharmacist/pharmacy representative must complete the following requirements to enroll their **closed system outpatient pharmacy:**

i. Review the TIRF REMS Access Education Program (*TIRF REMS Access Education Program*) and successfully complete the *Knowledge Assessment.*

ii. Complete and sign the *Closed System Outpatient Pharmacy Enrollment Form*. In signing the *Closed System Outpatient Pharmacy Enrollment Form*, the authorized closed system outpatient pharmacy representative is required to acknowledge the following:

a) I have reviewed the TIRF REMS Access Education Program, and I have completed the Knowledge Assessment. I understand the risks and benefits associated with TIRF medicines and the requirements of the TIRF REMS Access program for pharmacies.

b) I will ensure that all pharmacy staff who participate in dispensing TIRF medicines are educated on the risks associated with TIRF medicines and the requirements of the TIRF REMS Access program, as described in the *TIRF REMS Access Education Program*. This training should be documented and is subject to audit.

c) I understand that converting patients from one TIRF medicine to a different TIRF medicine must not be done on a microgram-per-microgram basis. I understand that TIRF medicines are not interchangeable with each other, regardless of route of administration, and that conversion may result in fatal overdose, unless conversion is done in accordance with labeled product-specific conversion recommendations (refer to the list of currently approved TIRF products located on the TIRF REMS Access website at www.TIRFREMSaccess.com/TirfUI/rems/products.action. Note, a branded TIRF medicine and its specific generic product(s) are interchangeable.

d) I understand that TIRF medicines are contraindicated for use in opioid non-tolerant patients.

e) I understand that the initial starting dose for TIRF medicines for all patients is the lowest dose, unless individual product labels provide product-specific conversion recommendations, and I understand that patients must be titrated individually.

f) I understand the importance of discussing the risks and benefits of TIRF medicines with patients and their caregivers, and in particular the importance of taking the drug as prescribed, not sharing with others, and proper disposal.

g) I understand that the product-specific Medication Guide must be given to the patient or their caregiver each time a TIRF medicine is dispensed.

h) I understand that a TIRF medicine will not be dispensed without obtaining a TIRF REMS Access prescription authorization number issued by the TIRF REMS Access program prior to dispensing the prescription. A TIRF REMS Access prescription authorization number verifies that the prescriber and pharmacy are enrolled and active, and that the patient has not been inactivated from the program.

i) I understand that all dispensing locations must be enrolled in the TIRF REMS Access program to dispense TIRF medicines

j) I understand that TIRF medicines can only be obtained from wholesalers/distributors that are enrolled in the TIRF REMS Access program.

k) I understand that our pharmacy will not sell, loan or transfer any TIRF inventory to any other pharmacy, institution, distributor, or prescriber.

l) I understand that our pharmacy must re-enroll in the TIRF REMS Access program every two (2) years.

m) I understand that TIRF medicines are only available through the TIRF REMS Access program. I understand that the pharmacy must comply with the TIRF REMS Access program requirements for outpatient closed system pharmacies.

f. *Inpatient Pharmacies:*

The authorized pharmacist must complete the following requirements to successfully enroll their **inpatient pharmacy:**

i. Review the TIRF REMS Access Education Program (*TIRF REMS Access Education Program*) and successfully complete the pharmacy *Knowledge Assessment.*

ii. Complete and sign the *Inpatient Pharmacy Enrollment Form*. In signing the *Inpatient Pharmacy Enrollment Form*, the authorized pharmacist is required to acknowledge the following:

   a) I have reviewed the TIRF REMS Access Education Program, and I have completed the Knowledge Assessment. I understand the benefits and risks associated with TIRF medicines and the requirements of the TIRF REMS Access program for pharmacies.

   b) I will ensure that our inpatient pharmacists are educated on the risks associated with TIRF medicines and the requirements of the TIRF REMS Access program, as described in the *TIRF REMS Access Education Program.*

   c) I understand that converting patients from one TIRF medicine to a different TIRF medicine must not be done on a microgram-per-microgram basis. I understand that TIRF medicines are not interchangeable with each other, regardless of route of administration, and that conversion may result in fatal overdose, unless conversion is done in accordance with labeled product-specific conversion recommendations (refer to the list of currently approved TIRF products located on the TIRF REMS Access website at www.TIRFREMSaccess.com/TirfUI/rems/products.action). Note, a branded TIRF medicine and its specific generic product(s) are interchangeable.

   d) I understand that TIRF medicines are contraindicated for use in opioid non-tolerant patients.

   e) I understand that the initial starting dose for TIRF medicines for all patients is the lowest dose, unless individual product labels provide product-specific conversion recommendations, and I understand that patients must be titrated individually.

   f) I understand that pharmacies within or associated with the healthcare facility that dispense to outpatients must be separately enrolled in and comply with the TIRF REMS Access program to dispense TIRF medicines to outpatients, as described in section B.2.d, above.

   g) I understand that our inpatient pharmacy must not dispense TIRF medicines for outpatient use.

   h) I understand that a prescriber who wants to discharge a patient with a TIRF medicine prescription, intended to be dispensed by an outpatient pharmacy, will be required to enroll in the TIRF REMS Access program, as described in section B.1 of this REMS.

i) I will establish, or oversee the establishment of, a system, order sets, protocols and/or other measures to help ensure appropriate patient selection and compliance with the requirements of the TIRF REMS Access program.

j) I understand that our pharmacy will not sell, loan or transfer any TIRF inventory to any other pharmacy, institution, distributor, or prescriber.

k) I understand that TIRF medicines can only be obtained from wholesalers/distributors that are enrolled in the TIRF REMS Access program.

l) I understand that our pharmacy must re-enroll in the TIRF REMS Access program every two (2) years.

m) I understand that TIRF medicines are available only through the TIRF REMS Access program. I understand and agree to comply with the TIRF REMS Access program requirements for inpatient pharmacies.

g. Pharmacies (authorized pharmacist) are required to re-enroll every two (2) years.

h. TIRF Sponsors will:

i. Ensure that pharmacy enrollment can successfully be completed via the TIRF REMS Access website, by mailing or faxing the forms.

ii. Ensure that, as part of the enrollment process, the following materials that are part of the TIRF REMS Access program are available to pharmacies. These materials are appended:

- The TIRF REMS Access Program Overview (*Independent Outpatient Pharmacy, Chain Outpatient Pharmacy, Closed System Outpatient Pharmacy or Inpatient Pharmacy, as applicable*)
- *TIRF REMS Access Education Program*
- *Knowledge Assessment*
- *Pharmacy Enrollment Form (Independent Outpatient, Chain Outpatient, Closed System Outpatient, or Inpatient, as applicable)*
- *Frequently Asked Questions (FAQs)*
- *TIRF REMS Access Website*

iii. Ensure that all enrollment forms are complete, and that the authorized pharmacist has successfully completed the Knowledge Assessment before activating a pharmacy's enrollment in the TIRF REMS Access program.

iv. For **chain and independent outpatient pharmacies** only, TIRF Sponsors will also ensure that the configurations to the pharmacy management system have been validated before enrolling a pharmacy in the TIRF REMS Access program.

v. For **closed system outpatient pharmacies** only, TIRF Sponsors will ensure that, prior to authorizing a pharmacy's enrollment as a closed system outpatient pharmacy, the pharmacy meets the requirements of being deemed a closed system outpatient pharmacy (see II.B.2.c)

vi. Ensure that pharmacies are notified when they are successfully enrolled in the TIRF REMS Access program, and therefore, certified to dispense TIRF medicines.

vii. Monitor education and enrollment requirements for pharmacies and inactivate non-compliant pharmacies. Upon initial activation of enrollment, pharmacies remain active until a corrective action of inactivation occurs or expiration of the enrollment period.

viii. Ensure that prior to first availability of the TIRF REMS Access program/website, *Dear Pharmacy Letters* will be sent (one for inpatient pharmacies and one for outpatient pharmacies). The target audience for the letter will include outpatient and inpatient pharmacies that dispense Schedule II drugs and may be involved in dispensing TIRF medicines. The letter will include information on the risks associated with the use of TIRF medicines and the requirements of the TIRF REMS Access program. The letter will be available on the TIRF REMS Access website for 1 year from the date of the mailing.

The *Dear Pharmacy Letters (Outpatient and Inpatient)* are part of the TIRF REMS Access program. These materials are appended.

3. **TIRF medicines will only be dispensed for outpatient use with evidence or other documentation of safe-use conditions.**

a. TIRF Sponsors will ensure that TIRF medicines will only be dispensed for outpatient use if there is documentation in the TIRF REMS Access program system that the dispensing pharmacy and prescriber are enrolled and active, and the patient is not inactive in the TIRF REMS Access program.

b. Patients are passively enrolled in the TIRF REMS Access program when their first TIRF medicine prescription is processed at the pharmacy. Patients may continue to receive TIRF medicines while passively enrolled, for up to ten working days, as described in section II.C.5. Prescribers and outpatient pharmacies (including closed system outpatient pharmacies) are enrolled, as previously described in sections B.1 and B.2, respectively.

c. For **chain and independent outpatient pharmacies**: Prior to dispensing TIRF medicines, enrolled outpatient pharmacies will electronically verify documentation of the required enrollments by processing the TIRF prescription through their pharmacy management system.

i. If the required enrollments are verified, a unique authorization code will be issued to allow processing and dispensing of the prescription to the patient.

ii. If one or more of the required enrollments cannot be verified, the TIRF REMS Access program system will reject the prescription (prior to a claim being forwarded to the payer) and the pharmacy will receive a rejection notice.

d. For **closed system outpatient pharmacies:** prior to dispensing TIRF medicines, enrolled closed system outpatient pharmacies will verify documentation of the required enrollments by contacting the TIRF REMS Access program at 1-866-822-1483, or via fax, and providing the required information from the TIRF prescription.

i. If the required enrollments are verified, the TIRF REMS Access program will provide a unique authorization code to allow processing and dispensing of the prescription to the patient.

ii. If one or more of the required enrollments cannot be verified, a rejection reason, and information regarding how to resolve the rejection, will be provided.

e. Following initial activation, patient PPAFs remain active until a trigger for inactivation occurs. Triggers for PPAF inactivation include:

i. The patient has not filled a prescription for more than six (6) months.

ii. The PPAF has expired.

iii. The patient is deceased.

iv. The patient chooses to no longer participate in the TIRF REMS Access program.

f. If an active patient transfers from an enrolled prescriber to a non-enrolled or inactive prescriber, the TIRF REMS Access program cannot fill the prescription for TIRF medicines until the new prescriber is active in the TIRF REMS Access program.

g. A patient may have more than one current prescriber (e.g., pain management specialist, primary care physician) provided that prescriptions for TIRF medicines are not for the same or overlapping period of treatment.

h. Documentation and verification of safe-use conditions are not required for prescriptions ordered within an inpatient healthcare setting and given to an inpatient.

C. Implementation System

1. TIRF Sponsors will ensure that wholesalers/distributors who distribute TIRF medicines are enrolled in the TIRF REMS Access program and comply with the program requirements for wholesale distributors.

2. The wholesaler/distributor enrollment process is comprised of the following steps that must be completed by the distributor's authorized representative, prior to receiving TIRF medicine inventory for distribution:

a. Review the distributor TIRF REMS Access program materials

b. Complete and sign the *Distributor Enrollment Form* and send it to the TIRF Sponsors (by fax or mail). In signing the *Distributor Enrollment Form*, each wholesaler/distributor is required to indicate they understand that TIRF medicines are available only through the TIRF REMS Access program and acknowledges that they must comply with the following program requirements:

i. The Wholesaler/Distributor will ensure that relevant staff are trained on the TIRF REMS Access program procedures and will follow the requirements of the TIRF REMS Access program.

ii. The Wholesaler/Distributor will ensure that TIRF medicines are only distributed to pharmacies whose enrollment has been validated in the TIRF REMS Access program.

iii. The Wholesaler/Distributor will provide complete, unblinded and unblocked data (i.e., EDI 867 transmission) to the TIRF REMS Access program including information on shipments to enrolled pharmacies.

iv. The Wholesaler/Distributor will cooperate with periodic audits or non-compliance

investigations to ensure that TIRF medicines are distributed in accordance with the program requirements.

c. TIRF Sponsors will ensure that all forms are complete prior to enrolling a distributor in the TIRF REMS Access program.

d. TIRF Sponsors will notify distributors when they are enrolled in the TIRF REMS Access program and, therefore, able to distribute TIRF medicines.

e. Upon initial activation, distributors remain active until an action of inactivation occurs, expiration of the enrollment period, or failure to comply with the pharmacy enrollment verification obligations. If a previously active distributor becomes inactive, the distributor may become active again by completing the distributor enrollment process in its entirety.

f. Distributors will be re-educated and re-enrolled in the TIRF REMS Access program every two (2) years.

g. The following distributor materials are part of the TIRF REMS Access program. These materials are appended:

- *Dear Distributor Letter*
- *Distributor Enrollment Form*
- *Frequently Asked Questions*

3. TIRF Sponsors will maintain a database of all enrolled entities (prescribers, pharmacies, patients, and distributors) and their status (i.e., active or inactive), and will monitor and evaluate implementation of the TIRF REMS Access program requirements.

4. For **chain and independent outpatient pharmacies,** TIRF Sponsors will develop a TIRF REMS Access program system that uses existing pharmacy management systems that allow for the transmission of TIRF REMS Access information using established telecommunication standards. The TIRF REMS Access program system will incorporate an open framework that allows a variety of distributors, systems vendors, pharmacies, and prescribers to participate, and that is flexible enough to support the expansion or modification of the TIRF REMS Access program requirements, if deemed necessary in the future.

5. For **closed system outpatient pharmacies,** TIRF Sponsors will develop a system to allow enrollment and verification of safe use conditions through a telephone system and/or fax. TIRF Sponsors will monitor distribution data and prescription data to ensure that only actively enrolled distributors are distributing, actively enrolled pharmacies are dispensing, and actively enrolled prescribers for outpatient use are prescribing TIRF medicines. Additionally, TIRF Sponsors will monitor to ensure that, when dispensing in an outpatient setting, TIRF medicines are only being dispensed to actively enrolled patients of actively enrolled prescribers. Corrective action or inactivation will be instituted by TIRF Sponsors if non-compliance is found.

6. TIRF Sponsors will monitor prescribers' compliance with the requirement to complete a *Patient-Prescriber Agreement Form* with each TIRF patient, and to submit it to the TIRF REMS Access program within ten (10) working days. A maximum of three prescriptions are allowed within 10 working days from when the patient has their first prescription filled. No further prescriptions will be dispensed after the 10 working day window until a completed *Patient-Prescriber Agreement Form* is received. This will be accomplished by reconciling the Patient-Prescriber Agreements submitted to the TIRF REMS Access

program with patient enrollment data captured through the pharmacy management system for **chain and independent outpatient pharmacies** or through the call center for **closed system outpatient pharmacies**.

7. TIRF Sponsors will monitor and evaluate all enrolled outpatient pharmacies (including closed system outpatient pharmacies), distributors, and the TIRF REMS Access program vendors to validate the necessary system upgrades and ensure the program is implemented as directed.
8. TIRF Sponsors will evaluate enrolled inpatient pharmacies' compliance with the TIRF REMS Access program requirements through surveys.
9. TIRF Sponsors will maintain a call center to support patients, prescribers, pharmacies, and distributors in interfacing with the TIRF REMS Access program.
10. TIRF Sponsors will ensure that all materials listed in or appended to the TIRF REMS Access program will be available through the TIRF REMS Access program website www.TIRFREMSaccess.com or by calling the TIRF REMS Access call center at **1-866-822-1483**.
11. TIRF Sponsors will notify pharmacies, prescribers, and distributors of forthcoming enrollment expiration and the need to re-enroll in the TIRF REMS Access program. Notifications for patients will be sent to the patient's prescriber.
12. If there are substantive changes to the TIRF REMS Access program, TIRF Sponsors will update all affected materials and notify pharmacies, prescribers, and distributors of the changes, as applicable. Notifications for patients will be sent to the patient's prescriber. Substantive changes to the TIRF REMS Access program are defined as:
    a. Significant changes to the operation of the TIRF REMS Access program.
    b. Changes to the Prescribing Information and Medication Guide that affect the risk-benefit profile of TIRF medicines.
13. Based on monitoring and evaluation of the REMS Elements to Assure Safe Use, TIRF Sponsors will take reasonable steps to improve implementation of these elements and to maintain compliance with the TIRF REMS Access program requirements, as applicable.

III. TIMETABLE FOR SUBMISSION OF ASSESSMENTS

TIRF NDA Sponsors will submit REMS Assessments to the FDA at 6 and 12 months from the date of the initial REMS approval, and annually thereafter. To facilitate inclusion of as much information as possible, while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. TIRF NDA Sponsors will submit each assessment so that it will be received by the FDA on or before the due date.

EXHIBIT 21

IN THE DISTRICT COURT OF CLEVELAND COUNTY

STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA, Plaintiff,	)	
-vs-	)	No. CJ-2017-816
PURDUE PHARMA, L.P.; et al., Defendants.	)	

* * * * *

VIDEOTAPED DEPOSITION OF JASON BEAMAN, D.O.

TAKEN ON BEHALF OF THE DEFENDANTS

IN OKLAHOMA CITY, OKLAHOMA

ON MARCH 26, 2019

COMMENCING AT 9:14 A.M.

* * * * *

instaScript, L.L.C.
101 Park Avenue, Suite 910
Oklahoma City, Oklahoma 73102
405.605.6880
schedule@instascript.net

REPORTED BY: BETH A. McGINLEY, CSR, RPR

A They were involved in facilitating the communications, but not in the actual criteria. They did not have any input into the criteria.

Q Can you tell me the particular input that Dr. Clauw had into the criteria?

A Well, Dr. Clauw would have been involved in all three steps, and I -- I can't tell you exactly what he wanted in or what -- wanted out, but he would have been involved in all three steps.

Q What is Dr. Clauw's medical specialty, if you know?

A I believe him to be a pain management physician.

Q Okay. What is Dr. Mazloomdoost's medical specialty, if you know?

A I believe him to be a pain management physician.

Q Do you know anything about Dr. Mazloomdoost's training or experience, other than you believe him to be a pain management specialist?

A No.

Q You never reviewed his CV or anything like that?

A I did not review his CV.

Q Do you know anything about Dr. Clauw's training or experience, other than having a general understanding that he is a pain management specialist?

A No.

Q What about Dr. Kolodny, do you know what kind of -- what is Dr. Kolodny's specialty, if you know?

A Dr. Kolodny is a specialist in addiction psychiatry.

Q Uh-huh. Can you tell me what input Dr. Mazloomdoost had into the criteria?

A It would be the same for Dr. Clauw, that he was involved in establishment of all three criteria. I can't point to any one condition or criteria that he recommended or didn't recommend.

Q Would the same answer -- would you have the same answer for Dr. Kolodny's input?

A Yes.

Q Nothing specific that you can point to that he -- that he offered or -- or requested be included in the criteria?

A Correct.

Q Okay. When did you and this group of other physicians develop this set of three criteria?

A It would have been -- I -- probably June or July.

Q Of 2018?

A Yes, ma'am.

Q And so you finalized the set of criteria, obviously, before you began your review of the actual

prescription data, correct?

A Yes. There was a condition that was added, and that was --

Q What was that?

A -- I believe, sickle cell anemia, which required me to go back and rereview records, applying that.

Q And you -- it was added. When was that condition added?

A In the fall sometime, but I can't be certain as to when.

Q And who added that condition?

A I -- I can't remember. I believe it may have been Dr. Manzloom- --

Q Mazloomdoost?

A Yes.

Q It wasn't your idea to add that?

A It was not.

Q Okay. Okay. Do you have any recollection of any particular communications you had with Dr. Mazloomdoost as to why he wanted to add sickle cell anemia?

A No.

Q Okay. Did you discuss that with the other physicians, as to whether or not they agreed with that addition?

A Yes.
Q And they did?
A They did.
Q Okay. All right. And, again, you would agree with me that this set of three criteria reflected on Page 2 of your disclosure was developed solely for use in this litigation, correct?
A Yes. It -- it was developed so that we could provide the objective review of the medical records.
Q What -- what you deemed to be an objective review --
A Yes.
Q -- of the medical records, correct?
A Correct.
Q Okay. Did you review or rely on any source material, written documents, or other publications, for your input into the criteria?
A I would say that my expertise as a physician comes from the frequent review of documentation and education and materials, and, certainly, I relied on that. Can I point to a specific document? Not necessarily. Certainly, we know that the 2016 CDC guidelines --
Q Uh-huh.
A -- list 90 MME, along with several specialty organizations.

knowledge of physicians prior to being involved in this case.

Q Okay. When you say "the knowledge of physicians," are you talking about the knowledge of physicians as to the risks and benefits of opioids?

A Yes.

Q So, prior to your involvement in this case, you did not have an opinion as to whether or not physicians in Oklahoma possessed the requisite knowledge of the risks and benefits in order to be able to responsibly prescribe opioid medications?

A Yes, to the best of my recollection.

Q Okay. So it's only since your involvement in this case that you have come to the conclusion or formed the opinion that the majority of physicians in the state of Oklahoma lack the requisite knowledge of the risks and benefits of opioids in order to be able to make responsible prescribing decisions?

A I think that's a fair statement.

Q Okay. And what information have you reviewed or what research have you done, since becoming involved in this case, that has led you to that conclusion?

A As -- as being an expert in this case, I have reviewed marketing material that says such things as opioids are not addicting, that certain opioid medications

are not addicting. I've seen referenced a concept of pseudoaddiction, as I understand it, is, if a patient is showing or exhibiting signs of opioid addiction, that the proposed solution was to give them even more of the addicting substance because the premise was that their pain was not being adequately treated and that their sym-- signs and symptoms of addiction were actually signs and symptoms of untreated pain and that they require more of the addictive substance.

I have seen information regarding money that was paid by pharmaceutical companies to different medical information dissemination venues, like CME, publications, and medical journals. Some of this, I've reviewed as part of this case; some of this, I have become aware through my reading outside of the case. But, definitely, just being involved in this case has opened my eyes to what physicians were told and to -- and -- and how that was told to them.

Q Okay. In the context of your work as an expert in this case, have you interviewed any physicians in the state of Oklahoma about information they have received, at any time, from opioid manufacturers? Marketing information.

A Not -- not as part of the involvement in this case.

Q Have you done research on that at all, outside this --

A I've had conversations. I haven't done formal research.

Q Okay. So you've just had sort of casual conversations, form here -- here and there, with physicians, about how or what type of pharmacy marketing material -- pharmaceutical marketing materials they may have received regarding opioids?

A And -- and their overall belief about opioids --

Q Okay.

A -- yes.

Q But, again, you've not done any formal research, either in the context of your work in this case or otherwise, regarding the extent to which physicians in the state of Oklahoma have been influenced by marketing information that they may have received from pharmaceutical manufacturers, have you?

A I -- I haven't done that research, no.

Q And you've not personally received information from any of the pharmaceutical manufacturers named in this case, about their opioid products, other than what you told me about earlier, which was seeing, perhaps, a pamphlet on Actiq at one point in time, correct?

A Not other than what we discussed earlier.

Q Okay. Do you need -- do you need --
A I'm good.
Q Okay.
A I'm good.
Q All right. You said that -- a moment ago, that you saw something in some of the materials that you've reviewed since you got involved in this case, where there was a -- something that proposed a solution to give more of a substance to a patient who was exhibiting signs of addiction, and you referred to the term "pseudoaddiction." What entity or entities proposed that solution that you referred to?
A I believe I've seen it several times, but the -- the information that comes to mind, I believe, was in marketing material by Cephalon.
Q By Cephalon?
A Yes.
Q Okay. And what was the drug that was being marketed in that material, Doctor?
A I can't recall.
Q Okay. Do you know what opioid medications Cephalon manufactures or has manufactured in the past?
A No, I would just be guessing.
Q You'd be guessing, okay.
A Yeah.

A It's a difficult question to answer --
Q Uh-huh.
A -- because I don't think medicine has decided on what the full benefit of opioids are. I certainly believe that we are doing our best to teach them the most recent, up-to-date consensus, but that may evolve, as with most things in medicine.
Q And that's a great point, Doctor. As with most things in medicine, the understanding of -- of disease processes, the understanding of medications and their appropriate uses, evolves over time; that's fair, correct?
A Including the influence of pharmaceutical companies and our knowledge of how much that influence actually changes prescribing habits.
Q But, again, that's not something you've done any research on, is it?
A No.
Q All right. And you don't intend to offer an opinion, as an expert in this case, on the impact of pharmaceutical marketing on -- on physicians in Oklahoma, as it relates to their prescribing habits for opioids?
A Not other than to say I believe physicians should not be interacting with pharmaceutical representatives on a regular basis.
Q Okay. Other than that --

A No.

Q -- you're not planning to come in and say that physicians have been influenced in a -- to a certain degree, that has caused them to prescribe some percentage more than they would otherwise have prescribed or things of that nature?

A No.

Q Okay. Let me ask you this -- and, again, I want to -- I'll -- you sort of answered this question. I want to make sure it's clear on the record because of how it was qualified.

Do you intend to offer an opinion, as an expert for the State, as to the number or percentage of physicians in the state of Oklahoma who lack the full, complete and accurate knowledge as to the risks and benefits of opioids, so as to be able to reasonably prescribe opioids?

A I -- I don't plan on offering that opinion.

Q All right, thank you. And you've never done any work to interview or otherwise collect data, formally collect data from Oklahoma physicians, as to what types of information they have received from pharmaceutical manufacturers about opioids, have you?

A I have not.

Q And you've never done any formal interviews or

collected any formal data regarding whether or to what extent Oklahoma physicians have been influenced in their prescribing habits based on information they've obtained by -- or from manufacturers, have you?

A I -- I have not personally collected. I think that there are articles that I've read that have had that information, but I didn't personally collect it and I don't plan on offering an opinion on that.

Q Okay. And you've certainly not interviewed or formally collected data from any patients regarding their experiences in being prescribed opioids by their physicians, are you?

A Well, I -- I -- I would think I would disagree with that. I have had numerous conversations with patients in my career, about their experience in being prescribed opioid medications, about -- from their physicians.

In an addiction medicine practice, and even in a psychiatric practice, it is commonplace to talk to patients about their opioid use, including what they were getting from their physicians, and how -- in my role as a consult psychiatrist at O- -- OSU Medical Center, I often, I would say almost daily, evaluated patients that had overdosed on opioid medications that had been prescribed by their physicians.

Q And when did you -- I'm sorry, I didn't mean -- were -- I didn't mean to interrupt you.

A I'm done.

Q Okay. And when did you do that? During what period of time were you evaluating, almost daily, patients that had been -- that had overdosed on opioid medication?

A Since starting at OSU Medical Center in July of 2015, until approximately one year ago. In the last year, it would be intermittently.

Q Okay. Let me make sure I've got the date. So starting in July of 2015, when you took on the position as the chair of the Department of Psychiatry and, what, Behavioral --

A Sciences.

Q -- Sciences -- until what date or what approximate date were you --

A Approximately 12 months from today.

Q Okay. So until sometime in March of 2018. So for two and a half years, approximately, you were seeing patients on a daily basis --

A Almost daily basis.

Q -- on an almost daily basis, that had overdosed on opioid medication?

A Yes.

Q Okay. So during that two-and-a-half-year

filled outpatient. So I think some prescriptions were prescribed by a physician in the hospital, but on discharge --

Q Uh-huh.

A -- so that the patient would have been handed the prescription. It did not include medications that were prescribed during the course of the hospitalization, itself.

Q Well, and did -- did the materials that you reviewed always include discharge prescriptions or prescriptions that were given upon discharge by a physician in the hospital? In other words, that's something different than an outpatient prescription; wouldn't you agree?

A Possibly, but I don't think I would know.

Q Okay. All right. So you don't know -- I guess what I'm getting at is: If there were prescriptions that were made to a patient in an inpatient setting, that are included among the 38,400-and-some-odd, you have no way of distinguishing whether they were made in an inpatient setting or an outpatient setting?

A Well, they were filled outpatient.

Q Okay. All right. So if they were filled outpatient, but they were made during an inpatient setting, do you know if medical records were requested

from the inpatient facility so that it -- so that a review could be done as to the basis for those prescriptions?

A No.

Q You don't know?

A No, I... no, I don't know.

Q Okay. All right. And -- and it indicates -- I think I know the answer to this, but in no -- in no instance did you or anyone in the group of individuals you mentioned, who have been involved in this review process, make contact with or communicate with any particular physician to determine whether or not the physician had performed a functional assessment evaluation, if -- if it seemed to be missing from the medical records?

A We did not communicate with any physicians located within the sample.

Q Okay. Let's go to your third criteria, which is the -- it says here, "The prescription was not provided for any of the following diagnoses." Are you with me on that?

A Yes, ma'am.

Q So I just want to make sure, again, I understand. If a prescription was, in fact, made for one of the listed diagnoses, you would nece- -- trying not to use the words "necessary" too much, so let me start over.

If the prescription was made for one of the

listed diagnoses on Page 2 of your disclosure, that prescription would be deemed to be not medically unnecessary?

A Correct.

Q Okay. Regardless of whether it met the other two criteria, correct?

A That is correct.

Q Okay.

A You had to meet all three criteria.

Q Okay. Let's talk about those particular diagnoses real quick. The first is post-cervical and lumbar laminectomy with epidural scarring and arachnoiditis. You see that?

A Yes.

Q Are you an expert in treating those conditions?

A No.

Q The next one is spinal cord injuries. Are you an expert in treating those conditions?

A No. Although I will tell you that it is very common for family medicine to treat the pain related to a spinal cord injury.

Q Okay. The next one is spastic neuropathic pain other than multiple sclerosis. Do you see that?

A Yes.

Q Are you an expert in treating that condition?

A Yes.
Q All right. Are you able to tell me how many times?
A No. It would have been related to my work as a hospitalist --
Q Uh-huh.
A -- upon discharging someone from the hospital, and would have been infrequent. I would say probably less than 10.
Q Less than 10 times, and that's in your work since be- -- since completing your residency?
A Correct.
Q Okay. On the occasions that you have prescribed medication -- opioid medications, post your residency, have -- have they always been prescriptions that would have met -- that -- well, have they always been prescriptions that would be not medically unnecessary under your criteria here?
A I don't believe any of my prescriptions would have met this criteria.
Q As being medically unnecessary?
A Yes.
Q Okay. So you believe all the prescriptions that you've ever made for opioids, during your career, have been not medically unnecessary?

A That is correct.

Q Okay. What are some of the conditions that you recall, either during your residency or after your residency, where you have found it to be appropriate or medically necessary to prescribe opioids?

A So when I prescribed opioids, I would say, in residency, the overwhelming majority would have probably been chronic pain. I had a attending physician who had a large panel of chronic pain patients and, when he was gone, out of the clinic, or if a patient needed an emergent visit, they would be put in the resident's schedule, including my own, and I would be asked to refill that patient's medication.

After residency -- also during residency, it would have been post-C-section or vaginal birth.

Q Uh-huh. Okay.

A Then after residency, it would be probably mostly related to a post-surgical patient.

Q Uh-huh.

A I can't think of any specific examples of when it was not a post-surgical patient, but certainly that could have existed.

Q Okay. So back when you were working with the attending physician that had the chronic pain patient population, what kinds of opioids were you prescribing?

Do you recall which ones?

A My best recollection is that it would have been hydrocodone, oxycodone and possibly MS Contin.

Q Okay. In terms of the patients that you have prescribed opioids for during the time you worked as a hospitalist, either post-surgical patients or post-C-section/vaginal birth patients, what opioids -- what type of opioids were you prescribing? Same thing?

A I believe it -- it would have been almost exclusively hydrocodone.

Q Hydrocodone, okay.

A Notwithstanding tramadol.

Q Okay. Is it your expert opinion, Doctor, that opioids should not, under any circumstances, be prescribed for post-surgical pain?

A No.

Q So you would concede that, in some cases, it is appropriate for opioids to be prescribed for post-surgical acute -- acute pain?

A Yes.

Q Okay. And -- and would you also agree that it is, sometimes, medically necessary to prescribe opioids for post-C-section or vaginal birth acute pain?

A I -- I think depending on the -- on the extent of, like, labial tear --

Q Uh-huh.
A -- or other trauma to the vagina, but, as a general rule, opioids should not be routinely used for post-vaginal birth pain.
Q Uh-huh.
A I would agree that they are sometimes appropriate for post-C-section pain.
Q Okay. Why did you not include post-surgical acute pain or -- or post-vaginal birth on your list in Item No. 3?
A Well, if they were acute pain, then they should not have been over 90 MME.
Q Okay. So, in your opinion, there is no circumstance in which a prescription of over 90 MME should be prescribed for any type of post-surgical acute pain? Is that your expert testimony, or expert opinion?
A That you should not give 90 MME to an opioid-naive individual.
Q Okay. So that's a little bit different than what I asked. So what -- what's an opioid-naive individual, Doctor? Explain --
A Somebody that has not taken an opioid before.
Q Okay. So let's take the -- the example of an opioid -- of an individual who is not opioid naive, okay? Is it your expert opinion that, with such an individual, a

prescription for over 90 MME should never be prescribed for post-surgical acute pain?

A I -- I -- I don't like speaking in absolutes, so I'm not going to say never.

Q Uh-huh.

A But I think that that would be rare.

Q Okay. But that's -- again, as we talked last time, that was -- that would be something that you, as an expert and a -- and a professional -- a physician, would leave to the individualized decision-making of the -- of the physician treating the patient?

A Making a -- a full risk/benefit analysis, yes.

Q Right, okay. Okay. Doctor, if -- get these Exhibits 9 and 10 in front of you again, these two spreadsheets we looked at a minute ago.

And, again, as I explained to you, these are the spreadsheets that we pulled from the MMIS data -- that's Exhibit 9 -- and then from the OK Expert 16 data, which is Exhibit 10, which we believe relate to the 245 prescriptions of Actiq or Fentora that were referred to in the petition.

Based on these spreadsheets that we pulled, it appears that the re- -- the statistical review that you and the review team that you've described reviewed -- or -- or I should say made determinations as to only three

of the 245; is that accurate?

A Yes.

Q Okay. And with regard to the three prescriptions of Actiq or Fentora out of the 245 referenced in the petition, of those three that were reviewed, you found that they were not medically unnecessary; is that correct?

A I don't know, because I'm not sure of the designation of the -- of the "Y" in the column.

Q So would we be able to compare that with the data you brought with you?

A Yes, we should be able to.

Q So let's do that, so we don't have any confusion.

A What page is that?

Q It's on the -- it's the last three lines of --

A Of --

Q -- the OK Expert 16 document.

A Okay.

Q Which is Exhibit No. 10. And there's an ICN number that corresponds which each -- with each of those.

A We're going to test the system here.

Q Uh-huh.

MR. DUCK: By the way, I sent electronic versions to --

A Not outside of the fact that they were part of a -- of a statistical analysis.

Q (By Ms. Patterson) Okay. But they weren't -- but -- but they weren't actually reviewed?

A They were not reviewed by me.

Q Okay. Or anyone, to your knowledge, for the --

A Not to my knowledge.

Q Okay. So, as an expert, sitting here in this case, do you plan to offer an opinion to the jury in this case, as to whether or not any of the claims in -- at Lines 1 through 242 of Exhibit 10, were medically unnecessary?

MR. DUCK: Objection to form.

A I would say I don't plan on offering an opinion, one way or the other, except to -- my testimony that a certain percentage of the prescriptions that I reviewed were medically unnecessary, certainly as that -- and that would be extrapolated to the 245.

Q (By Ms. Patterson) So the only way you would be able to offer an opinion, as to the -- as to prescriptions 1 through 242 on this particular spreadsheet, would be to extrapolate based on the fact that three out of 245 were found to be not medically unnecessary?

A Well, the --

MR. DUCK: Objection to form.

A The three out of the 245 were part of the larger sample.

Q (By Ms. Patterson) Uh-huh.

A And this is -- the -- the State is claiming, and I agree with it, that this is an indivisible injury, so I would not separate out the -- the three from 245 or the 245 out from the 8,000 or the 8,000 out from nine million.

Multiple patients were prescribed multiple different opioids for multiple different reasons. It's not clean-cut and indivisible, so, I mean, I think that you can draw broad conclusions based on the three out of 245, but I would not -- I would not limit it.

MS. PATTERSON: Objection, nonresponsive.

Q (By Ms. Patterson) You understand that Actiq and Fentora are -- are rather unique in the particular indication that -- that -- that they have, right?

A In that they are approved for cancer --

Q Right.

A -- related breakthrough pain.

Q Correct.

A Yes.

Q Okay. And so based on what I've seen in this data, okay, you reviewed -- you and your team reviewed only three of 245 distinct Actiq and Fentora prescriptions and you found that the three that you reviewed were not

medically unnecessary, correct?

A Correct.

Q Okay. Is it your plan to test- -- to -- to provide the jury with an expert opinion that any of the other 242 Actiq and Fentora prescriptions listed on Exhibit No. 10 were medically unnecessary?

MR. DUCK: Objection to form.

A Other than that they would have been included in the sample for which Dr. Gibson analyzed.

Q (By Ms. Patterson) Well -- well, they weren't included in the sample. We already estab- --

A They were included in the statistical analysis, not in the sample, but they were included in the universe in which Dr. Gibson analyzed.

Q Right. Well --

A The nine million.

Q Oh, well, sure, they were included in the nine million. That's a given. But they weren't included in the statistical sample that he had you review, were they?

A They were not.

Q Okay. Okay. One last thing I wanted to ask you about Exhibit 10. If you'd go to the last page -- and this is, again, on the OK Expert 16, and if you look in the "C Stratum 3" column and the "Sample Stratum" columns.

In the "C Stratum 3", column those three prescriptions that we looked at, at Lines 243, 44 and 45, are all listed as medium, do you see that, on the last page?

A Yes, I do.

Q Okay. And I think we both are under the same assumption that that relates to the stratums that you assisted Dr. Gib- -- Gibson in coming up with, correct?

A I -- I believe that to be likely, yes.

Q And then over in the next column, though, there's the word "High" next to those three lines, but that column, for every other prescription on this data -- on this spreadsheet, is empty. So do you know what the -- the designation "High" there means?

A I do not.

Q Okay. Doctor, do you recall, in your deposition last time, you talked about a different group of prescriptions for Actiq or Fentora that you thought might exist, and I think you used the term -- or you referenced a group of 2700 prescriptions for Actiq or Fentora?

A Yes.

Q Okay. Have you thought any more about that since your last deposition, to determine where you got that information?

A No.

Q Okay.

A It's -- it's my recollection that the 2700 was a larger time frame than what was listed at the 245.

Q Okay.

A But that's as much understanding as I have about it.

Q Okay. And the 245, as we talked about last time, or at least according to the State's petition, was -- and this is Exhibit 3 to the State's petition -- was from the time period -- they were dispensed between 1/1 of 2007 and 6/21 of 2017. That's what Exhibit 3 says --

A Okay.

Q -- if you'll at look it. Okay. Again, that's Exhibit 3 to the petition.

But you think the 2700 prescriptions that you were thinking about in your last deposition covered just a -- a broader period of time?

A Yes.

Q Okay. Do you know if any of those 2700 prescriptions that you referred to in your last deposition are contained in the very large spreadsheet that you brought me today as Exhibit No. 2?

A I do not.

Q You don't know, one way or the other?

A I do not. We did not do the -- the sample based on individualized medications or manufacturers or whatnot.

Q Right. So, in order for me to determine whether or not any of -- there are any other prescriptions for Actiq or Fentora in what you've brought me as Exhibit No. 2, I'd have to go back -- well, what would I have to do? Would -- do you know?

A I would not know.

Q Okay. All right. But, as you point out, there's no way, in looking at what you brought, to determine what particular opioid medication is associated with any of these prescriptions in the databa- -- or in the spreadsheet you brought, correct?

A Not in what I brought today, no.

Q Okay. I asked you, in your last deposition, whether the State has undertaken any kind of analysis, that you're aware of, to determine which of the 2700 prescriptions of Actiq or Fentora were excessive or unnecessary, and you answered "Yes." And I said, "Who did that for the State?" And you said, "I did." Is that still accurate testimony?

A Yeah, in that it would have been included in the nine million of which we did a sample, of which I did a review of a subset of that and then provided Dr. Gibson that information.

Q Okay. But, again, you cannot provide me with a number of -- of how many, if any, of the 2700 prescriptions you may have determined to be medically unnecessary, can you?

A I can't provide you any --

MR. DUCK: Objection to form.

A I can't provide you any specific information on specific medications or manufacturers.

Q (By Ms. Patterson) Because you didn't look at that?

A I did not look at that for the purpose of my review.

Q Okay. Okay. Let's look at 912853... okay. Got it.

Okay, Doctor, let's --

A Are you done with Exhibit 2 for now?

Q We -- well, no, we're probably going to actually use it to look up some of this stuff that I'm going to show you on some specific --

A Okay.

Q -- patients.

So what I'm going to show you right now, I'm going to mark as Exhibit 11 for this deposition, is...

MR. DUCK: Thanks.

Q (By Ms. Patterson) ...a document that was

previously marked as Exhibit 18 at your prior deposition. And then I'm going to mark Exhibit No. 12, a document that was previously marked as Exhibit 19 --

MR. DUCK: Thank you.

Q (By Ms. Patterson) -- at your prior deposition. And --

A If I could just have a second to --

Q You sure can.

A -- review this.

Q Yep. And I'll just tell you, just to be clear for the record, and then you can have as much time as you need: These -- both of these documents relate to a patient who had a identifier number of 912853, if you want to --

MR. DUCK: And, I'm sorry, can you say that one more time?

MS. PATTERSON: Sure. Now, this is not the ICN number.

MR. DUCK: ID.

THE WITNESS: Oh. 912?

MS. PATTERSON: It's -- it's 912853. It's the de-identified member number.

MR. DUCK: 196. It's Page 196.

THE WITNESS: And row?

MR. DUCK: Oh. 13467.

EXHIBIT 22

IN THE DISTRICT COURT OF CLEVELAND COUNTY

STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA,	)	
Plaintiff,	)	
-vs-	)	No. CJ-2017-816
PURDUE PHARMA, L.P., et al.,	)	
Defendants.	)	

VIDEO DEPOSITION OF ADRIANE FUGH-BERMAN

TAKEN ON BEHALF OF THE DEFENDANTS

IN OKLAHOMA CITY, OKLAHOMA

ON MARCH 6, 2019

COMMENCING AT 9:05 A.M.

INSTASCRIPT, LLC
101 PARK AVENUE, SUITE 910
OKLAHOMA CITY, OKLAHOMA 73102
(405) 605-6880
www.instascript.net

REPORTED BY: KIM GLOVER, CSR, RPR, RMR, CLR

defendants, 11, 12, and 13, the Watson Actavis defendants. I also represent those defendants. All right?

A Okay. Thank you.

Q Prior to --

MR. BECKWORTH: Just objection real quick. There's also a joint defense agreement, so you understand these lawyers are also working together. That wasn't fairly told in this line of questioning.

MS. PATTERSON: I'll object to the representation, but that's fine, Mr. Beckworth.

Q (By Ms. Patterson) Do you understand that these are the defendants that have been sued in this case?

A Yes.

Q Okay. Now, before I showed you this petition and went over with you the specific defendants who are actually named in this case, did you know who the defendants were in this case?

A I knew about most of them. I'm not sure about Actavis.

Q So you knew that there were Purdue defendants?

A Yes.

Q And you knew that they were Johnson & Johnson or Janssen defendants?
A Yes.
Q And you knew that there were Teva or Cephalon defendants?
A Yes.
Q Do you know about the Actavis entities?
A I don't think so.
Q Have you ever heard of Actavis, LLC, or Actavis Pharma?
A Yes.
Q Do you know what products, if any, those companies manufacture that are opioids?
A I would not be able to name them, no.
Q Okay. What about Watson Laboratories and Watson Pharma, do you know what opioid medications those companies have, in the past or currently, manufactured?
A Watson makes a number of generics, but I don't recall exactly what opioids they make.
Q Okay. Are you aware of Watson making anything, other than generic medications?
A I'm not sure.
Q Okay. Do you know if Actavis makes only generic medications?

A I don't know.

Q Let me ask you just a few general questions before we get into more specific areas.

First of all, the petition that I have provided you that was filed by the State of Oklahoma refers to an opioid epidemic. And it refers to that throughout the document, but just so you are with me, if you will turn to the second page of the document, which is a table of contents. And you will see down under the section -- no. You were -- right there. Right there. Yeah, you're right.

Second page of the document, it's a table of contents, and you will see there's a section entitled "Factual Allegations."

Do you see that, down toward the middle?

A Yes.

Q And you will see in Subheading A there, for example, it says, "Defendants' conduct created a devastating opioid epidemic in Oklahoma."

Do you see that?

A Yes.

Q All right. Do you believe that there is an opioid epidemic in this country currently?

MR. BECKWORTH: Hold on. just a

second. Objection. It's beyond the scope of her report. She's not here to testify as an epidemiologist.

I would also state for the record that your client, Nancy, and every other one has admitted that there is an opioid epidemic and a crisis.

Her testimony and her report is very clearly set out in her disclosure. She is not here as a drafter of a petition, she's not here as a lawyer, and she's certainly not here as an epidemiologist.

So, with that, I will instruct you that, if you can answer the question about epidemiology, you're free to do so.

MS. PATTERSON: And I'll just object for the record, Brad. If you're going to do this all day long, we're going to be here a long time and we're going to have a problem getting finished.

You know that's not an appropriate speaking objection. Okay?

MR. BECKWORTH: Disagree.

MS. PATTERSON: I get to ask the questions. You can object to scope and then let's just move on. Okay?

you see that?

A Yes.

Q And I see the reference -- or that term, "complementary medicine," used a number of other places in your CV. Very briefly, what is complementary medicine?

A So there have been various terms that have been used to describe therapies or practices that are not routinely taught in medical schools or routinely practiced by medical doctors.

So, over time, those terms have included complementary medicine, alternative medicine, integrative medicine, et cetera.

So complementary medicine is -- is one of those terms, but they are really all the same.

Q Okay. All right. Moving on up the list there on the first page, there is a reference to your work as a consultant for the George Washington University School of Public Health and Health Services.

And I note in there it says, "Analyze prescription drug marketing data in the District of Columbia." Do you see that?

A Yes.

Q And I noticed that some other places in

your CV there are references to work you have done specific to the District of Columbia, which is where you live; correct?

A Yes.

Q All right. Have you analyzed prescription drug marketing data in the State of Oklahoma?

A I have not.

Q Okay. Are you aware of any studies, research, or articles that have analyzed prescription drug marketing data in the State of Oklahoma?

A There are -- there are many research articles that have looked at pharmaceutical marketing practices nationally, and there is no reason to think that those practices would be any different in the State of Oklahoma.

Q But, to answer my question, are you aware of any studies, research, or articles that have specifically analyzed prescription drug marketing data in the State of Oklahoma?

A Well, I'm not aware of any published studies that have -- that have examined general pharmaceutical marketing in the State of Oklahoma. I don't think that those studies are actually necessary for looking at the effect of pharmaceutical marketing

of opioids in the State of Oklahoma.

We have the companies, we have -- we have documents -- I have documents and sales calls and plans for marketing from several companies to specific Oklahoma physicians.

Q Okay. Are you finished with your answer?

A Yes.

MS. PATTERSON: Objection, nonresponsive.

Q (By Ms. Patterson) My question is: Are you aware of any studies, research, or articles that have specifically analyzed prescription drug marketing data in the State of Oklahoma?

MR. BECKWORTH: Objection. She has answered it several times.

THE WITNESS: There -- I have not seen published studies in the medical literature on pharmaceutical marketing practices specifically in the State of Oklahoma.

Q (By Ms. Patterson) Okay. As I understand one of your prior answers, I think what you're telling us is that you believe you can rely, for purposes of your opinions in this case, on studies and research that have been done on a national level

regarding prescription drug marketing practices?

A That would be part of what I would rely on.

Q What else do you rely on?

A On the companies' -- on companies' own documents, including call notes and including plans for pharmaceutical marketing and there are -- and the numbers of call visits, for example, that occurred in the State of Oklahoma.

Q So the only information you have on call notes, with regard to calls made on doctors in the State of Oklahoma, is based on the information that was provided to you by the lawyers for the State; correct?

A They provided me with some call notes. There are many others, and at some point, I actively prevented them from providing me with additional call notes, because there were so many of them.

Q You actively prevented counsel for the State from providing you with additional call notes. Is that what I understood you to say?

A I have examples of -- I have some examples of call notes.

Q Right. I understand. But your understanding is that you have been provided --

A There are many of them, and my understanding is that there are many other call notes that are -- can also be used as examples.

Q Okay. All I'm trying to understand is what you've looked at and what you think is out there.

A I have looked at numerous call notes. I have a sample of them here.

Q Sure. I understand.

A There are many more that exist.

Q I understand. And you have not -- let me do it this way.

Your understanding from your interactions with counsel for the State is that there are -- there's a large group of call notes, but you have only been provided a subset of that; correct?

A I have been provided with a subset of call notes, because there are so many of them, yes.

Q Okay. Do you know what percentage of the universe of call notes that the State has that you have been provided?

A I do not.

Q Okay. Have you asked to review -- as we sit here today, have you asked to review any additional call notes?

A I was provided some call notes and

and their patients than that of other morphine alternatives" --

Q (By Ms. Patterson) You don't need to read it to me. If you can just point me --

A Okay.

Q -- tell me what page it's on.

A Sorry. It's on Page 10.

Q Page 10, okay.

A So this is Oklahoma's --

Q Okay.

A -- sales manager.

Q Okay.

A The --

Q Is there any other --

A -- information in that --

Q I'm sorry. I didn't mean to cut you off.

MR. BECKWORTH: Well, it keeps happening. Why don't you -- you can complete an answer, despite the interruptions.

Q (By Ms. Patterson) Yeah. I'm not trying to -- you talk slowly and you do kind of stop at times, and so sometimes I think you're finished with your answer. And I'm not trying to cut you off.

MR. BECKWORTH: Well, good. Then

you won't mind her continuing.

THE WITNESS: And the -- I'm pausing because I just want to make sure that I'm really thorough in my answer.

I feel like there was another point in here where I also mentioned Eric Wayman. So Wayman also states, in a different point in the deposition, that the total prescription level is highly correlated to call activity.

And, again, he -- he is the -- he is the Oklahoma sales manager, so --

Q (By Ms. Patterson) Have you ever spoken to or interviewed Mr. Wayman?

A I have not.

Q Everything you know about what Mr. Wayman believes went on in Oklahoma is based on your review of his deposition. Is that fair?

A That's fair.

Q Okay. Other than the references to Mr. Wayman's deposition that appear in a couple of different places in Exhibit No. 8, can you point to me -- point me to any other discussion in Section B of your expert disclosure where you discuss any particular marketing tactic that was used by any of the defendants with any prescriber in the State of

Oklahoma?

A Again, information -- national information would not exclude Oklahoma and is relevant to Oklahoma.

I have not -- I -- to the best of my recollection, I have not included other information specific to marketing of opioids in Oklahoma specifically in this report.

Q Okay. Have you -- have you done any research to determine whether there is any particular marketing tactic or sales tactic that any of the defendants have employed in order to market opioids specific to the State of Oklahoma?

A Such research is unnecessary, given the information from the call notes of the drug reps --

Q So the answer is no, you haven't done it.

MR. BECKWORTH: Let --

THE WITNESS: -- for the --

MR. BECKWORTH: Hold on a second.

THE WITNESS: -- defendants.

MR. BECKWORTH: Excuse me.

Q (By Ms. Patterson) Have you done it?

MR. BECKWORTH: No. Objection. You're not going to keep interrupting her.

MS. PATTERSON: It's a yes-or-no question.

MR. BECKWORTH: It's not. She can answer it however she chooses. Your question was -- and you cut her off. You said, "Such research is necessary given the information from the call notes of the drug reps" --

MS. PATTERSON: I think she actually said it's unnecessary.

MR. BECKWORTH: I'm reading it, unnecessary.

You can finish your answers whenever you need to. Okay?

THE WITNESS: Call notes can be very important, because they reflect marketing messages that a company has given to the drug reps to convey to physicians.

We know there is an opioid use and overdose problem in Oklahoma. We know that there were many drug rep visits from -- from companies represented here to physicians in Oklahoma.

We have call notes from two of those companies that reflect marketing messages that were used nationally, and Oklahoma is not an exception to marketing tactics that would be used nationally.

that --

A Several factors.

Q Okay. And when you say that if a person -- you said, "If a person who dies from a street drug started off on prescription drugs, how do you count that? Do you count that as a street death or a drug death?"

Now, you're not saying that every person that dies from an overdose of street drugs necessarily started by taking a prescription opioid, are you?

A No, but there are data showing that four out of five heroin addicts started off on prescription opioids.

Q Okay. And do you have any data as to the percentage of those prescriptions that were made to those particular individuals were medically unnecessary?

A Ah, so that's a -- that's a great point. So some of those prescriptions would have been given to someone who then goes on for -- to -- to use heroin. The person may have been given them for pain at some point and became addicted to them. They might have been given to them at some point, saved some, started using them later. They may have been

prescribed a -- an inappropriate amount of opioids that then somebody else got into and started taking. So it might be -- it -- it might be a relative, a friend, a kid, a houseguest who's using a prescription opioid that they weren't actually prescribed.

But in all of those cases, the fact that over-prescribing occurred in the first place and that people have bottles of opioids in their medicine cabinets is contributing to opioid use disorder, opioid overdoses, and opioid death. All of those go back to over-prescribing.

MS. PATTERSON: Objection, nonresponsive.

Q (By Ms. Patterson) Is all prescribing of opioids, in your opinion, over-prescribing?

A No. We've already discussed that there are --

Q Okay.

A -- actually appropriate uses of -- of opioids.

Q Okay. And would you agree, Doctor, that different medical professionals disagree on the appropriate uses for opioids, the medically appropriate uses for opioids?

A Medical professionals may disagree on

this, but the science on it is quite clear.

Q Okay. All right. But you're not here to testify as an expert on that, are you?

A I'm not here to testify on what?

Q On the science behind what's -- what's appropriate -- an appropriate use of opioids, a medically appropriate use of opioids?

A I'm happy to testify that there is not evidence that opioids are effective for chronic pain. That's not --

Q Are you here to testify --

A -- my opinion. That is also the opinion of the U.S. Government in the form of CBC guidelines, the A/DOD guidelines, and --

Q So your -- well, let me make sure I understand. It's your testimony that the U.S. Government's position is that the prescription -- that the use of opioids for chronic pain is -- is inappropriate?

A That's not exactly what I said.

Q Okay. That's what I thought I heard, so you can clarify that.

MR. BECKWORTH: She said CBC and DOD. Just let's be clear. Her scope of her report is what it is. That's what she is being offered to

Q Have you interviewed or communicated with any patients in the State of Oklahoma about the opioid medications they've been provided or prescribed by their practitioners?

A No.

Q All right. And in terms of -- again, just to be clear, you have not spoken to or interviewed any of the doctors on any of the documents that you have been shown today -- any of the doctors in the State of Oklahoma about what, if anything, about pharmaceutical manufacturer or marketing materials has influenced their prescribing decisions?

A Although I have not interviewed physicians, that wouldn't -- that wouldn't be high yield, anyway. Physicians don't think that they're influenced by pharmaceutical marketing, but, in fact, they are, and there is robust academic literature on the fact that they are influenced, despite what they think.

Q All right.

A And there's lots of studies in social psychology literature that explains why that's true.

Q In your opinion, are there any legitimate prescriptions that have been made by any physicians in the State of Oklahoma for opioids, at

any time?

A As I stated before, there are legitimate reasons to prescribe opioids, in end-of-life care, in cancer-related pain, in acute pain.

There are several clinical scenarios in which it's absolutely appropriate to prescribe opioids.

Although I don't have specific information on opioid prescribing by physicians in Oklahoma, I would certainly hope that -- that some of the prescriptions that they write are actually appropriate.

Q Can you name for me any physician in the State of Oklahoma who has been influenced by pharmaceutical company marketing to over-prescribe Actiq or Fentora?

MR. BECKWORTH: Objection to form.

THE WITNESS: Well, we have evidence of influence by -- by sales reps for companies of opioids other than Actiq and Fentora. We do know that there were national --

Q (By Ms. Patterson) My question is specific to Actiq and Fentora. I'm asking you to name doctors.

MR. BECKWORTH: Hold on a second. If we're going to be interrupting the witness, we're not going to stick around.

So go ahead and finish your question -- your answer, Doctor.

THE WITNESS: There are certainly national marketing campaigns that would be expected to have influenced physicians in Oklahoma.

I'm certainly hoping that there will be call notes available from Cephalon reps, and I would be happy to analyze those.

Q (By Ms. Patterson) Do you know if those have been produced?

A I do not, but --

Q The documents that are in these folders that Mr. Beckworth marked, I think, as Exhibit 48, those are additional call notes, but you haven't looked at any of those documents yet; right?

A I have looked at some of them and not others.

Q And you have told us that you plan to look at additional documents that are provided by counsel for the State; correct?

A Yes. That's correct.

Q Do you plan to amend your disclosure

EXHIBIT 23

IN THE DISTRICT COURT OF CLEVELAND COUNTY

STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA, Plaintiff,	)	
-vs-	)	No. CJ-2017-816
PURDUE PHARMA, L.P.; et al., Defendants.	)	

* * * * *

VIDEOTAPED DEPOSITION OF MEL POHL, M.D., DFASAM

TAKEN ON BEHALF OF THE DEFENDANTS

IN OKLAHOMA CITY, OKLAHOMA

ON MARCH 8, 2019

COMMENCING AT 9:07 A.M.

* * * * *

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REPORTED BY: BETH A. McGINLEY, CSR, RPR

A Other than the addiction-related medications?

Q (By Mr. Ercole) Yes.

A No.

Q Okay. With respect to that situation you just described, where you visited a pharmaceutical company at a booth during a -- a conference, do you recall any -- strike that.

With respect to that situation you just described, did you ever visit with any representatives for Cephalon at a conference?

A I can't recollect that I have.

Q So, sitting here today, you can't recall any communications that you had with Cephalon after -- well, strike that.

Sitting here today, can you recall any communications you've ever had with -- with Cephalon?

A No.

Q Sitting here today, can you recall any conversations you've ever had with Teva about opioid medicines, as we've defined it?

A No.

Q Sitting here today, are -- can you recall any conversations you had with any other -- that -- of the defendants in this case, about opioid medicines?

A Yes.

MR. CUTLER: Object to the form.

Q (By Mr. Ercole) Okay. How about -- have you ever heard of the company Actavis, LLC?

A No.

Q Have you ever heard of the company Watson Laboratories?

A I might have heard of them, but I couldn't tell you what they did.

Q Are there -- you don't recall having any convers- -- communications with that company?

A No.

Q Any communications you recall with Actavis, LLC?

A No.

Q Any communications that you can recall with -- strike that.

Have you ever heard of the company Actavis Pharma?

A No.

Q And are you -- in this case, you're not giving any opinions regarding Actavis Pharma, correct?

MR. CUTLER: Object to the form.

A Correct.

Q (By Mr. Ercole) And you're not giving any opinions with respect to Actavis, LLC?

MR. CUTLER: Object to the form.

A Correct.
Q (By Mr. Ercole) And you're not giving any opinions with respect to Watson Laboratories, correct?
MR. CUTLER: Object to the form.
A Correct.
Q (By Mr. Ercole) Okay. You've mentioned that you've used marketing materials in some of the presentations that you've given -- strike that.
You mentioned you've used mar- -- marketing materials from pharmaceutical companies in connection with presentations you've given on opioids --
A Yes.
Q -- is that fair?
A Yes.
Q Okay. With respect to those presen- -- strike that.
With respect to those marketing materials, have you ever utilized any marketing materials involving Cephalon?
A I think not.
Q Okay. Have you ever utilized any marketing materials regarding Teva, with respect to opioids, as we've defined it?
MR. CUTLER: Object to the form.
A I think not.

Q (By Mr. Ercole) Okay. Just give me one second, if that's okay.

I'm trying to figure out a way of streamlining things because there are numerous defendants in this case and I want to make sure that I'm trying to get you out of here as quickly as we can, so --

A Understood.

Q Dr. Pohl, since you've never reviewed any marketing materials involving Cephalon -- correct?

MR. CUTLER: Object to the form, mischaracterizes --

MR. ERCOLE: Sorry.

MR. CUTLER: -- his testimony.

Q (By Mr. Ercole) Have you reviewed any marketing materials disseminated, involving Cephalon?

MR. CUTLER: Same objection.

A No, not that I recall.

Q (By Mr. Ercole) Because you're -- you haven't reviewed any, you're not giving an opinion about any of those materials, correct?

MR. CUTLER: Object to the form, mischaracterizes his testimony and mischaracterizes his disclosure.

A Correct.

Q (By Mr. Ercole) Okay. And you haven't -- I

MR. CUTLER: Object to the form.

A Yes.

Q (By Mr. Ercole) And some doctors may not consider medical literature; is that fair to say?

MR. CUTLER: Object to the form.

A It is. I -- I wanted to go back to --

Q (By Mr. Ercole) Yeah.

A -- the doctor who chooses to prescribe based on prior experience.

Q Yeah.

A That's the least valuable of all the lists that you've just enumerated, because that's just anecdotal, related to, you know, small circumstances. Ideally, we base our decisions on large circumstances, such as a medical article.

Q And when you say "small" -- so --

A So if you have -- you -- you've prescribed this medicine for 10 patients, that's an N of 10. You know, you -- you -- you'd really rather see an N of 2,000.

Q Sure.

A You know, how does it work in a large number of patients compared to a small number of patients.

Q Well, and let me -- let me -- just for the sake of, you know, intellectual discussion, let me push back on that just a little bit, if it's fair.

So with -- would you agree, though, that a prescriber that has had success with a particular medicine for a number of patients, over an extended period of time, may want to -- and -- and -- may want to consider that experien- -- a positive experience with the medicine in writing a prescription?

MR. CUTLER: Objection, form, completely speculative, vague.

A I think that's what we do as physicians, but I wouldn't say it's nearly as valuable as a controlled study.

Q (By Mr. Ercole) Would you agree that in terms of controlled studies and what's actually published in the medical literature, that that lags behind, in some instances, what's actually going on in practice?

MR. CUTLER: Object to the form, calls for speculation, outside the scope of his testimony.

A Yeah, I'd suspect the answer is maybe.

Q (By Mr. Ercole) Okay. Just de- -- just depends?

A It does.

MR. CUTLER: Same objections.

Q (By Mr. Ercole) Would you -- Dr. Pohl, would you agree that if chronic pain patients are screened for potential substance abuse issues and then monitored appropriately by prescribers, that the benefits of opioids

can outweigh the risks?

MR. CUTLER: Object to the form, calls for speculation, vague.

A I think that they can outweigh the risks, on -- on occasion, yes.

Q (By Mr. Ercole) And just depends on the particular circumstances at issue?

A On all the variables --

MR. CUTLER: Object to the form.

A -- yes.

Q (By Mr. Ercole) Yeah. And those circumstances are individualized; would you agree with that?

MR. CUTLER: Object to the form.

A I would agree with that.

MR. ERCOLE: What -- what time is it? Do we have a time?

THE WITNESS: 12:08.

MR. ERCOLE: Okay. You -- I'm happy to keep going. You let me know when you want to stop for lunch.

THE WITNESS: I'm ready anytime.

MR. CUTLER: If we can stop now, I'd -- I could use a break, anyway, if -- if you all are fine stopping now.

THE WITNESS: That would be good.

MR. ERCOLE: Yeah, I'm going to -- I was going

to move on to a -- another topic, so this is as good a time as any --

THE WITNESS: Okay.

MR. ERCOLE: -- so let's go off the record now.

THE VIDEOGRAPHER: Off the record at 12:07 p.m., end of Media No. 2.

(Recess was had from 12:07 p.m. to 1:05 p.m.)

THE VIDEOGRAPHER: We are back on the record, this is Media No. 3, at 1:05 p.m.

Q (By Mr. Ercole) Good afternoon, Dr. Pohl.

A Good afternoon.

Q Earlier today, we were discussing some of the presentations that you've given at various times regarding opioids. Do you recall that?

A Yes.

Q Okay. And you mentioned, in -- in some of your presentations, you've referred to or used marketing materials from pharmaceutical manufacturers. Do you recall that testimony?

A Yes.

Q Which specific companies' marketing materials have you used?

A Purdue Pharma, particularly, and ads for -- excuse me -- OxyContin. And I don't know that it's specific to any pharmaceutical company, but the

back one more.

With respect to the patients you see, the patients you see have all become addicted to some type of substance, correct?

A Correct.

MR. CUTLER: Object to the form.

Q (By Mr. Ercole) Okay. So you have not actually monitored patients who are not addicted to opioid medicines, for --

MR. CUTLER: Object --

Q (By Mr. Ercole) -- decades, correct?

MR. CUTLER: Object to the form.

A That's correct.

Q (By Mr. Ercole) And so based upon your personal experience, then, you would not know whether or not patients are benefiting or not benefiting from chronic opioid therapy until they come to you and, in that instance, they're -- they've suffered some type of addiction, correct?

A You know --

MR. CUTLER: Object to the form, vague, compound, mischaracterizes his earlier testimony.

A And I would say that, you know, I've based my opinions on the broad efficacy of opioids on -- on the literature that I've referenced here.

Q (By Mr. Ercole) And -- and the literature you're referencing would be the -- is it "Efficacy of Long-Acting Opioids with Respect to Chronic Pain"?

MR. CUTLER: Object to the form.

A Yes.

Q (By Mr. Ercole) Okay. And you're not giving an opinion with respect to the efficacy of opioids with respect to treating -- strike that.

You're not giving an opinion with respect to the efficacy of -- of short-acting opioids to treat immediate or acute pain, correct?

MR. CUTLER: Object to the form.

A No, but I have -- I have an opinion about that. I mean, the -- the data that is quoted in the CDC study that I also reference suggests that short-term use of an opioid can result in long-term reliance on that opioid. So I'm of the opinion that minimizing the use of opioids in acute pain would be appropriate.

Q (By Mr. Ercole) And you used the word "minimizing the use of opioids with respect to acute pain." You would agree with me that opioids can be effective in treating acute pain, correct?

A Well --

MR. CUTLER: Object to the form, vague.

A Opioids are effective in treating acute pain

because it's short-lived and all of the problems, the -- the harms are minimized in that, so there -- they are beneficial -- the -- they are effective in treating pain. Whether they're beneficial or not is really a -- a different issue, because some people -- I mean, I can't tell you how many patients tell me that they got 60 pills from a surgeon for a wisdom tooth being pulled and they took one and didn't like the way they felt and didn't take any more, so that's a trend in our country that is also problematic for acute pain.

Q (By Mr. Ercole) And at least -- and I think you used the word -- I think your -- your testimony talks about -- uses the word "rarely be -- be used daily for the treatment of chronic painful conditions." Do you see that?

A Where are we looking?

Q Sure. In your disclosure, the -- what I just -- what we just looked at, "rarely be used daily" --

A On the second page?

Q Ye- -- it's on the first page, still.

A Just -- just help me find the sentence and I'll --

Q Yeah, sure. It says --

A I just want to confirm.

Q It's what we were talking about before --

A Oh, yeah.
Q -- "Opioids should rarely be used daily for the treatment of chronic painful conditions."
A I would agree with that, yes.
Q Okay. And there are -- there are instances, correct, where -- strike that.
Are you aware of -- of instances where patients have benefited from the long-term use of opioid therapy for chronic non-cancer pain?
MR. CUTLER: Object to the form.
A And I -- I think that I -- I would wonder if any patient really benefits from chronic use of opioids. I think that people perceive that they suffer less when they take an opioid, but, in actual fact, whether they're benefiting, whether it -- it -- it helps them, as an organism, have a better life, have a better functional life, is in question, in my mind.
Q (By Mr. Ercole) Have you spoken with doctors that have talked to you about benefits that their patients have had with respect to long-term chronic pain?
MR. CUTLER: Object to the form.
A Yeah, I -- I mean, I've heard from people, when I lecture or when I discuss this topic, and, you know, I read the -- the -- for the response to the CDC guidelines, you know, there are people who affirm that they have been

is --

A Absolutely. Absolutely. False and misleading. I think that the company that created that ad knew that that was false and misleading.

Q So what is the basis for your opinion that the advertisement was false and misleading?

A Because there's no data to suggest that opioids made life better and they claimed that opioids made life better. Where -- where was the data to support that contention? You know, the -- and the fact that you couldn't get addicted if you had chronic pain, where was the data for that, other than in the Porter and Jick letter to the editor of The New England Journal? So, yeah.

Q Doctor, have you conducted a -- let me start over.

Doctor, have you conducted a systematic review of the literature on the risks of addiction associated with opioids?

MR. CUTLER: Object to the form.

A I'm sorry, say the question again.

Q (By Mr. Tam) Have you conducted a systematic review of the medical literature on the risks of addiction associated with opioids?

A "Systematic review" is probably not an accurate

way to characterize it. I've reviewed reams of literature on this topic. I -- I read voraciously about everything, but it's not done in a systematic way.

Q Certainly, as, you know, an addiction specialist, you've conducted research; I get that.

So just to make my question clear: As to the issue of the risk of addiction associated with opioids, you have not done a systematic review of the literature, have you?

A And I'll --

MR. CUTLER: Object to the form.

A -- state again that I've reviewed a lot of literature, depending -- I mean, I guess I need a definition of "systematic review." I -- I don't want to exaggerate the systematic nature of my review, but I've reviewed reams of literature on this topic.

Q (By Mr. Tam) Can you identify any study at the time -- let me start over.

Can you -- at the time you saw these advertisements in The Journal of the Medical -- let me start over.

At the time you saw the advertisements in The Journal of the American Medical Association, can you i- -- identify any study that demonstrated that the advertisement was false or misleading?

MR. CUTLER: Object to the form.

A You're saying at --

MR. CUTLER: Asked and answered.

A At the time that I saw this ad, were there -- did I -- the studies didn't exist. The studies that I'm referencing now weren't available. I mean, those have come since that time. Were there studies at that time? None that I'm aware of, I...

Q (By Mr. Tam) And you can't identify any doctor in Oklahoma who saw that advertisement, can you?

MR. CUTLER: Object to the form.

A No.

Q (By Mr. Tam) And you cannot identify any Oklahoma doctor who relied on that advertisement in writing a prescription for OxyContin, can you?

MR. CUTLER: Object to the form --

A I can't, but I can assume that people in Oklahoma read the same medical journals that I do. The Journal of the American Medical Association is a nationally-distributed journal to all members of the AMA, so I -- I would assume that they saw it, but I -- I haven't spoken to any Oklahoma doctors to confirm that.

Q (By Mr. Tam) Even if you assume that some doctors in Oklahoma may have seen that advertisement, you don't know whether any of those Oklahoma doctors relied on

EXHIBIT 24

IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel.,
MIKE HUNTER, ATTORNEY GENERAL
OF OKLAHOMA,
Plaintiff,
vs. No. CJ-2017-816
PURDUE PHARMA L.P.;
PURDUE PHARMA, INC.;
THE PURDUE FREDERICK
COMPANY;
TEVA PHARMACEUTICALS
USA, INC.;
CEPHALON, INC.;
JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-McNEIL-JANSSEN
PHARMACEUTICALS, INC., n/k/a
JANSSEN PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICA,
INC., n/k/a JANSSEN
PHARMACEUTICALS, INC.;
ALLERGAN, PLC, f/k/a
ACTAVIS PLC, f/k/a ACTAVIS, INC.,
f/k/a WATSON PHARMACEUTICALS, INC.;
WATSON LABORATORIES, INC.;
ACTAVIS LLC; and
ACTAVIS PHARMA, INC.,
f/k/a WATSON PHARMA, INC.,

Defendants.
_____/

VIDEOTAPED DEPOSITION OF WAYNE ARTHUR VAN ZEE, M.D.
TAKEN ON BEHALF OF THE DEFENDANTS
ON FEBRUARY 26, 2019, BEGINNING AT 9:07 A.M.
IN OKLAHOMA CITY, OKLAHOMA

VIDEOTAPED BY: Gabe Pack
REPORTED BY: D. Luke Epps, CSR, RPR

certification for that.

Q (BY MR. HOFFMAN) Do you consider yourself to be or do you hold yourself out as a marketing expert?

A I hold myself as somebody knowledgeable about the marketing of OxyContin.

Q Okay. And other than the 2009 article, which we're going to talk about in a moment, have you published on the topics of either pharmaceutical marketing or the marketing of OxyContin at any other point in time?

A No.

Q And you -- you are currently employed at the Stone Mountain Health Services. I guess it's the St. Charles Clinic; is that right?

A Correct.

Q Okay. And what do you do there?

A I'm a primary care general internist.

Q And you mentioned this a moment ago, but just tell me briefly, what kinds of patients do you see on a -- on a daily basis?

A Well, as a general internist, they're -- they're virtually all adults over age 18, and you see a variety of chronic medical problems from hypertension, diabetes, COPD, black lung cancer,

chronic renal insufficiency, so those are common medical problems. I've been a prescriber of buprenorphine since 2003, so that's 16 years now, and about 20 percent of my practice is taking care of patients with opioid use disorder.

Q Okay. If you can estimate, approximately how many patients do you see per day?

A I would see between 16 and 20 patients a day.

Q And do you currently prescribe opioids for patients who have chronic pain?

MR. PATE: Object to form.

THE WITNESS: I --

MR. PATE: Ask you asking -- hold on. You're asking him how he prescribes opioids?

MR. HOFFMAN: I'm just asking if he -- if he prescribes opioids currently for patients who have chronic pain.

MR. PATE: Patients in his own practice?

MR. HOFFMAN: Correct.

THE WITNESS: Yes. I prescribe opioids for some of my patients with chronic pain.

Q (BY MR. HOFFMAN) How many, approximately, patients do you believe you have who are in chronic pain for whom you prescribe opioids?

A 200 to 250.
Q And for some of those patients, do you currently prescribe OxyContin?
A I do not.
Q None of those patients, none of the 200 to 250, you don't prescribe OxyContin for any of them?
A I do not.
Q What --
A I prescribe oxycodone, which is a short-acting oxycodone, but no sustained-release oxycodone.
Q What other opioids do you prescribe to these approximately 200 to 250 patients who are in chronic pain?
A Short-acting oxycodone, short-acting hydrocodone, fentanyl patches on occasion, morphine, both immediate release and sustained release, and methadone.
Q So you mentioned with morphine, you prescribe both the immediate release or IR as well as the controlled-release, which is also sometimes referred to as extended-release or long-acting; is that right?
A Correct.
Q You mentioned earlier you do not prescribe

A Well, that's -- that's the primary one. I was a volunteer medical -- volunteer medical director at a nonprofit residential drug treatment facility for several years, and no medications were used in that situation, but the current practice is that, no, I don't use other things besides behavioral health interventions, 12-step treatment, 12-step programs and buprenorphine treatment.

Q Okay. You do use, you mentioned earlier, several different types of opioids to treat chronic pain; is that right?

A I do.

Q So based upon that, I take it you would agree that opioids can be safe and effective when used according to the FDA-approved labeling?

A No. I don't agree with that. I think there are -- I think they can be safe, but they're not always safe, and I don't -- I think it's almost misnomered to say that opioids are safe because opioids can inherently be addictive, and there are safer ways to prescribe opioids than others, but I don't know any situation where I could feel completely safe in.

Q Okay. And my question was -- was specific. I said would you agree that opioids can

be safe and effective when used according to the FDA-approved labeling, and I think that's a clarification you just gave me is that they can be; is that right?

MR. PATE: Objection. Misstates his testimony. He answered your question.

Q (BY MR. HOFFMAN) Would you agree that they can be safe and effective when used according to the FDA-approved labeling?

MR. PATE: Object to form. Asked and answered.

Q (BY MR. HOFFMAN) You can go ahead and answer.

MR. PATE: You can also look at your prior answer if you need to because you've already answered this question.

Q (BY MR. HOFFMAN) He hasn't answered it, but even if he has, I want to clarify. So do you know which question you're answering now, Doctor?

A You asked me if opioids can -- prescription opioids can be safe and effective.

Q When used according to the FDA-approved labeling.

A They can be.

Q And that's why you've prescribed them to

200 to 250 of your current patients; right?

A Right.

Q Okay. I don't think we've marked your article yet, so let's go ahead and mark your article. I guess I need another exhibit sticker. My plan for marking them in advance has failed miserably, so let me remark this. Let me just -- I'll mark your copy, Doctor, and I'll give it back to you. We'll mark as Exhibit 3 your article -- the copy of your article that you've brought with you here today. It's entitled "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health," excuse me, "Tragedy," and you are the sole author; is that right?

(Exhibit 3 marked for identification.)

A Correct.

Q And as we mentioned earlier, there's some highlighting and some notes on here, and those were all placed on the document by you?

A Those are -- those were put -- those are my handwriting. Those are my notes.

Q Okay. Let me hand that back to you and I'll provide copies.

MR. PATE: I have it.

MR. HOFFMAN: You have it?

MR. PATE: Exhibit 3?

Q (BY MR. HOFFMAN) Correct. Now, this -- this article, which is Exhibit 3, this was published in the American Journal of Public Health; is that right?

A That's correct.

Q Did you submit this article to any other journals?

A I submitted an earlier version to other journals, yes.

Q Which journals did you submit to?

A Annals of Internal Medicine.

THE COURT REPORTER: I'm sorry?

THE WITNESS: Annals of Internal Medicine. A-N-N-A-L-S of Internal Medicine, a much earlier version.

Q (BY MR. HOFFMAN) Any other -- excuse me. Any other journals to which you submitted an earlier version?

A I don't think so.

Q So what happened with the earlier version that you submitted to the Annals of Internal Medicine? Did they reject it?

A They did.

Q Did they tell you why?

EXHIBIT 25

IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel.,
MIKE HUNTER, ATTORNEY GENERAL
OF OKLAHOMA,

Plaintiff,

vs. No. CJ-2017-816

(1) PURDUE PHARMA, L.P.,
(2) PURDUE PHARMA, INC.,
(3) THE PURDUE FREDERICK COMPANY;
(4) TEVA PHARMACEUTICALS USA, INC.;
(5) CEPHALON, INC.;
(6) JOHNSON & JOHNSON;
(7) JANSSEN PHARMACEUTICALS, INC.;
(8) ORTHO-McNEIL-JANSSEN
PHARMACEUTICALS, INC., n/k/a
JANSSEN PHARMACEUTICALS, INC.;
(9) JANSSEN PHARMACEUTICA, INC.;
n/k/a JANSSEN PHARMACEUTICALS, INC.;
(10) ALLERGAN, PLC, f/k/a ACTAVIS PLC,
f/k/a ACTAVIS, INC., f/k/a WATSON
PHARMACEUTICALS, INC.;
(11) WATSON LABORATORIES, INC.;
(12) ACTAVIS LLC; and
(13) ACTAVIS PHARMA, INC.;
f/k/a WATSON PHARMA, INC.;
Defendants.

VIDEOTAPED DEPOSITION
OF TEVA 3230(C)(5) WITNESS
JOHN HASSLER
TAKEN ON BEHALF OF THE PLAINTIFFS
ON JANUARY 30, 2019, BEGINNING AT 9:08 A.M.
IN OKLAHOMA CITY, OKLAHOMA

VIDEOTAPED BY: Gabriel Pack

REPORTED BY: Lacy Antle, CSR, RPR

question.

Q (BY MR. DUCK) Sometimes Teva funds or sponsors or even conducts clinical studies itself after FDA approval for purposes of marketing, right?

MR. FIORE: Object to form and scope.

THE WITNESS: I don't look at it quite that way. The company will fund studies that look at specific attributes of the product that we want to better understand and characterize which can have a beneficial effect in terms of promoting those branded products.

Q (BY MR. DUCK) Teva does what it can to understand physicians' concerns with any of its products, right?

A Yes.

MR. FIORE: Object to form.

Q (BY MR. DUCK) And if Teva identifies a concern that is preventing physicians from prescribing its drugs, Teva will perform research into that concern, right?

MR. FIORE: Object to form and scope.

THE WITNESS: At times.

Q (BY MR. DUCK) And if the research yields favorable results for Teva, Teva can then use those result to promote its drugs and overcome those

concerns, correct?

MR. FIORE: Object to form and scope.

THE WITNESS: Only if that trial qualifies and is recognized by the FDA in order to incorporate the outcomes of the trial into the label, so in order to use the material promotionally, it has to be part of the label.

Q (BY MR. DUCK) Is it true that the only clinical studies or research that Teva references in promotion are those that have been submitted to the FDA as part of the label?

MR. FIORE: Object to the form and scope.

THE WITNESS: In a proactive manner, for our sales force to use data and messaging proactively, it has to be PARC approved and PARC approved materials have to be consistent with the product labeling.

Q (BY MR. DUCK) What does PARC approved mean?

A That that material has been submitted through a review process where regulatory, medical, legal and marketing assess the piece to be consistent with the label, accurate, fair balanced and compliant with laws and regulations. Once it's been approved, then it can be used promotionally.

Q Is the FDA involved in that approval

process at all?

MR. FIORE: Object to the form.

THE WITNESS: The FDA receives all of the branded PARC-approved materials after they've been approved when they're being used in the field, except for Actiq, which required presubmission of all promotional materials to the FDA prior to their use.

Q (BY MR. DUCK) Why the difference?

A Actiq was approved under a regulation that's called Subpart H and it allows for an expedited FDA review, but more stringent and restricted controls on what -- what can be done with the product in the marketplace following review.

Q Why was Actiq approved under Subpart H?

MR. FIORE: Object to form and scope.

THE WITNESS: I don't know the specific criteria that Subpart H represents. My understanding is that is for products that have a very important unmet need that the FDA feels an urgency to prioritize the evaluation and move the product to market, but I don't know that that's accurate, that's just my understanding, based on what I've heard. I'm not particularly familiar with Subpart H.

Q (BY MR. DUCK) Does Exhibit 4 reflect every single clinical study that Teva funded, sponsored or conducted related to Actiq and Fentora?

MR. FIORE: Object to form.

THE WITNESS: To the best of my knowledge but I -- to go back to your earlier question, I didn't ask the question whether there was anything that would be an investigated or initiated study that could have been -- received a grant, whether they were included.

Q (BY MR. DUCK) What do you mean by "investigated or initiated"?

A If an investigator came to Cephalon or to Teva and had an idea for a study proposal that they wanted to investigate and pursue with their hospital and have their own independent ethics and hospital review to qualify that study, there were grants made that would allow for investigator initiated trials, which were not company controlled. Typically those are phase four studies, and there are phase four studies listed in here, so they may be included, but I didn't ask the question.

Q By "investigator,"you mean a third-party researcher?

A Yes.

Q Now, by this time was Actiq also being made in a generic form by Teva?

A Yes.

Q Does this include any of its sales and marketing expended for the generic form of Actiq?

MR. FIORE: Object to form.

THE WITNESS: No, there aren't any sales and marketing initiatives. There are product announcements initiatives for the generic products and there's allocation of expenses for generic products, but they're not -- they're not allocated to a specific product. So it's all lumped together for all of Teva's generics, they're not split out for any specific product.

Q (BY MR. DUCK) Do the amounts we see for sales and marketing on this Exhibit 2 include amounts expended on non-branded marketing?

MR. FIORE: Object to form.

THE WITNESS: For the branded product, any expenses related to sales and marketing, which would include any medical affairs expenses as well, would be included in these numbers that were attributed back to the brand.

Q (BY MR. DUCK) So yes, these numbers do include non-branded marketing?

MR. FIORE: Object to form.

THE WITNESS: If there was any.

Q (BY MR. DUCK) Well, Teva and Cephalon have conducted non-branded marketing related to opioids, true?

A Yes.

MR. FIORE: Object to form and scope.

Q (BY MR. DUCK) Teva and Cephalon have -- new question.

Teva and Cephalon have conducted non-branded marketing about the problem of pain generally, right?

MR. FIORE: Object to form and scope.

THE WITNESS: Yes.

Q (BY MR. DUCK) And when Teva does non-branded marketing about opioids generally or pain generally, Teva does not mention its products, true?

MR. FIORE: Object to form and scope.

THE WITNESS: If it's non-branded promotion that the company controls, then it cannot mention a product.

Q (BY MR. DUCK) Otherwise the FDA would have to take a look at the information, because branded marketing is regulated by the FDA?

A It would be submitted --

MR. FIORE: Object to form. Lacks foundation. Assumes facts not in evidence and scope.

THE WITNESS: It would be submitted to the FDA and if it included Actiq specific information it would be submitted prior to use.

Q (BY MR. DUCK) But non-branded marketing is not submitted to the FDA, true?

MR. FIORE: Same objection.

THE WITNESS: That's correct. It still goes through the PARC-approval process if Teva or Cephalon controls the content, but it is not submitted to the FDA.

Q (BY MR. DUCK) And Teva makes generic opioids, right?

MR. FIORE: Object to form.

THE WITNESS: Yes.

Q (BY MR. DUCK) Generic opioids are used to treat pain, correct?

MR. FIORE: Object to the form and scope.

THE WITNESS: Yes.

Q (BY MR. DUCK) And between the years 2013 and 2016, you'd agree with me that Teva in fact conducted non-branded marketing about opioids and

pain?

MR. FIORE: Object to form and scope.

THE WITNESS: Yes.

Q (BY MR. DUCK) So even though Teva may not mention its generic products in this non-branded marketing, Teva's generic products do benefit from non-branded marketing about opioids and pain that Teva conducts, true?

MR. FIORE: Object to form and scope.

THE WITNESS: It can if there's application for use of those products in managing that disease state, it -- those non-branded disease state materials also may recommend other approaches, other therapies that are not related to Teva.

Q (BY MR. DUCK) Well, Teva conducts non-branded marketing with the intent to further its business, right?

MR. FIORE: Object to form and scope.

THE WITNESS: It conduct -- it conducts non-branded marketing with the intent of improving management of specific disease states. Where it's appropriate to use a Teva product, it would benefit from that use, but in managing the disease state, there may be many other options and choices that a physician would make that Teva would support as part

write "DAW" on an OxyContin prescription because they wanted to have the actual OxyContin branded drug dispensed instead of the identical generic OxyContin drug?

MR. FIORE: Objection to form and scope. Calls for speculation.

THE WITNESS: I don't know why they would do that for this product that I don't have any exposure to Purdue's branding or service offerings. I know that in other areas on other brands that I've worked on, there are services or support that's provided in conjunction with the brand that's not available on a generic that might lead a physician to write a branded product.

Q (BY MR. DUCK) Kind of like someone might buy a Lexus because you get free carwashes at the dealership?

MR. FIORE: Objection to form and scope.

You can answer in your personal capacity if you can.

Q (BY MR. DUCK) It's a pretty good analogy, right?

MR. FIORE: Same objection.

THE WITNESS: There would be other services that accompany the product could lead you

to purchase one product over another.

Q (BY MR. DUCK) Because it's really just a Toyota, we all know that, right?

MR. FIORE: Same objection.

THE WITNESS: I can't validate the authenticity of this document, it's not Teva's document, but I also was not aware that Oxycodone ER contained abuse deterrent properties and so I may have misstated a question earlier, an answer to a question earlier.

Q (BY MR. DUCK) Did Cephalon ever engage in any nonbranded marketing in conjunction with another opioid manufacturer?

MR. FIORE: Objection to form and scope.

THE WITNESS: How -- can you describe what you're looking for in any more detail?

Q (BY MR. DUCK) Sure. Let's -- there's a few different things that I'm thinking of, but first, did Teva and another opioid manufacturer ever work together to create material that would be disseminated that was nonbranded information about opioids?

MR. FIORE: Objection to form and scope.

THE WITNESS: There were instances when third parties would submit requests for support from

multiple companies to create disease state management materials and Cephalon or Teva would have donated money to address those requests, which may have been made by others, but I don't categorize that as nonbranded marketing, so much as educational grants to provide educational information on disease state.

I'm not aware -- nothing comes to mind right now of initiatives where Cephalon and another company controlled the content of a marketing piece that was nonbranded and distributed, I'm not thinking of any.

Q (BY MR. DUCK) What about Teva and another opioid manufacturer?

MR. FIORE: Same objection.

THE WITNESS: Nothing comes to mind.

Q (BY MR. DUCK) But the situation you described, for example, may be where an association like the American Academy of Pain Medicine solicits requests for funding from multiple opioid manufacturers, is that the situation you were envisioning, you were thinking of?

MR. FIORE: Objection to form and scope.

THE WITNESS: Any company that would be involved in pain management that has -- would have

an interest in furthering education in that regard could be approached by a third-party organization to produce materials and Teva or Cephalon could have issued a grant in support of the those materials that provided partial funding, but at that time may not and probably would not have known whether other companies, or which other companies, or philanthropes or foundations would have been contributing to that project as well.

Q (BY MR. DUCK) What copromoting or copromotion agreements has Cephalon entered into with another manufacturer?

A I'm not aware of any copromote.

Q Other than the Purdue agreement that we discussed today, what other distribution -- supply and distribution agreements does Teva have with other opioid manufacturers?

A There is a supply agreement that Teva manufacturers Norco and Kadian for Allergan and there's a manufacturing agreement where Teva manufactures Embeda, or Embeda, for Pfizer.

Q How do you spell that drug?

A I think that it's E-m-b-e-d-a.

Q It's an opioid?

A I believe it's a morphine product.

Q Okay. What other supply and distribution agreements?

A That's all that I'm aware of.

Q Just three total?

A Yes.

Q The generic OxyContin that Teva has with Purdue is the only supply and distribution agreement between Teva and Purdue?

MR. FIORE: Objection to form.

THE WITNESS: As far as I know, yes.

Q (BY MR. DUCK) Put aside supply and distribution agreements, are there any other type of agreements that Teva has with opioid manufacturers?

MR. FIORE: Objection to form and scope.

THE WITNESS: Not that I've seen.

Q (BY MR. DUCK) And the Allergan and Pfizer agreements, Teva is the supplier?

MR. FIORE: Objection to form.

THE WITNESS: Yes, Teva manufactures the product for those other organizations.

Q (BY MR. DUCK) In the Purdue agreement, Teva is the distributor, the buyer, right?

A That's correct.

Q And is that Purdue agreement the only agreement with an opioid company where Teva is the

buyer and distributor?

A That's the only one that I'm aware of.

Q And did you do anything to look for others?

A I asked for all of them.

Q Who did you ask?

A The -- my counsel.

Q Who at Teva maintains these contracts?

A I believe they would be maintained in the legal department.

Q And are all three of these contracts still active?

A To my knowledge, yes.

Q Are there any expired contracts related to the supply and distribution of opioids that existed that you haven't listed here?

A Earlier in the afternoon we talked about an agreement that Watson had, but I don't believe that that still exists, that there's any ongoing work there.

Q Is the MS Contin agreement the only one regarding Watson that you're aware of?

MR. FIORE: Objection to form.

THE WITNESS: Yeah, that's all I remember.

Q (BY MR. DUCK) Anything else, prior