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Attorneys for the Utah Division of Consumer Protection

**BEFORE THE DIVISION OF CONSUMER PROTECTION
OF THE DEPARTMENT OF COMMERCE
OF THE STATE OF UTAH**

IN THE MATTER OF: **PURDUE PHARMA L.P.**, a Delaware limited partnership; **PURDUE PHARMA INC.**, a New York Corporation; **THE PURDUE FREDERICK COMPANY**, a Delaware corporation; **RICHARD SACKLER, M.D.**, individually and as an owner, officer, director, member, principal, manager, and/or key employee of the above named entities; and **KATHE SACKLER, M.D.**, individually and as an owner, officer, director, member, principal, manager, and/or key employee of the above named entities; **Respondents.**	**MOTION FOR LEAVE TO FILE REDACTED NOTICE OF AGENCY ACTION** **DCP Legal File No. CP-2019-005** **DCP Case No. 107102**

On January 30, 2019, the Utah Division of Consumer Protection (Division) issued a redacted Administrative Citation against Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Dr. Richard Sackler, and Dr. Kathe Sackler (Respondents) alleging violations of the Utah Consumer Sales Practices Act, Utah Code § 13-11-1 *et seq.*, and filed a

Motion to Convert Informal Hearing. On February 12, 2019, the Presiding Officer granted the Division's motion to convert this matter to a formal adjudicative proceeding pursuant to Utah Code § 63G-4-202(3) and Utah Admin. Code R152-6-1(B). *See* February 12, 2019 Order on Motion to Convert Informal Hearing, and Notice of Prehearing Conference ("February 12, 2019 Order"). Respondents subsequently filed a Motion to Set Aside Order to Convert Informal Hearing. On February 26, 2019, the February 12, 2019 Order was set aside, with permission to file a renewed motion to convert this proceeding to a formal adjudicative proceeding after the Division files a Notice of Agency Action pursuant to U.C.A. Section 63G-4-201. *See* February 26, 2019 Order on Motion to Set Aside Order to Convert Informal Hearing, Notice of Prehearing Conference, and Order to File Responsive Pleadings ("February 26, 2019 Order").

In its February 26, 2019 Order, the Presiding Officer directed the Division to file and serve a Notice of Agency Action within ten days of the Order. Specifically, the Division must serve an unredacted version of the Notice of Agency Action on Respondents, the Acting Director for the Utah Division of Consumer Protection, and the Presiding Officer. The Division can file a redacted version of the Notice of Agency Action as a public document, "if filed with a motion and supporting documentation asserting a basis for the document to be redacted, and asserting the basis for such redacted information to be protected or maintained as confidential." February 26, 2019 Order. The Division's Notice of Agency Action includes the Administrative Citation, which contains information that has been deemed confidential. Therefore, the Division hereby seeks leave to file a public version of the Notice of Agency Action containing a redacted Administrative Citation. The Division reached out to counsel for the Respondents to determine if they oppose this motion. Counsel for Purdue has indicated that Purdue does not oppose this

motion. The Division has not received a response from counsel for Kathe Sackler or counsel for Richard Sackler.

The Division requests leave to file the Notice of Agency Action with a redacted version of the Administrative Citation to protect the confidentiality of information contained in the Administrative Citation that is subject to Case Management Order No. 2: Protective Order, entered *In re: National Prescription Opiate Litigation*, MDL No. 2804 (N.D. Ohio) (the "MDL Protective Order"), attached as Ex. A. Information that has already been made public or is not subject to the MDL Protective Order has not been redacted. However, unless and until the parties agree that other information included in the Administrative Citation is not subject to the MDL Protective Order, or a Court or administrative body determines it can be made public, the Division is bound by the MDL Protective Order.

The Division gained access to certain information in the Administrative Citation only after agreeing to be bound by the MDL Protective Order. Therefore, the Division must restrict access to the redacted information contained within the Administrative Citation to comply with the Order of the MDL Court. Accordingly, the Division respectfully requests that it be allowed to publicly file the Notice of Agency Action with a redacted version of the Administrative Citation.

WHEREFORE, the Division moves the Presiding Officer to grant the instant motion and permit the Division to publicly file the Notice of Agency Action with a redacted version of the Administrative Citation as tendered herewith.

DATED this 8th day of March, 2019.

SEAN D. REYES
UTAH ATTORNEY GENERAL

/s/ Robert Wing
Robert G. Wing (4445)
Kevin M. McLean (16101)
Assistant Attorneys General

CERTIFICATE OF SERVICE

I certify that I have this day served the foregoing document on the parties of record in this proceeding set forth below:

By first class mail, postage prepaid:

Purdue Pharma, L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901

Purdue Pharma Inc.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901

The Purdue Frederick Company
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901

Snell & Wilmer L.L.P.
Attn: Elisabeth McOmber
15 West South Temple, Suite 1200
Salt Lake City, UT 84101

Richard Sackler, M.D.
9901 E. Powder Run Road
Alta, UT 84092

Kathe Sackler, M.D.
136 Wells Hill Road
Easton, CT 06612-1556

Cohne Kinghorn
Attn: Patrick Johnson and Paul Moxley
111 East Broadway, 11th Floor
Salt Lake City, UT 84111

By electronic mail:

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Paul LaFata
Paul.LaFata@dechert.com

DATED this 8th day of March, 2019.

/s/ Kevin McLean, Assistant Attorney General

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION **This document relates to:** ***All Cases***	**Case No.: 1:17-md-2804-DAP** **Honorable Dan Aaron Polster**

CASE MANAGEMENT ORDER NO. 2: PROTECTIVE ORDER

I. Scope of Order

1. Disclosure and discovery activity in this proceeding may involve production of confidential, proprietary, and/or private information for which special protection from public disclosure and from use for any purpose other than prosecuting this litigation would be warranted. Accordingly, the parties hereby stipulate to and petition the Court to enter the following Stipulated Protective Order ("Protective Order" or "Order"). Unless otherwise noted, this Order is also subject to the Local Rules of this District and the Federal Rules of Civil Procedure on matters of procedure and calculation of time periods. Unless otherwise stated, all periods of time provided for in this Order are calculated as calendar days

2. This Protective Order shall govern all hard copy and electronic materials, the information contained therein, and all other information produced or disclosed during this proceeding, captioned as *In re: National Prescription Opiate Litigation* (MDL No. 2804), Case No. 1:17-CV-2804, which includes any related actions that have been or will be originally filed in this Court, transferred to this Court, or removed to this Court and assigned there ("the Litigation"). All materials produced or adduced in the course of

discovery, including all copies, excerpts, summaries, or compilations thereof, whether revealed in a document, deposition, other testimony, discovery response or otherwise, by any Party to this Litigation (the "Producing Party") to any other party or parties (the "Receiving Party"). This Protective Order is binding upon all the Parties to this Litigation, including their respective corporate parents, subsidiaries and affiliates and their respective attorneys, principals, agents, experts, consultants, representatives, directors, officers, and employees, and others as set forth in this Protective Order.

3. Third parties who so elect may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order and thereby become a Producing Party for purposes of this Protective Order.

4. The entry of this Protective Order does not preclude any party from seeking a further order of this Court pursuant to Federal Rule of Civil Procedure 26(c).

5. Nothing herein shall be construed to affect in any manner the admissibility at trial or any other court proceeding of any document, testimony, or other evidence.

6. This Protective Order does not confer blanket protection on all disclosures or responses to discovery and the protection it affords extends only to the specific information or items that are entitled to protection under the applicable legal principles for treatment as confidential.

II. Definitions

7. Party. "Party" means any of the parties in this Litigation at the time this Protective Order is entered, including officers and directors of such parties. If additional parties are added other than parents, subsidiaries or affiliates of current parties to this Litigation, then their ability to receive Confidential Information and/or Highly Confidential

Information as set forth in this Protective Order will be subject to them being bound, by agreement or Court Order, to this Protective Order.

8. Discovery Material. "Discovery Material" means any information, document, or tangible thing, response to discovery requests, deposition testimony or transcript, and any other similar materials, or portions thereof. To the extent that matter stored or recorded in the form of electronic or magnetic media (including information, files, databases, or programs stored on any digital or analog machine-readable device, computers, Internet sites, discs, networks, or tapes) ("Computerized Material") is produced by any Party in such form, the Producing Party may designate such matters as confidential by a designation of "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" on the media. Whenever any Party to whom Computerized Material designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL is produced reduces such material to hardcopy form, that Party shall mark the hardcopy form with the corresponding "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" designation.

9. Competitor. Competitor means any company or individual, other than the Designating Party, engaged in the design; development; manufacture; regulatory review process; dispensing; marketing; distribution; creation, prosecution, pursuit, or other development of an interest in protecting intellectual property; and/or licensing of any product or services involving opioids; provided, however, that this section shall not be construed as limiting the disclosure of Discovery Material to an Expert in this Litigation, so long as the notice required under Paragraph 38 is provided to the Designating Party prior to any such disclosure where required, and so long as no Discovery Material produced by one Defendant is shown to any current employee or consultant of a different Defendant,

except as provided in Paragraphs 33 or 34.

10. Confidential Information. "Confidential Information" is defined herein as information that the Producing Party in good faith believes would be entitled to protection on a motion for a protective order pursuant to Fed. R. Civ. P. 26(c) on the basis that it constitutes, reflects, discloses, or contains information protected from disclosure by statute or that should be protected from disclosure as confidential personal information, medical or psychiatric information, personnel records, Confidential Protected Health Information, protected law enforcement materials (including investigative files, overdose records, narcane, coroner's records, court records, and prosecution files), research, technical, commercial or financial information that the Designating Party has maintained as confidential, or such other proprietary or sensitive business and commercial information that is not publicly available. Public records and other information or documents that are publicly available may not be designated as Confidential Information. In designating discovery materials as Confidential Information, the Producing Party shall do so in good faith consistent with the provisions of this Protective Order and rulings of the Court. Nothing herein shall be construed to allow for global designations of all documents as "Confidential."

11. Highly Confidential Information. "Highly Confidential Information" is defined herein as information which, if disclosed, disseminated, or used by or to a Competitor of the Producing Party or any other person not enumerated in Paragraphs 32 and 33, could reasonably result in possible antitrust violations or commercial, financial, or business harm. In designating discovery materials as Highly Confidential Information, the Producing Party shall do so in good faith consistent with the provisions of this Protective

Order and rulings of the Court. Nothing herein shall be construed to allow for global designations of all documents as "Highly Confidential."

12. Manufacturer Defendant: Manufacturer Defendant means any Defendant in this litigation that manufactures any Opioid Product for sale or distribution in the United States.

13. Distributor Defendant: Distributor Defendant means any Defendant in this litigation that distributes any Opioid Product in the United States other than a product they manufacture or license for manufacture.

14. Retail Defendant: Retail Defendant means any Defendant in this litigation that sells or distributes any Opioid Product directly to consumers in the United States.

15. Receiving Party. "Receiving Party" means a Party to this Litigation, and all employees, agents, and directors (other than Counsel) of the Party that receives Discovery Material from a Producing Party.

16. Producing Party. "Producing Party" means a Party to this Litigation, and all directors, employees, and agents (other than Counsel) of the Party or any third party that produces or otherwise makes available Discovery Material to a Receiving Party, subject to paragraph 3.

17. Protected Material. "Protected Material" means any Discovery Material, and any copies, abstracts, summaries, or information derived from such Discovery Material, and any notes or other records regarding the contents of such Discovery Material, that is designated as "Confidential" or "Highly Confidential" in accordance with this Protective Order.

18. Outside Counsel. "Outside Counsel" means any law firm or attorney who

represents any Party for purposes of this litigation.

19. In-House Counsel. "In-House Counsel" means attorney employees of any Party.

20. Counsel. "Counsel," without another qualifier, means Outside Counsel and In- House Counsel.

21. Independent Expert. "Independent Expert" means an expert and/or independent consultant formally retained, and/or employed to advise or to assist Counsel in the preparation and/or trial of this Litigation, and their staff who are not employed by a Party to whom it is reasonably necessary to disclose Confidential Information or Highly Confidential Information for the purpose of this Litigation.

22. This Litigation. "This Litigation" means all actions in MDL No. 2804, *In re: National Prescription Opiate Litigation* or hereafter subject to transfer to MDL No. 2804.

III. Designation and Redaction of Confidential Information

23. For each document produced by the Producing Party that contains or constitutes Confidential Information or Highly Confidential Information pursuant to this Protective Order, each page shall be marked "CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER", or "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER" or comparable notices.

24. Specific discovery responses produced by the Producing Party shall, if appropriate, be designated as Confidential Information or Highly Confidential Information by marking the pages of the document that contain such information with the notation "CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER", or "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER" or comparable notices.

25. Information disclosed through testimony at a deposition taken in connection with this Litigation may be designated as Confidential Information or Highly Confidential Information by designating the portions of the transcript in a letter to be served on the court reporter and opposing counsel within thirty (30) calendar days of the Producing Party's receipt of the certified transcript of a deposition. The court reporter will indicate the portions designated as Confidential or Highly Confidential and segregate them as appropriate. Designations of transcripts will apply to audio, video, or other recordings of the testimony. The court reporter shall clearly mark any transcript released prior to the expiration of the 30-day period as "HIGHLY CONFIDENTIAL—SUBJECT TO FURTHER CONFIDENTIALITY REVIEW." Such transcripts will be treated as Highly Confidential Information until the expiration of the 30-day period. If the Producing Party does not serve a designation letter within the 30-day period, then the entire transcript will be deemed not to contain Confidential Information or Highly Confidential Information and the "HIGHLY CONFIDENTIAL—SUBJECT TO FURTHER CONFIDENTIALITY REVIEW" legend shall be removed.

26. In accordance with this Protective Order, only the persons identified under Paragraphs 33 and 34, below, along with the witness and the witness's counsel may be present if any questions regarding Confidential Information or Highly Confidential are asked. This paragraph shall not be deemed to authorize disclosure of any document or information to any person to whom disclosure is prohibited under this Protective Order.

27. A Party in this Litigation may designate as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" any document, material, or other information produced by, or testimony given by, any other person or entity that the designating Party reasonably believes

qualifies as the designating Party's Confidential Information or Highly Confidential Information pursuant to this Protective Order. The Party claiming confidentiality shall designate the information as such within thirty (30) days of its receipt of such information. Any Party receiving information from a third party shall treat such information as Highly Confidential during this thirty (30) day period while all Parties have an opportunity to review the information and determine whether it should be designated as confidential. Any Party designating third party information as Confidential Information or Highly Confidential Information shall have the same rights as a Producing Party under this Protective Order with respect to such information.

28. This Protective Order shall not be construed to protect from production or to permit the "Confidential Information" or "Highly Confidential Information" designation of any document that (a) the party has not made reasonable efforts to keep confidential, or (b) is at the time of production or disclosure, or subsequently becomes, through no wrongful act on the part of the Receiving Party or the individual or individuals who caused the information to become public, generally available to the public through publication or otherwise.

29. In order to protect against unauthorized disclosure of Confidential Information and Highly Confidential Information, a Producing Party may redact certain Confidential or Highly Information from produced documents, materials or other things. The basis for any such redaction shall be stated in the Redaction field of the metadata produced pursuant to the Document Production Protocol or, in the event that such metadata is not technologically feasible, a log of the redactions. Specifically, the Producing Party may redact:

(i) Personal Identifying Information. The names, home addresses, personal email addresses, home telephone numbers, Social Security or tax identification numbers, and other private information protected by law of (a) current and former employees (other than employees' names and business contact information) and (b) individuals in clinical studies or adverse event reports whose identity is protected by law.

(ii) Privileged Information. Information protected from disclosure by the attorney-client privilege, work product doctrine, or other such legal privilege protecting information from discovery in this Litigation. The obligation to provide, and form of, privilege logs will be addressed by separate Order.

(iii) Third Party Confidential Information. If agreed to by the Parties or ordered by the Court under Paragraph 78, information that is protected pursuant to confidentiality agreements between Designating Parties and third parties, as long as the agreements require Designating Parties to redact such information in order to produce such documents in litigation.

30. To the extent any document, materials, or other things produced contain segregated, non-responsive Confidential or Highly Confidential Information concerning a Producing Party's non-opioid products (or, in the case of Plaintiffs, concerning programs, services, or agencies not at issue in this litigation), the Producing Party may redact that segregated, non-responsive, Confidential or Highly Confidential information except (a) that if a Producing Party's non-opioid product is mentioned in direct comparison to the Producing Party's opioid product, then the name and information about that product may not be redacted or (b) if the redaction of the name and information about the Producing Party's non-opioid product(s) would render the information pertaining to Producing Party's opioid product meaningless or would remove the context of the information about

Producing Party's opioid product, the name and information about the other product may not be redacted. Nothing in this paragraph shall restrict Plaintiffs' right and ability to request information about such other products nor restrict Defendants' right to object to or otherwise seek protection from the Court concerning any such request.

31. Pursuant to 21 C.F.R. §§ 314.430(e) & (f) and 20.63(f), the names of any person or persons reporting adverse experiences of patients and the names of any patients who were reported as experiencing adverse events that are not redacted shall be treated as confidential, regardless of whether the document containing such names is designated as CONFIDENTIAL INFORMATION. No such person shall be contacted, either directly or indirectly, based on the information so disclosed without the express written permission of the Producing Party.

IV. Access to Confidential and Highly Confidential Information

32. General. The Receiving Party and counsel for the Receiving Party shall not disclose or permit the disclosure of any Confidential or Highly Confidential Information to any third person or entity except as set forth in Paragraphs 33 and 34.

33. In the absence of written permission from the Producing Party or an order of the Court, any Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by Paragraph 33.l) and its contents shall not be disclosed to any person unless that person falls within at least one of the following categories:

a. Outside Counsel and In-House Counsel, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel;

b. Vendor agents retained by the parties or counsel for the parties, provided

that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;

c. Individual Parties;

d. Present or former officers, directors, and employees of a Party, provided that former officers, directors, or employees of the Designating Party may be shown documents prepared after the date of his or her departure only to the extent counsel for the Receiving Party determines in good faith that the employee's assistance is reasonably necessary to the conduct of this Litigation and provided that such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Nothing in this paragraph shall be deemed to permit the showing of one defendant's Confidential Information to an officer, director, or employee of another defendant, except to the extent otherwise authorized by this Order;

e. Stenographic employees and court reporters recording or transcribing testimony in this Litigation;

f. The Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;

g. Formally retained independent experts and/or consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;

h. Any individual(s) who authored, prepared, or previously reviewed or received the information;

i. To the extent contemplated by Case Management Order One, dated April 11, 2018 (Dkt. No. 232), those liability insurance companies from which any Defendant has sought or may seek insurance coverage to (i) provide or reimburse for the defense of the Litigation and/or (ii) satisfy all or part of any liability in the Litigation.

j. State or federal law enforcement agencies, but only after such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Disclosure pursuant to this subparagraph will be made only after the Designating Party has been given ten (10) days' notice of the Receiving Party's intent to disclose, and a description of the materials the Receiving Party intends to disclose. If the Designating Party objects to disclosure, the Designating Party may request a meet and confer and may seek a protective order from the Court.

k. Plaintiff's counsel of record to any Plaintiff with a case pending in MDL 2804 shall be permitted to receive the Confidential Information of any Producing Party regardless of whether that attorney is counsel of record in any individual action against the Producing Party and there shall be no need for such counsel to execute such acknowledgement because such counsel is bound by the terms of this Protective Order;

l. Counsel for claimants in litigation pending outside this Litigation and arising from one or more Defendants' manufacture, marketing, sale, or distribution of opioid products for use in this or such other action in which the Producing Party is a Defendant in that litigation, provided that the proposed recipient agrees to be bound by this Protective Order and completed the certification

contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Plaintiffs' Liaison Counsel shall disclose to all Defendants at the end of each month a cumulative list providing the identity of the counsel who have executed such acknowledgements and will receive Confidential and Highly Confidential Information pursuant to this Order and a list of the case name(s), number(s), and jurisdiction(s) in which that counsel represents other claimants. Neither the receipt of information pursuant to this paragraph nor the provision of the certification shall in any way be deemed a submission, by the claimant represented by counsel in such outside litigation, to the jurisdiction of this Court or any other federal court or a waiver of any jurisdictional arguments available to such claimant, provided, however, that any such recipient of documents or information produced under this Order shall submit to the jurisdiction of this Court for any violations of this Order.; or

m. Witnesses during deposition, who may be shown, but shall not be permitted to retain, Confidential Information; provided, however, that, unless otherwise agreed by the relevant Parties or ordered by the Court, no Confidential Information of one defendant may be shown to any witness who is a current employee of another defendant who is not otherwise authorized to receive the information under this Order.

34. In the absence of written permission from the Producing Party or an order of the Court, any Highly Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by Paragraph 34.j) and its contents shall not be disclosed to any person unless

that person falls within at least one of the following categories:

a. Outside Counsel and In-House Counsel of any Plaintiff, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel. Information designated as Highly Confidential by any Defendant may be disclosed to one In-House counsel of another Defendant, provided that the In-House counsel (i) has regular involvement in the Litigation, (ii) disclosure to the individual is reasonably necessary to this Litigation, and (iii) the individual completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Except as otherwise provided in this Order or any other Order in this Litigation, no other Employees of a Defendant may receive the Highly Confidential information of another. Any information designated as Highly Confidential shall be disclosed to an In-House Counsel for any Plaintiff only to the extent Outside Counsel for that Plaintiff determines in good faith that disclosure to the In-House Counsel is reasonably necessary to the Litigation;

b. Vendor agents retained by the parties or counsel for the parties, provided that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;;

c. Individual Parties that have produced the designated information;

d. Stenographic employees and court reporters recording or transcribing testimony in this Litigation;

e. The Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;

f. Formally retained independent experts and/or consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;

g. Any individual(s) who authored, prepared or previously reviewed or received the information;

h. State or federal law enforcement agencies, but only after such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Disclosure pursuant to this subparagraph will be made only after the Designating Party has been given ten (10) days' notice of the Receiving Party's intent to disclose, and a description of the materials the Receiving Party intends to disclose. If the Designating Party objects to disclosure, the Designating Party may request a meet and confer and may seek a protective order from the Court.

i. Plaintiff's counsel of record to any Plaintiff with a case pending in MDL 2804 shall be permitted to receive the Confidential Information of any Producing Party regardless of whether that attorney is counsel of record in any individual action against the Producing Party and there shall be no need for such counsel to execute such acknowledgement because such counsel is bound by the terms of this Protective Order;

j. Counsel for claimants litigation pending outside this Litigation and arising from one or more Defendants' manufacture, marketing, sale, or distribution of opioid products for use in this or such other action in which the Producing Party is a Defendant in that litigation, provided that the proposed recipient

agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Plaintiffs' Liaison Counsel shall disclose to all Defendants at the end of each month a cumulative list providing the identity of the counsel who have executed such acknowledgements and will receive Confidential and Highly Confidential Information pursuant to this Order and a list of the case name(s), number(s), and jurisdiction(s) in which that counsel represents other claimants. Neither the receipt of information pursuant to this paragraph nor the provision of the certification shall in any way be deemed a submission, by the claimant represented by counsel in such outside litigation, to the jurisdiction of this Court or any other federal court or a waiver of any jurisdictional arguments available to such claimant; or

k. Witnesses during deposition, who may be shown, but shall not be permitted to retain, Highly Confidential Information; provided, however, that, unless otherwise agreed by the relevant Parties or ordered by the Court, no Highly Confidential Information of one defendant may be shown to any witness who is a current employee of another defendant who is not otherwise authorized to receive the information under this Order.

35. With respect to documents produced to Plaintiffs, documents designated as "HIGHLY CONFIDENTIAL" will be treated in the same manner as documents designated "CONFIDENTIAL," except that Plaintiffs may not disclose Highly Confidential Information to In-House Counsel (or current employees) of any Competitor of the Producing Party, except as otherwise provided in this Order or any other Order in this Litigation.

36. In the event that In-House Counsel (or current employees) of any Competitor of the Producing Party is present at the deposition of an employee or former employee of the Producing Party, prior to a document designated as Highly Confidential being used in the examination, such In-House Counsel (current employees) of any Competitor of the Producing Party shall excuse himself or herself from the deposition room without delaying or disrupting the deposition.

V. Confidentiality Acknowledgment

37. Each person required under this Order to complete the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound, shall be provided with a copy of this Protective Order, which he or she shall read, and, upon reading this Protective Order, shall sign an Acknowledgment, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Protective Order and shall abide by its terms. These Acknowledgments are strictly confidential. Unless otherwise provided in this Order, Counsel for each Party shall maintain the Acknowledgments without giving copies to the other side. The Parties expressly agree, and it is hereby ordered that, except in the event of a violation of this Protective Order, there will be no attempt to seek copies of the Acknowledgments or to determine the identities of persons signing them. If the Court finds that any disclosure is necessary to investigate a violation of this Protective Order, such disclosure will be pursuant to separate court order. Persons who come into contact with Confidential Information or Highly Confidential Information for clerical or administrative purposes, and who do not retain copies or extracts thereof, are not required to execute Acknowledgements, but must comply with the terms of this Protective Order.

VI. Litigation Experts and Consultants.

38. Formally Retained Independent Experts and Consultants. Subject to the provisions of this Protective Order, all Confidential Information or Highly Confidential Information may be disclosed to any formally retained independent expert or consultant who has agreed in writing pursuant to Paragraph 37 or on the record of a deposition to be bound by this Protective Order. The party retaining an independent expert or consultant shall use diligent efforts to determine if the independent expert or consultant is currently working with or for a Competitor of a Producing Party in connection with a Competitor's opioid product. Prior to the initial disclosure of any information designated as Confidential Information or Highly Confidential Information to an expert or consultant who is currently working with or for a Competitor of the Producing Party in connection with a Competitor's opioid product, the party wishing to make such a disclosure ("Notifying Party") shall provide to counsel for the Producing Party in writing, which may include by e- mail, a statement that such disclosure will be made, identifying the general subject matter category of the Discovery Material to be disclosed, providing the nature of the affiliation with the Competitor entity and name of the Competitor entity, and stating the general purpose of such disclosure; the specific name of the formally retained independent expert or consultant need not be provided. The Producing Party shall have seven (7) days from its receipt of the notice to deliver to the Notifying Party its good faith written objections (if any), which may include e-mail, to such disclosure to the expert or consultant.

39. Absent timely objection, the expert or consultant shall be allowed to receive Confidential and Highly Confidential Information pursuant to the terms of this Protective Order. Upon and pending resolution of a timely objection, disclosure to the expert or

consultant shall not be made. If the Notifying Party desires to challenge to the Producing Party's written objection to the expert or consultant, the Notifying Party shall so inform the Producing Party in writing, within ten (10) days of receipt of the Producing Party's written objection, of its reasons for challenging the objection. The expert or consultant shall then be allowed to receive Confidential and Highly Confidential Information pursuant to the terms of this Protective Order after seven (7) days from receipt of the Producing Party's timely challenge to the written objection to the expert or consultant, unless within that seven day period, the Producing Party seeks relief from the Court pursuant to the procedures for discovery disputes set forth in Section 9(o) of Case Management Order One, or the Parties stipulate to an agreement. Once a motion is filed, disclosure shall not occur until the issue is decided by the Court and, if the motion is denied, the appeal period from the Court order denying the motion has expired. In making such motion, it shall be the Producing Party's burden to demonstrate good cause for preventing such disclosure.

VII. Protection and Use of Confidential and Highly Confidential Information

40. Persons receiving or having knowledge of Confidential Information or Highly Confidential Information by virtue of their participation in this proceeding, or by virtue of obtaining any documents or other Protected Material produced or disclosed pursuant to this Protective Order, shall use that Confidential Information or Highly Confidential Information only as permitted by this Protective Order. Counsel shall take reasonable steps to assure the security of any Confidential Information or Highly Confidential Information and will limit access to such material to those persons authorized by this Protective Order.

41. Nothing herein shall restrict a person qualified to receive Confidential

Information and Highly Confidential Information pursuant to this Protective Order from making working copies, abstracts, digests and analyses of such information for use in connection with this Litigation and such working copies, abstracts, digests and analyses shall be deemed to have the same level of protection under the terms of this Protective Order. Further, nothing herein shall restrict a qualified recipient from converting or translating such information into machine-readable form for incorporation in a data retrieval system used in connection with this Litigation, provided that access to such information, in whatever form stored or reproduced, shall be deemed to have the same level of protection under the terms of this Protective Order.

42. All persons qualified to receive Confidential Information and Highly Confidential Information pursuant to this Protective Order shall at all times keep all notes, abstractions, or other work product derived from or containing Confidential Information or Highly Confidential Information in a manner to protect it from disclosure not in accordance with this Protective Order, and shall be obligated to maintain the confidentiality of such work product and shall not disclose or reveal the contents of said notes, abstractions or other work product after the documents, materials, or other thing, or portions thereof (and the information contained therein) are returned and surrendered pursuant to Paragraph 46. Nothing in this Protective Order requires the Receiving Party's Counsel to disclose work product at the conclusion of the case.

43. Notwithstanding any other provisions hereof, nothing herein shall restrict any Party's Counsel from rendering advice to that Counsel's clients with respect to this proceeding or a related action in which the Receiving Party is permitted by this Protective Order to use Confidential Information or Highly Confidential Information and, in the course thereof, relying upon such information, provided that in rendering such advice, Counsel

shall not disclose any other Party's Confidential Information or Highly Confidential Information other than in a manner provided for in this Protective Order.

44. Nothing contained in this Protective Order shall prejudice in any way the rights of any Party to object to the relevancy, authenticity, or admissibility into evidence of any document or other information subject to this Protective Order, or otherwise constitute or operate as an admission by any Party that any particular document or other information is or is not relevant, authentic, or admissible into evidence at any deposition, at trial, or in a hearing

45. Nothing contained in this Protective Order shall preclude any Party from using its own Confidential Information or Highly Confidential Information in any manner it sees fit, without prior consent of any Party or the Court.

46. To the extent that a Producing Party uses or discloses to a third party its designated confidential information in a manner that causes the information to lose its confidential status, the Receiving Party is entitled to notice of the Producing Party's use of the confidential information in such a manner that the information has lost its confidentiality, and the Receiving Party may also use the information in the same manner as the Producing Party.

47. If a Receiving Party learns of any unauthorized disclosure of Confidential Information or Highly Confidential Information, it shall immediately (a) inform the Producing Party in writing of all pertinent facts relating to such disclosure; (b) make its best effort to retrieve all copies of the Confidential Information or Highly Confidential Information; (c) inform the person or persons to whom unauthorized disclosures were made of all the terms of this Protective Order; and (d) request such person or persons execute the Acknowledgment that is attached hereto as Exhibit A.

48. Unless otherwise agreed or ordered, this Protective Order shall remain in force after dismissal or entry of final judgment not subject to further appeal of this Litigation.

49. Within ninety (90) days after dismissal or entry of final judgment not subject to further appeal of this Litigation, or such other time as the Producing Party may agree in writing, the Receiving Party shall return all Confidential Information and Highly Confidential Information under this Protective Order unless: (1) the document has been offered into evidence or filed without restriction as to disclosure; (2) the Parties agree to destruction to the extent practicable in lieu of return;[1] or (3) as to documents bearing the notations, summations, or other mental impressions of the Receiving Party, that Party elects to destroy the documents and certifies to the producing party that it has done so.

50. Notwithstanding the above requirements to return or destroy documents, Plaintiffs' outside counsel and Defendants' outside counsel may retain (1) any materials required to be retained by law or ethical rules, (2) one copy of their work file and work product, and (3) one complete set of all documents filed with the Court including those filed under seal, deposition and trial transcripts, and deposition and trial exhibits. Any retained Confidential or Highly Confidential Discovery Material shall continue to be protected under this Protective Order. An attorney may use his or her work product in subsequent litigation, provided that the attorney's use does not disclose or use Confidential Information or Highly Confidential Information.

[1] The parties may choose to agree that the Receiving Party shall destroy documents containing Confidential Information or Highly Confidential Information and certify the fact of destruction, and that the Receiving Party shall not be required to locate, isolate and return e-mails (including attachments to e-mails) that may include Confidential Information or Highly Confidential Information, or Confidential Information or Highly Confidential Information contained in deposition transcripts or drafts or final expert reports.

VIII. Changes in Designation of Information

51. If a Party through inadvertence produces any Confidential Information or Highly Confidential Information without labeling or marking or otherwise designating it as such in accordance with the provisions of this Protective Order, the Producing Party may give written notice to the Receiving Party that the document or thing produced is deemed "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" and should be treated as such in accordance with the provisions of this Protective Order, and provide replacement media, images, and any associated production information to conform the document to the appropriate designation and facilitate use of the revised designation in the production. The Receiving Party must treat such documents and things with the noticed level of protection from the date such notice is received. Disclosure, prior to the receipt of such notice of such information, to persons not authorized to receive such information shall not be deemed a violation of this Protective Order. Any Producing Party may designate as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" or withdraw a "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" designation from any material that it has produced consistent with this Protective Order, provided, however, that such redesignation shall be effective only as of the date of such redesignation. Such redesignation shall be accomplished by notifying Counsel for each Party in writing of such redesignation and providing replacement images bearing the appropriate description, along with the replacement media, images, and associated production information referenced above. Upon receipt of any redesignation and replacement image that designates material as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL", the Receiving Party shall (i) treat such material in accordance with this Protective Order; (ii) take reasonable steps to notify any persons known to have possession of any such material of such redesignation under this

Protective Order; and (iii) promptly endeavor to procure all copies of such material from any persons known to have possession of such material who are not entitled to receipt under this Protective Order. It is understood that the Receiving Party's good faith efforts to procure all copies may not result in the actual return of all copies of such materials.

52. A Receiving Party does not waive its right to challenge a confidentiality designation by electing not to mount a challenge promptly after the original designation is disclosed. If the Receiving Party believes that portion(s) of a document are not properly designated as Confidential Information or Highly Confidential Information, the Receiving Party will identify the specific information that it believes is improperly designated and notify the Producing Party, in writing or voice-to-voice dialogue, of its good faith belief that the confidentiality designation was not proper and must give the Producing Party an opportunity to review the designated material, to reconsider the circumstances, and, if no change in designation is offered, to explain, in writing within seven (7) days, the basis of the chosen designation. If a Receiving Party elects to press a challenge to a confidentiality designation after considering the justification offered by the Producing Party, it shall notify the Producing Party and the Receiving Party shall have seven (7) days from such notification to challenge the designation by commencing a discovery dispute under the procedures set forth in Section 9(o) of Case Management Order One. The ultimate burden of persuasion in any such challenge proceeding shall be on the Producing Party as if the Producing Party were seeking a Protective Order pursuant to Fed. R. Civ. P. 26(c) in the first instance. Until the Court rules on the challenge, all Parties shall continue to afford the material in question the level of protection to which it is entitled under the Producing Party's designation. In the even that a designation is changed by the Producing Party or by Court Order, the Producing Party shall provide replacement media,

images, and associated production information as provided above.

IX. Inadvertent Production of Documents

53. Non-Waiver of Privilege. The parties agree that they do not intend to disclose information subject to a claim of attorney-client privilege, attorney work product protection, common-interest privilege, or any other privilege, immunity or protection from production or disclosure ("Privileged Information"). If, nevertheless, a Producing Party discloses Privileged Information, such disclosure (as distinct from use) shall be deemed inadvertent without need of further showing under Federal Rule of Evidence 502(b) and shall not constitute or be deemed a waiver or forfeiture of the privilege or protection from discovery in this case or in any other federal or state proceeding by that party (the "Disclosing Party"). This Section shall be interpreted to provide the maximum protection allowed by Federal Rule of Evidence 502(d).

54. Notice of Production of Privileged Information. If a Party or non-Party discovers that it has produced Privileged Information, it shall promptly notify the Receiving Party of the production in writing, shall identify the produced Privileged Information by Bates range where possible, and may demand that the Receiving Party return or destroy the Privileged Information. In the event that a Receiving Party receives information that it believes is subject to a good faith claim of privilege by the Designating Party, the Receiving Party shall immediately refrain from examining the information and shall promptly notify the Designating Party in writing that the Receiving Party possesses potentially Privileged Information. The Designating Party shall have seven (7) days to assert privilege over the identified information. If the Designating Party does not assert a claim of privilege within the 7-day period, the information in question shall be deemed non-privileged.

55. Recall of Privileged Information. If the Designating Party has notified the Receiving Party of production, or has confirmed the production called to its attention by the Receiving Party, the Receiving Party shall within fourteen (14) days of receiving such notification or confirmation: (1) destroy or return to the Designating Party all copies or versions of the produced Privileged Information requested to be returned or destroyed; (2) delete from its work product or other materials any quoted or paraphrased portions of the produced Privileged Information; and (3) ensure that produced Privileged Information is not disclosed in any manner to any Party or non-Party. The following procedures shall be followed to ensure all copies of such ESI are appropriately removed from the Receiving Party's system:

i. Locate each recalled document in the document review/production database and delete the record from the database;

ii. If there is a native file link to the recalled document, remove the native file from the network path;

iii. If the database has an image load file, locate the document image(s) loaded into the viewing software and delete the image file(s) corresponding to the recalled documents. Remove the line(s) corresponding to the document image(s) from the image load file;

iv. Apply the same process to any additional copies of the document or database, where possible;

v. Locate and destroy all other copies of the document, whether in electronic or hardcopy form. To the extent that copies of the document are contained on write-protected media, such as CDs or DVDs, these media shall be discarded, with the exception of production media received from the recalling party, which shall be treated as

described herein;

vi. If the document was produced in a write-protected format, the party seeking to recall the document shall, at its election, either (i) provide a replacement copy of the relevant production from which the document has been removed, in which case the receiving party shall discard the original production media; or (ii) allow the receiving party to retain the original production media, in which case the receiving party shall take steps to ensure that the recalled document will not be used; and

vii. Confirm that the recall of ESI under this procedure is complete by way of letter to the party seeking to recall ESI.

56. Notwithstanding the above, the Receiving Party may segregate and retain one copy of the clawed back information solely for the purpose of disputing the claim of privilege. The Receiving Party shall not use any produced Privileged Information in connection with this Litigation or for any other purpose other than to dispute the claim of privilege. The Receiving Party may file a motion disputing the claim of privilege and seeking an order compelling production of the material at issue; the Designating Party may oppose any such motion, including on the grounds that inadvertent disclosure does not waive privilege.

57. Within 14 days of the notification that such Privileged Information has been returned, destroyed, sequestered, or deleted ("Clawed-Back Information"), the Disclosing Party shall produce a privilege log with respect to the Clawed-Back Information. Within 14 days after receiving the Disclosing Party's privilege log with respect to such Clawed-Back Information, a receiving party may notify the Disclosing Party in writing of an objection to a claim of privilege or work-product protection with respect to the Clawed-Back Information. Within 14 days of the receipt of such notification, the Disclosing Party

and the objecting party shall meet and confer in an effort to resolve any disagreement concerning the Disclosing Party's privilege or work-product claim with respect to such Clawed-Back Information. The parties may stipulate to extend the time periods set forth in this paragraph.

58. If, for any reason, the Disclosing Party and Receiving Party (or parties) do not resolve their disagreement after conducting the mandatory meet and confer, the Receiving Party may request a conference with the Court pursuant to the procedures set forth in Case Management Order One. The Disclosing Party bears the burden of establishing the privileged or protected nature of any Privileged Information.

59. Nothing contained herein is intended to or shall serve to limit a party's right to conduct a review of documents, ESI or information (including metadata) for relevance, responsiveness and/or segregation of privileged and/or protected information before production. Nothing in this Order shall limit the right to request an in-camera review of any Privileged Information.

60. In the event any prior order or agreement between the parties and/or between the parties and a non-party concerning the disclosure of privileged and/or work product protected materials conflicts with any of the provisions of this Order, the provisions of this Stipulated Order shall control.

61. Nothing in this Order overrides any attorney's ethical responsibilities to refrain from examining or disclosing materials that the attorney knows or reasonably should know to be privileged and to inform the Disclosing Party that such materials have been produced.

X. Filing and Use at Trial of Protected Material

62. Only Confidential or Highly Confidential portions of relevant documents

are subject to sealing. To the extent that a brief, memorandum, or pleading references any document designated as Confidential or Highly Confidential, then the brief, memorandum or pleading shall refer the Court to the particular exhibit filed under seal without disclosing the contents of any confidential information. If, however, the confidential information must be intertwined within the text of the document, a party may timely move the Court for leave to file both a redacted version for the public docket and an unredacted version for sealing.

63. Absent a Court-granted exception based upon extraordinary circumstances, any and all filings made under seal shall be submitted electronically and shall be linked to this Stipulated Protective Order or other relevant authorizing order. If both redacted and unredacted versions are being submitted for filing, each version shall be clearly named so there is no confusion as to why there are two entries on the docket for the same filing.

64. If the Court has granted an exception to electronic filing, a sealed filing shall be placed in a sealed envelope marked "CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER." The sealed envelope shall display the case name and number, a designation as to what the document is, the name of the party on whose behalf it is submitted, and the name of the attorney who has filed the sealed document. A copy of this Stipulated Protective Order, or other relevant authorizing order, shall be included in the sealed envelope.

65. A Party that intends to present Confidential Information or Highly Confidential Information at a hearing shall bring that issue to the Court's and Parties' attention without disclosing the Confidential Information or Highly Confidential Information. The Court may thereafter make such orders, including any stipulated orders, as are necessary to govern the use of Confidential Information or Highly Confidential Information

at the hearing. The use of any Confidential Information or Highly Confidential Information at trial shall be governed by a separate stipulation and/or court order.

XI. Information or Highly Confidential Information Requested by Third Party; Procedure Following Request.

66. If any person receiving Discovery Material covered by this Protective Order (the "Receiver") is served with a subpoena, a request for information, or any other form of legal process that purports to compel disclosure of any Confidential Information or Highly Confidential Information covered by this Protective Order ("Request"), the Receiver must so notify the Designating Party, in writing, immediately and in no event more than five (5) court days after receiving the Request. Such notification must include a copy of the Request.

67. The Receiver also must immediately inform the party who made the Request ("Requesting Party") in writing that some or all the requested material is the subject of this Protective Order. In addition, the Receiver must deliver a copy of this Protective Order promptly to the Requesting Party.

68. The purpose of imposing these duties is to alert the interested persons to the existence of this Protective Order and to afford the Designating Party in this case an opportunity to protect its Confidential Information or Highly Confidential Information. The Designating Party shall bear the burden and the expense of seeking protection of its Confidential Information or Highly Confidential Information, and nothing in these provisions should be construed as authorizing or encouraging the Receiver in this Litigation to disobey a lawful directive from another court. The obligations set forth in this paragraph remain in effect while the Receiver has in its possession, custody or control Confidential Information or Highly Confidential Information by the other Party in this Litigation.

69. Materials that have been designated as Confidential or Highly Confidential Discovery Material shall not be provided or disclosed to any third party in response to a request under any public records act, or any similar federal, state or municipal law (collectively, the "Public Disclosure Laws"), and are exempt from disclosure pursuant to this Protective Order. If a Party to this Litigation receives such a request, it shall (i) provide a copy of this Protective Order to the Requesting Party and inform it that the requested materials are exempt from disclosure and that the Party is barred by this Protective Order from disclosing them, and (ii) promptly inform the Designating Party that has produced the requested material that the request has been made, identifying the name of the Requesting Party and the particular materials sought. If the Designating Party seeks a protective order, the Receiving Party shall not disclose such material until the Court has ruled on the request for a protective order. The restrictions in this paragraph shall not apply to materials that (i) the Designating Party expressly consents in writing to disclosure; or (ii) this Court has determined by court order to have been improperly designated as Confidential or Highly Confidential Discovery Material. The provisions of this section shall apply to any entity in receipt of Confidential or Highly Confidential Discovery Material governed by this Protective Order. Nothing in this Protective Order shall be deemed to (1) foreclose any Party from arguing that Discovery Material is not a public record for purposes of the Public Disclosure Laws; (2) prevent any Party from claiming any applicable exemption to the Public Disclosure Laws; or (3) limit any arguments that a Party may make as to why Discovery Material is exempt from disclosure.

XII.HIPAA-Protected Information

70. General. Discovery in this Litigation may involve production of "Protected Health Information" as that term is defined and set forth in 45 C.F.R. § 160.103, for which special protection from public disclosure and from any purpose other than prosecuting this Action is warranted

71. "Protected Health Information" shall encompass information within the scope and definition set forth in 45 C.F.R. § 160.103 that is provided to the Parties by a covered entity as defined by 45 C.F.R. § 160.103 ("Covered Entities") or by a business associate of a Covered Entity as defined by 45 C.F.R. § 160.103 ("Business Associate") in the course of the Litigation, as well as information covered by the privacy laws of any individual states, as applicable.

72. Any Party who produces Protected Health Information in this Litigation shall designate such discovery material "Confidential Protected Health Information" in accordance with the provisions of this Protective Order.

73. Unless otherwise agreed between counsel for the Parties, the designation of discovery material as "Confidential Protected Health Information" shall be made at the following times: (a) for documents or things at the time of the production of the documents or things; (b) for declarations, correspondence, expert witness reports, written discovery responses, court filings, pleadings, and other documents, at the time of the service or filing, whichever occurs first; (c) for testimony, at the time such testimony is given by a statement designating the testimony as "Confidential Protected Health Information" made on the record or within thirty (30) days after receipt of the transcript of the deposition. The designation of discovery material as "Confidential Protected Health

Information" shall be made in the following manner: (a) or documents, by placing the notation "Confidential Protected Health Information" or similar legend on each page of such document; (b) for tangible things, by placing the notation "Confidential Protected Health Information" on the object or container thereof or if impracticable, as otherwise agreed by the parties; (c) for declarations, correspondence, expert witness reports, written discovery responses, court filings, pleadings, and any other documents containing Protected Health Information, by placing the notation "Confidential Protected Health Information" both on the face of such document and on any particular designated pages of such document; and (d) for testimony, by orally designating such testimony as being "Confidential Protected Health Information" at the time the testimony is given or by designating the portions of the transcript in a letter to be served on the court reporter and opposing counsel within thirty (30) calendar days after receipt of the certified transcript of the deposition.

74. Pursuant to 45 C.F.R. § 164.512(e)(1), all Covered Entities and their Business Associates (as defined in 45 C.F.R. § 160.103), or entities in receipt of information from such entities, are hereby authorized to disclose Protected Health Information pertaining to the Action to those persons and for such purposes as designated in herein. Further, all Parties that are entities subject to state privacy law requirements, or entities in receipt of information from such entities, are hereby authorized to disclose Protected Health Information pertaining to this Action to those persons and for such purposes as designated in herein. The Court has determined that disclosure of such Protected Health Information is necessary for the conduct of proceedings before it and that failure to make the disclosure would be contrary to public interest or to the detriment of one or more parties to the proceedings.

75. The Parties shall not use or disclose Protected Health Information for any purpose other than the Litigation, including any appeals. The Parties may, inter alia, disclose Protected Health Information to (a) counsel for the Parties and employees of counsel who have responsibility for the Litigation; (b) the Court and its personnel; (c) Court reporters; (d) experts and consultants; and (e) other entities or persons involved in the Litigation.

76. Within sixty days after dismissal or entry of final judgment not subject to further appeal, the Parties, their counsel, and any person or entity in possession of Protected Health Information received pursuant to this Order shall destroy or return to the Covered Entity or Business Associate such Protected Health Information.

77. Nothing in this Order authorizes the parties to obtain Protected Health Information through means other than formal discovery requests, subpoenas, depositions, pursuant to a patient authorization, or any other lawful process.

XIII. Information Subject to Existing Obligation of Confidentiality Independent of this Protective Order.

78. In the event that a Party is required by a valid discovery request to produce any information held by it subject to an obligation of confidentiality in favor of a third party, the Party shall, promptly upon recognizing that such third party's rights are implicated, provide the third party with a copy of this Protective Order and (i) inform the third party in writing of the Party's obligation to produce such information in connection with this Litigation and of its intention to do so, subject to the protections of this Protective Order; (ii) inform the third party in writing of the third party's right within fourteen (14) days to seek further protection or other relief from the Court if, in good faith, it believes such information to be confidential under the said obligation and either objects to the Party's

production of such information or regards the provisions of this Protective Order to be inadequate; and (iii) seek the third party's consent to such disclosure if that third party does not plan to object. Thereafter, the Party shall refrain from producing such information for a period of fourteen (14) days in order to permit the third party an opportunity to seek relief from the Court, unless the third party earlier consents to disclosure. If the third party fails to seek such relief, the Party shall promptly produce the information in question subject to the protections of this Protective Order, or alternatively, shall promptly seek to be relieved of this obligation or for clarification of this obligation by the Court.

XIV. Miscellaneous Provisions

79. Nothing in this Order or any action or agreement of a party under this Order limits the Court's power to make any orders that may be appropriate with respect to the use and disclosure of any documents produced or use in discovery or at trial.

80. Nothing in this Protective Order shall abridge the right of any person to seek judicial review or to pursue other appropriate judicial action to seek a modification or amendment of this Protective Order.

81. In the event anyone shall violate or threaten to violate the terms of this Protective Order, the Producing Party may immediately apply to obtain injunctive relief against any person violating or threatening to violate any of the terms of this Protective Order, and in the event the Producing Party shall do so, the respondent person, subject to the provisions of this Protective Order, shall not employ as a defense thereto the claim that the Producing Party possesses an adequate remedy at law.

82. This Protective Order shall not be construed as waiving any right to assert a claim of privilege, relevance, or other grounds for not producing Discovery

Material called for, and access to such Discovery Material shall be only as provided for by separate agreement of the Parties or by the Court.

83. This Protective Order may be amended without leave of the Court by agreement of Outside Counsel for the Parties in the form of a written stipulation filed with the Court. The Protective Order shall continue in force until amended or superseded by express order of the Court, and shall survive and remain in effect after the termination of this Litigation.

84. Notwithstanding any other provision in the Order, nothing in this Protective Order shall affect or modify Defendants' ability to review Plaintiffs' information and report such information to any applicable regulatory agencies.

85. This Order is entered based on the representations and agreements of the parties and for the purpose of facilitating discovery. Nothing herein shall be construed or presented as a judicial determination that any documents or information designated as Confidential or Highly Confidential by counsel or the parties is subject to protection under Rule 26(c) of the Federal Rules of Civil Procedure or otherwise until such time as the Court may rule on a specific document or issue.

IT IS SO ORDERED.

Dated: 5/15/18

/s/Dan Aaron Polster
Honorable Dan Aaron Polster
United States District Judge

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION **This document relates to:** ***All Cases***	**Case No.: 1:17-md-2804-DAP** **Honorable Dan Aaron Polster**

EXHIBIT A TO CASE MANAGEMENT ORDER NO. _2_____

ACKNOWLEDGMENT AND AGREEMENT TO BE BOUND BY PROTECTIVE ORDER

The undersigned agrees:

I declare under penalty of perjury that I have read in its entirety and understand the Protective Order (CMO No. __) that was issued by the United States District Court for the Northern District of Ohio on 5/15, 2018 in *In re: National Prescription Opiate Litigation* (the "Protective Order").

I agree to comply with and to be bound by all the terms of the Protective Order, and I understand and acknowledge that failure to so comply could expose me to sanctions and punishment in the nature of contempt. I solemnly promise that I will not disclose in any manner any information or item that is subject to the Protective Order to any person or entity except in strict compliance with the provisions of the Protective Order.

I further agree to submit to the jurisdiction of the United States District Court for the Northern District of Ohio for the purposes of enforcing terms of the Protective Order, even if such enforcement proceedings occur after termination of these proceedings.

Date: 1/8/2019

City and State where sworn and signed: Salt Lake City, Utah

Printed Name: Kevin McLean - Assistant Attorney General

Signature: Kevin McLean

REDACTED CITATION 1 - PUBLIC

(As redacted when issued Jan 30, 2019.)

Utah Division of Consumer Protection
160 East 300 South, Second Floor
PO Box 146704
Salt Lake City, UT 84114-6704
PH. (801) 530-6601/FAX (801) 530-6001

**BEFORE THE DIVISION OF CONSUMER PROTECTION
OF THE DEPARTMENT OF COMMERCE
OF THE STATE OF UTAH**

IN THE MATTER OF: **PURDUE PHARMA L.P., a Delaware limited partnership; PURDUE PHARMA INC., a New York corporation; THE PURDUE FREDERICK COMPANY, a Delaware corporation; RICHARD SACKLER, M.D., individually and as an owner, officer, director, member, principal, manager, and/or key employee of the above named entities; and KATHE SACKLER, M.D., individually and as an owner, officer, director, member, principal, manager, and/or key employee of the above named entities;** **Respondents.**	**ADMINISTRATIVE CITATION** **DCP Legal File No. CP-2019-___** **DCP Case No. 107102**

PURSUANT TO THE AUTHORITY granted by Utah Code § 13-2-6, which empowers the Division of Consumer Protection ("Division") to issue a citation upon reasonable cause to believe a person has violated or is violating any statute listed in Utah Code § 13-2-1, it appears, upon information and belief, that Respondents have violated the *Utah Consumer Sales Practices Act* (CSPA), Utah Code § 13-11-1 *et seq.* The Division incorporates by reference all information in the Notice to this Citation. The Division alleges:

RESPONDENTS

1. Respondent Purdue Pharma L.P. is a limited partnership organized and existing under the laws of the State of Delaware with its principal place of business located in Stamford,

Connecticut. During all relevant times, Purdue Pharma L.P. has manufactured substantial amounts of prescription opioids that have been, and continue to be, distributed and sold in Utah. Purdue Pharma L.P. has engaged in consensual commercial dealings with Utah and its citizens and has purposefully availed itself of the advantages of conducting business with and within Utah.

2. Respondent Purdue Pharma Inc. is a corporation organized and existing under the laws of New York State with its principal place of business located in Stamford, Connecticut. During all relevant times, Purdue Pharma Inc. has manufactured substantial amounts of prescription opioids that have been, and continue to be, distributed and sold in Utah. Purdue Pharma Inc. has engaged in consensual commercial dealings with Utah and its citizens and has purposefully availed itself of the advantages of conducting business with and within Utah.

3. Respondent The Purdue Frederick Company is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located in Stamford, Connecticut. During all relevant times, The Purdue Frederick Company has manufactured substantial amounts of prescription opioids that have been, and continue to be, distributed and sold in Utah. The Purdue Frederick Company has engaged in consensual commercial dealings with Utah and its citizens and has purposefully availed itself of the advantages of conducting business with and within Utah.

4. Purdue Pharma L.P., Purdue Pharma Inc. and The Purdue Frederick Company will be referred to collectively as "Purdue."

5. Respondent Richard Sackler, M.D. is an individual with a residence in Connecticut and at least one residence in Alta, Utah, now titled in the name of Superior View LLC c/o Richard Sackler, MD, with an assessed value of over $3 million. [redacted]

Upon information and belief, Respondent Richard Sackler joined Purdue in 1971 as an assistant to his father, Raymond Sackler. Richard Sackler served as head of Purdue's Marketing Department and of its Research and Development Department, before serving as President of Purdue from 1999-2003, where he oversaw the early marketing of OxyContin. From 2003 to approximately 2014, he served as Co-Chairman of the Purdue Board. Richard Sackler was a Board Member of Purdue until July of 2018 when a wave of litigation was filed against Purdue. Upon information and belief, Richard Sackler has long held an ownership interest in Purdue and continues to hold an ownership interest in Purdue. Richard Sackler is the listed inventor on a number of patents assigned to Purdue, including a patent for "drug substitution therapy in drug-dependent human subjects," known in lay terms as addiction treatment. In other words, having caused the opioid epidemic, Richard Sackler, through his companies, is poised to profit further from the aftermath.

6. Respondent Kathe Sackler, M.D. is an individual with a residence in Connecticut. She is the daughter of Mortimer Sackler, one of the three original founders of Purdue, and she has served as a member of the board of directors of Purdue since the 1990s. In addition to her role on the Board, Kathe Sackler served as the Senior Vice President of Purdue.

7. Richard Sackler and Kathe Sackler, M.D. will, at times, be referred to collectively as the "Sackler Respondents."

8. Utah has personal jurisdiction over Respondents Richard and Kathe Sackler because they personally directed Purdue to conduct the deceptive or unfair acts or practices alleged herein that took place in Utah. The Sackler Respondents are "suppliers" within the

meaning of the CSPA because, through their direct involvement in Purdue's business, they indirectly solicited and engaged in the sales of opioids in Utah; by express statutory provision, they need not deal directly with their customers. Utah Code § 13-11-3(6). Through their decisions and directives at Purdue, the Sackler Respondents knowingly caused the unlawful promotion and sales of Purdue's opioids in Utah. Business activities that the Sackler Respondents directed include Purdue's employment of a substantial number of sales representatives nationwide, including in Utah, to visit doctors in their local offices for the purpose of delivering deceptive marketing messages and encouraging such doctors to write prescriptions for Purdue's opioid products. They determined the methods by which prescribers were targeted by Purdue's sales representatives, how often the doctors were visited, and what messages and strategies were used with them. Among other things, the Sackler Respondents directed Purdue's sales representatives, including those in Utah, to promote the use of opioids at high doses and for long periods of time, which was unfair and misleading, and which increased Purdue's revenue, but magnified the risk to the State of Utah and its residents.

9. Respondents are subject to the Division's jurisdiction because the actionable conduct was committed wholly or partly within Utah; because conduct committed outside Utah constituted an attempt to commit a violation within Utah; and because transactional resources located within Utah used by Respondents directly or indirectly facilitated a violation or attempted violation. Utah Code § 13-2-6(4).

BACKGROUND AND INFORMATION

10. Opioid abuse and addiction is a national public health crisis. According to the Centers for Disease Control ("CDC"), over 70,000 Americans died of a drug overdose in 2017, of

which 67.8 percent (47,600) involved opioids. The number of deaths and the prevalence of opioids were both worse in 2017 than a year prior.[1]

11. Utah is not immune from the effects of this opioid crisis. According to the CDC, Utah lost 1,884 people to drug overdose deaths between 2014 and 2016, and the "main driver" of these deaths was prescription and illicit opioids.[2] In 2017, there were 456 opioid-related overdose deaths in Utah—a rate of 15.5 deaths per 100,000, which is higher than the national rate of 14.9 deaths per 100,000.[3]

12. The Respondents' misconduct, including its consistent, intentional failure to comply with its legal obligations, has led to an epidemic of prescription opioid abuse in Utah. This epidemic resulted in a nearly 600% increase in prescription opioid-related deaths in Utah between 1999 and 2007,[4] 466 prescription opioid-related deaths in Utah in 2016 alone,[5] and millions drained annually from State resources.

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[1] Ctr. for Disease Control & Prevention, *Drug Overdose Deaths*, https://www.cdc.gov/drugoverdose/data/statedeaths.html According to the CDC, over 63,000 Americans died of a drug overdose in 2016, of which 66.4 percent (42,249) reportedly involved opioids. (Ctr. for Disease Control & Prevention, Morbidity and Mortality Weekly Report, March 30, 2016, *Overdose Deaths*, 2015-2016, https://www.cdc.gov/mmwr/volumes/67/wr/mm6712a1.htm?s_cid=mm6712a1_w.)

[2] Ctr. for Disease Control & Prevention, *Drug Overdose Deaths*, https://www.cdc.gov/drugoverdose/data/statedeaths.html (Number and age-adjusted rates of drug overdose deaths by state, US 2014, 2015, 2016).

[3] Ctr. for Disease Control & Prevention, Morbidity and Mortality Report, December 28, 2018, *Drug and Opioid-Involved Overdose Deaths - United States*, 2015-2017, https://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm?s_cid=mm675152e1_w#T1_down.

[4] Ctr. Disease Control & Prevention, Morbidity and Mortality Weekly Report, Feb. 19, 2010 59(06), *Adult Use of Prescription Opioid Pain Medications --- Utah, 2008*, https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5906a1.htm?s_cid=mm5906a1_w.

[5] *Utah Opioid Summary*, Nat'l Inst. on Drug Abuse, https://www.drugabuse.gov/drugs-abuse/opioids/opioidsummaries-by-state/utah-opioid-summary.

13. This epidemic has drained State resources from the criminal justice,[6] social services and welfare,[7] education,[8] and healthcare systems.[9] Prescription opioid abuse costs the citizens and State of Utah approximately $238 million in healthcare costs each year.[10]

14. Prescription opioids are powerful pain-reducing medications. They include non-synthetic derivatives of the opium poppy (also called "opiates," such as codeine and morphine), partially-synthetic derivatives (such as hydrocodone and oxycodone), and fully-synthetic derivatives (such as fentanyl and methadone).

15. While opioids can dampen the perception of pain, they also can create an addictive, euphoric high. At higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy

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[6] *The High Price of the Opioid Crisis*, Pew Charitable Trusts July 2017, http://www.pewtrusts.org/~/media/assets/2017/07/highpriceofopioidcrisis_infographic_final.pdf?la=en. In 2013, $7.6 billion was spent nationally on criminal justice costs associated with prescription opioid abuse, and 96% of the costs fell to state and local governments.

[7] The Nat'l Ctr. on Addiction and Substance Abuse, *Shoveling Up II: The impact of substance abuse on federal, state, and local budgets* 27 (2009), http://www.centeronaddiction.org/addictionresearch/reports/shoveling-iiimpact-substance-abuse-federal-state-and-local-budgets. In 2005, state governments spent 27% of the amount they spend on healthcare to fund the social services related to substance abuse.

[8] *Id.* at 24. In 2005, approximately 12.2% of federal government education spending "was spent coping with the impact of substance abuse and addiction."

[9] Matric Global Advisors, *Health Care Costs from Opioid Abuse: A state-by-state analysis* 5 (2015), http://drugfree.org/wp-content/uploads/2015/04/Matrix_OpioidAbuse_040415.pdf; Kohei Hasegawa et al., *Epidemiology of Emergency Department Visits for Opioid Overdose: A population-based study*, 89 Mayo Clinic Proceedings 462, 465, 467 (2014) (there are about two times as many opioid overdoses in Emergency Department among publicly-insured individuals than among individuals with private insurance and publicly-insured individuals are approximately twice as likely to have a second visit to the Emergency Departments for opioid overdose as are privately-insured individuals); Cong. Research Serv.,*Medicaid's Federal Medical Assistance Percentage (FMAP)* 14–15 (2016), https://fas.org/sgp/crs/misc/R43847.pdf (the State of Utah pays for approximately 30% of publicly funded healthcare expenses).

[10] Matric Global Advisors, *Health Care Costs from Opioid Abuse: A state-by-state analysis* 5 (2015), http://drugfree.org/wp-content/uploads/2015/04/Matrix_OpioidAbuse_040415.pdf.

will experience withdrawal symptoms—including severe anxiety, nausea, headaches, tremors, delirium, and pain—which are often prolonged, if opioid use is delayed or discontinued. When using opioids continuously, patients grow tolerant to their analgesic effects (i.e. to relief of pain)—requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose. Prescription opioids are no less addictive than heroin. No other medication routinely used for a nonfatal condition kills patients so frequently.[11] When used long-term to treat chronic pain conditions, those risks are amplified.

16. The Respondents have intentionally engaged, and continue to engage, in an aggressive marketing campaign to overstate the benefits and misstate and conceal the risks of treating chronic pain with opioids in order to increase their profits. Utah law prohibits suppliers from using misleading or deceptive practices to market their products. Nonetheless, Purdue disseminated misstatements through multiple channels, representing opioids as beneficial in treating chronic pain long-term, and as having a low risk of addiction. This campaign included websites, promotional materials distributed in Utah, conferences available to Utah prescribers, dinner programs held in Utah for Utah prescribers, guidelines for doctors, thousands of personal visits between Respondents' sales representatives and Utah prescribers in their medical offices, and other such modes of communication. Purdue also helped cultivate a narrative that pain was undertreated and pain treatment should be a higher priority for health care providers. This paved the way for increased prescribing of opioids for chronic pain.

[11] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, *Reducing the Risks of Relief, the CDC Opioid-Prescribing Guideline*, at 1503 (Apr. 21, 2016).

17. In addition, Purdue paid at least two Utah doctors to be "key opinion leaders." They wrote promotional materials supporting opioids as the best approach to pain management, and prescribed lethal amounts of opioids to Utah residents from their Salt Lake City offices.[12]

18. Purdue's marketing campaign enabled Purdue to overcome the longstanding medical consensus that opioids were unsafe for the treatment of chronic pain. Purdue's campaign resulted in a significant increase in the number of opioids prescribed nationwide. In fact, between 1999 and 2015, the number of opioids prescribed nationwide tripled.[13] Not surprisingly, deaths from prescription opioid use quadrupled between 1999 and 2011.[14] Between 2002 and 2015, the number of opioid prescriptions dispensed in Utah increased by over one million. In 2015, Utah prescribers wrote 73.1 opioid prescriptions per 100 persons, compared to the national average of 70 opioid prescriptions per 100 persons.[15]

19. The increase in opioid prescriptions to treat chronic pain correlates with an increase in the number of people becoming addicted to opioids and seeking prescription opioids for non-medical purposes.[16] Nationally, the number of people who take prescription opioids for

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[12] Deseret News, *The untold story of how Utah doctors and Big Pharma helped drive the national opioid epidemic*, (Oct. 26, 2017), https://www.deseretnews.com/article/900002328/the-untold-story-of-how-utah-doctors-and-bigpharma-helped-drive-the-national-opioid-epidemic.html.

[13] Guy, Gery et al., *Vital Signs: Changes in Opioid Prescribing in the United States, 2006* – 2015, CDC Morbidity and Mortality Weekly Report (MMWR), July 7, 2017, https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm

[14]Li Hui Chen et al., *Drug-poisoning Deaths Involving Opioid Analgesics: United States, 1999–2011*, 166 Nat'l Ctr.for Health Statistics Data Brief (Sept. 2014), https://www.cdc.gov/nchs/data/databriefs/db166.pdf.

[15] National Institute on Drug Abuse, Opioid-Related Overdose Deaths, https://www.drugabuse.gov/drugsabuse/opioids/opioid-summaries-by-state/utah-opioid-summary.

[16] Chronic pain is often defined as any pain lasting more than 12 weeks. National Institutes of Health, NIH.

non-medical purposes is now greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.[17] In Utah alone, data from the Substance Abuse and Mental Health Services Administration indicates that from 2012-2014, between 7.3% and 8.54% of 18 - 25 year-olds used prescription opioids for non-medical purposes.[18]

20. This increase in addiction and non-medical demand has corresponded with an increase in "diversion." Diversion occurs when the prescription opioid supply chain breaks and the drugs are transferred from legitimate channels to illegitimate ones.

21. The legitimate supply chain for prescription opioids begins with the manufacture and packaging of the pills. Manufacturers, including Purdue, then transfer the pills to distribution companies. Distributors then supply opioids to pharmacies and other healthcare providers, which then dispense the drugs to consumers. Diversion to illicit use can occur anywhere in the supply chain, from a distribution truck or pharmacy robbery, to a curious teenager taking pills a parent inadvertently left accessible.

MedlinePlus, Spring, 2011, https://medlineplus.gov/magazine/issues/spring11/articles/spring11pg5-6.html.

[17] Substance Abuse and Mental Health Servs. Admin., *Results from the 2015 National Survey on Drug Use and Health: Detailed Tables*, https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015.pdf.

[18] Substance Abuse and Mental Health Servs. Admin., *2012-2014 National Survey on Drug Use and Health Substate Age Group Tables* 143 (2015), https://www.samhsa.gov/data/sites/default/files/NSDUHsubstateAgeGroupTabs2014/NSDUHsubstateAgeGroupTabs2014.pdf (in Utah, though statistics varied according to substate region, 4.15% of people age 12-15, and 3.03% of people 26+, engage in the non-medical use of prescription pain relievers).

22. Of the 2.2 million opioid prescriptions issued in Utah in 2015 (nearly one prescription per Utah resident), studies suggest that as many as 281,600 of those prescriptions were diverted to non-medical uses.[19]

23. The extent to which opioids are diverted into illicit use is even more concerning because Utah has the second highest high-dose opioid prescription rate in the United States.[20]

24. In 2017, Carbon County had the highest opioid prescribing rate in Utah, at 154.1 prescriptions per 100 residents.[21] The county with the next highest prescribing rate was Sevier, with 108.2 prescriptions per 100 residents. By comparison, the rates in Salt Lake and Tooele Counties were 63.2 and 64.0 prescriptions per 100 residents, respectively.

25. One result is that the economic impacts of the opioid epidemic seen nation and state–wide, are even more pronounced in some of the communities least equipped to address them.

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[19] *Opioid Pain Reliever Prescriptions*, Nat'l Inst. on Drug Abuse, https://www.drugabuse.gov/drugsabuse/opioids/opioid-summaries-by-state/utah-opioid-summary. The studies estimate that the percentage of prescription opioids that are diverted to illegitimate purposes ranges from 1.9 percent to 12.8 percent of total prescriptions. B.L. Wilsey et al., *Profiling Multiple Provider Prescribing of Opioids, Benzodiazepines, Stimulants, and Anorectics*, 112 Drug and Alcohol Dependence 99 (2010) (estimating that 12.8% of prescriptions are diverted); N. Katz et al., *Usefulness of Prescription Monitoring Programs for Surveillance– Analysis of Schedule II Opioid Prescription Data in Massachusetts, 1996–2006*, 19 Pharmacoepidemiology and Drug Safety 115 (2010) (estimating the diversion rate at 7.7% when defining likely diversion as patients that obtain opioids from at least 3 prescribers and at least 3 pharmacies in a year); D.C. McDonald & K.E. Carlson, *Estimating the Prevalence of Opioid Diversion by "Doctor Shoppers" in the United States*, 8 PLOS ONE (2013) (estimating the diversion rate at 1.9% of all prescriptions and 4% of total grams dispensed).

[20] *Annual Surveillance Report of Drug-Related Risks and Outcomes: United States, 2017*, Ctr. Disease Control & Prevention, 10 https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf.

[21] Centers for Disease Control and Prevention, U.S. County Prescribing Rates (2017), https://www.cdc.gov/drugoverdose/maps/rxcounty2017.html.

Carbon County ranks 11th in the nation for the highest per-capita opioid costs, coming in at a staggering $6,365.[22]

26. According to Purdue's reporting through Open Payments, Purdue has given Utah prescribers almost $200,000 in gifts and other payments during the five-year period between 2013-2017. According to Purdue's marketing records, from 2006-2017, Respondents employed [redacted] sales representatives in Utah to visit Utah prescribers in their medical offices and deliver direct marketing messages, both verbal and written. [redacted] Utah prescribers prescribed more opioids for their patients than they otherwise would have.[23]

27. Utah ranked 7th in the United States for prescription drug poisoning deaths from 2013-2015, "which . . . outpaced deaths due to firearms, falls, and motor vehicle crashes."[24]

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[22] Alex Brill & Scott Ganz, *The Geographic variation in the Cost of the Opioid Crisis*, American Enterprise Institute 8 (Mar. 2018).

[23] *See also* Scott E. Hadland, Arladne Rivera-Aguirre, Brandon D.L. Marshall, Magdalena Cerda, *Association of Pharmaceutical Industry Marketing of Opioid Products With Mortality From Opioid-Related Overdoses*, JAMA (Jan.. 18, 2019); Fn. 9 -11 supra.

[24] Utah Department of Health, *Prescription Drug Overdoses*, http://health.utah.gov/vipp/topics/prescription-drugoverdoses/.

28. Respondents' actions have caused significant harm to the State and its agencies, including the costs of (a) medical care, therapeutic and prescription drugs, and other treatments for patients suffering from opioid-related addiction, overdoses, or disease, or from medical conditions exacerbated by opioid abuse; (b) treatment of infants born with opioid-related addiction or medical conditions; (c) law enforcement and public safety measures necessitated by the opioid crisis; (d) opioid-related counseling and rehabilitation services; (e) welfare for children whose parents suffer from opioid-related disease or incapacitation; (f) expenditures under Medicaid for purchases of prescription opioids for non-medical, illegitimate, or other improper purposes; and (g) emergency room care. These costs continue to mount.

29. In this administrative petition, the State describes these harms not to recover them, but so that they may be weighed in determining the civil penalties appropriate for Purdue's conduct.

OPIOID PAINKILLERS AND RESPONDENTS' DECEPTIVE MARKETING

30. Prescription opioids are powerful pain-reducing medications that include non-synthetic, partially-synthetic, and fully-synthetic derivatives of the opium poppy. While these drugs can have benefits when used properly, and under appropriate medical supervision, they also pose serious risks. In March of 2016, the FDA emphasized the "known serious risk[] of . . . addiction"—"even at recommended doses"—of all opioids."[25] In particular, government agencies have warned that "continuing opioid therapy for 3 months

[25] *FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics,* FDA (Sep. 10, 2013); *see also FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death,* FDA (Mar. 22, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

substantially increases risk for opioid use disorder,"[26] and that opioid risks include "misuse, addiction, overdose and death, especially with long term use."[27]

31. Given these risks, the marketing, distribution, and sale of prescription opioids are heavily regulated under Utah and federal law. Utah's Pharmacy Practice Act, Utah Code § 58-17b-101, *et seq.*, Utah's Controlled Substances Act, Utah Code § 58-37-1, *et seq.*, and numerous professional regulations related to persons who handle, prescribe, and dispense controlled substances provide strict controls and requirements throughout the opioid distribution chain. These provisions of Utah law also incorporate and reference federal law regarding the marketing, distribution, and sale of prescription opioids, including the Federal Controlled Substances Act, 21 U.S.C. § 801, *et seq.*, and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321, *et seq.*

32. As discussed below, despite the dangers of prescription opioids, the Respondents fraudulently marketed them through misleading statements that mischaracterized the true magnitude of those risks and overstated the benefits of opioids in a deliberate effort to increase profits by deceiving prescribers, who reasonably relied on such representations. The Respondents' actions created an inflated market for prescription opioids, which caused injury to healthcare programs and other third-party payors of healthcare costs, including the costs of opioid prescriptions, and led to massive diversion of these drugs from legitimate to illegitimate channels. As a result of the Respondents' wrongful acts, Utah and its citizens suffered injuries and damages.

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[26] 2016 CDC Guideline at 21.

[27] CDC Opioid Overdose, Prescription Opioid Data, *https://www.cdc.gov/drugoverdose/data/prescribing.html*.

I. Purdue made misleading statements about the risks and benefits of opioids.

33. In the mid-1990s, at about the time Purdue introduced its drug OxyContin to the marketplace, the medical community was aware of both the risks of opioids and the relative ineffectiveness of long-term opioid use. Dr. Russell Portenoy, whose theories were later adopted by Purdue, acknowledged the prevailing medical understanding regarding use of opioids long-term for non-cancer pain:

> The traditional approach to chronic non-malignant pain does not accept the longterm administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effect over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutatory mood changes, but adverse effects will inevitably occur thereafter.[28]

Thus, in 1994, conventional wisdom predicted that opioids would appear effective in the short term, but prove ineffective over time with increasing negative effects.

34. The medical community knew that published reports associated opioid use "with heightened pain and functional impairment, neuropsychological toxicity, prevarication about drug use, and poor treatment response."[29] Dr. Portenoy noted: "the problematic nature of opioid therapy in some patients is unquestionable, and the potential adverse impact of all possible outcomes related to treatment, including physical dependence, deserves to be addressed."[30]

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[28] Russell Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt, 247 (1994).

[29] Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: A Review of the Critical Issues*, 11 J. Pain & Symptom Mgmt. 203, 206 (1996).

[30] *Id.*

35. Dr. Portenoy argued in favor of expanding the use of opioids, pointing to evidence from opioid use among cancer patients. He posited that there was a population of patients without cancer who could benefit from long-term opioid use. Even then, he admitted, "controlled trials suggest favorable outcomes, but are very limited. The generalizability of these data are questionable due to the brief periods of treatment and follow-up."[31]

36. Dr. Portenoy claimed that the lack of evidence should not deter doctors from prescribing opioids, arguing there was a lack of data that non-malignant pain generally, or any patient subgroup with non-malignant pain (such as those with neuropathic pain, low back pain, headache, or idiopathic pain), are inherently unresponsive to opioid drugs. Consequently, he believed, opioid therapy could not be withheld based on the assumption that any particular pain or patient group will inevitably fail to benefit.[32]

37. Purdue seized on, and intentionally distorted, Dr. Portenoy's work, emphasizing the benefits of opioids for chronic pain, but failing to convey the limitations of existing research and the cautions for their use. Where Portenoy proposed a clinical experiment with "appropriate monitoring," Purdue, through its marketing, expanded the "empirical treatment" to thousands of busy primary care physicians, nurse practitioners, physician assistants, and other prescribers, none of whom had Dr. Portenoy's expertise.

38. Purdue's business and marketing model nationalized an experiment in the absence of good evidence. Purdue hired other health care professionals that Purdue identified as "key opinion leaders" and, through an extensive marketing scheme, set about convincing the rest of the medical establishment, patients, and policy makers to participate willingly in the

[31] *Id.*

[32] *Id.*

experiment. Purdue did so by deceptively presenting the experimental hypotheses as facts – that (a) opioids would be more effective than alternatives at treating chronic non-cancer pain long-term; and (b) the risks of addiction and associated problems were both slight and manageable. Purdue's factual claims were unsubstantiated and, unfortunately for the many Utahns who have suffered as a result, untrue.

39. Purdue has made statements through its sales representatives visiting Utah doctors, websites, promotional materials, conferences, guidelines for doctors, and other modes of communication that suggested that the risk of opioid addiction when used for chronic pain was low — statements directly contrary to established scientific evidence.

40. Purdue's marketing claims also differ from the safety warnings that Purdue must place on many of its opioid products. In fact, Purdue has been repeatedly fined or otherwise sanctioned for its misleading statements in marketing opioids.

A. Purdue seeded the science of opioid efficacy and risk with flawed and biased research.

41. Rather than rigorously test the safety and efficacy of opioids for long-term use, Purdue created scientific support for its marketing claims by sponsoring studies that were methodologically flawed, and biased, and which drew inappropriate conclusions from prior evidence. It then published studies with favorable outcomes and suppressed the problematic ones. The result was a body of literature whose primary purpose was to promote the use of opioids for chronic pain but which was passed off as legitimate scientific research. Subsequent studies then cited—and continue to cite—this research to insidious effect. The body of evidence on which physicians rely to prescribe opioids now fully incorporates Purdue's skewed science.

42. For example, Purdue-sponsored studies, and the Purdue marketing materials that cited them, regularly made claims that the risk of psychological dependence or addiction is low absent a history of substance abuse. One such study, published in the journal *Pain* in 2003 and widely referenced since (with nearly 600 citations in Google Scholar),[33] ignored previous Purdue-commissioned research showing addiction rates between 8% and 13%—far higher than Purdue acknowledged was possible in its mainstream marketing. Purdue relegated those earlier studies to less prominent headache journals, where it knew they would be less widely read.[34]

43. Instead, to support the claim that OxyContin rarely was addictive, the *Pain* article reached back to a 1980 letter to the editor—not an article, but a letter—in the *New England Journal of Medicine*.[35] That letter, the "Porter-Jick Letter," appeared as follows:

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[33] C. Peter N. Watson et al., *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial in painful diabetic neuropathy,* 105 Pain 71 (2003).

[34] Lawrence Robbins, *Long-Acting Opioids for Severe Chronic Daily Headache*, 10(2) Headache Quarterly 135
(1999); Lawrence Robbins, *Works in Progress: Oxycodone CR, a Long-Acting Opioid, for Severe Chronic Daily Headache*, 19 Headache Quarterly 305 (1999).

[35] J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302(2) New England Journal of Medicine 123 (1980).

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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44. The Porter-Jick Letter does not reflect any study, but simply describes a review of the charts of hospitalized patients who had received opioids. The Porter-Jick Letter notes that the review found almost no references to signs of addiction, though there is no indication that staff were instructed to assess or document signs of addiction. And because the opioids were administered in a hospital, there was no risk of patients taking more or higher doses than were prescribed.

45. The Porter-Jick Letter has become a mainstay in scientific literature, with more than 1,000 citations in Google Scholar. Purdue, for example, has cited it in support of Purdue's patently false marketing claim that "less than 1%" of opioid patients become addicted, most prominently in its 1998 "I Got My Life Back" video. Yet Purdue failed to disclose either the nature of the citation (a letter, not a study) or any of its serious limitations. Dr. Jick later complained that drug companies "pushing out new pain drugs" had misused the Letter—citing it to conclude that their opioids were not addictive, even though "that's not in any

shape or form what we suggested in our letter."[36] In June 2017, the *New England Journal of Medicine*, citing a new analysis of the Porter-Jick Letter's citation history, added this editor's note to its online version of the Letter: "For reasons of public health, readers should be aware that this letter has been 'heavily and uncritically cited' as evidence that addiction is rare with opioid therapy."

46. Purdue published other research supporting chronic opioid therapy that was just as flawed as the 2003 *Pain* article. One such Purdue-sponsored study, which featured two Purdue-employed authors and appeared in the Journal of Rheumatology in 1999, misleadingly suggested that OxyContin was safe and effective as a long-term treatment for osteoarthritis.[37] Patients were given OxyContin only for 30 days. Only 106 of the 167 patients continued the study after their appropriate dose was determined, and most who left did so due to ineffective pain control or side effects from the drug. While acknowledging the short-term nature of the trial, the authors still drew the unsupported conclusion that "[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids longterm."

47. [redacted]

[36] National Public Radio, *Doctor Who Wrote 1980 Letter on Painkillers Regrets That It Fed The Opioid Crisis*, (June 16, 2017), http://www.npr.org/sections/healthshots/2017/06/16/533060031/.

[37] Jacques R. Caldwell et al., *Treatment of Osteoarthritis Pain with Controlled Release Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial*, 26:4 Journal of Rheumatology 862-868 (1999).

[redacted]

48. Another Purdue-authored study, published in the *Clinical Journal of Pain* in 1999, misleadingly implied that OxyContin was safe and effective as a long-term treatment of back pain.[38] This study, too, had a high dropout rate and, though it concerned a chronic condition, it followed patients on OxyContin only between four and seven days. The study was not set up to consider long-term risks, including the risk of addiction, but blithely concluded that "common opioid side effects can be expected to become less problematic for the patient as therapy continues."

B. Purdue worked with professional associations to create treatment guidelines that overstated the benefits and understated the risks of opioids.

49. Treatment guidelines were particularly important to Purdue in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but also are cited

[38] Martin E. Hale et al., *Efficacy and Safety of Controlled-Release Versus Immediate-Release Oxycodone: Randomized, Double-Blind Evaluation in Patients with Chronic Back Pain*, 15(3) Clinical Journal of Pain 179-183 (Sept. 1999).

throughout the scientific literature and referenced by third-party payors in determining whether they should cover prescriptions. Purdue financed and collaborated with two groups, in particular, on guidelines that have been, and continue to be, broadly influential in Utah and nationwide.

1. AAPM/APS Guidelines

50. The American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") each received substantial funding from Purdue. In 1997, AAPM and APS issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," that endorsed using opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was, at the time, a paid speaker for Purdue and later became a senior executive for the company. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained, though it lingers on elsewhere on the internet.

51. AAPM and APS also issued a 2001 set of recommendations, titled "Definitions Related to the Use of Opioids for the Treatment of Pain," that advanced the unsubstantiated concept of "pseudoaddiction." The term, coined by Dr. Haddox in a 1989 journal article, reflects the idea that signs of addiction may actually be the manifestation of undertreated pain and will resolve once the pain is effectively treated—i.e., with more or higher doses of opioids.[39] The 2001 AAPM/APS recommendations claimed "clock-watch[ing]," "drug

[39] David E. Weismann & J. David Haddox, *Opioid Pseudoaddiction—an Iatrogenic Syndrome*, 36 Pain 363-366 (1989).

seeking," and "[e]ven such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain [pain] relief."

52. Notes taken by Purdue's sales representatives in Utah show that the sales representatives discussed the false concept of pseudoaddiction with Utah doctors. Dr. Lynn Webster, a key opinion leader in Salt Lake City who was funded by Purdue, admitted in 2012 that pseudoaddiction was "already something we are debunking as a concept" and became "too much of an excuse to give patients more medication. It led us down a path that caused harm."[40]

53. The 2016 CDC Guideline rejects the concept of pseudoaddiction, explaining that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use" and that physicians should "reassess[] pain and function within 1 month" to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[41]

54. In 2009, AAPM and APS issued comprehensive opioid prescribing guidelines ("2009 AAPM/APS Guidelines"), drafted by a 21-member panel, that promoted opioids as "safe and effective" for treating chronic pain. The panel made what it termed "strong recommendations" despite "low quality evidence," and concluded that the risk of addiction is manageable for patients, even patients with a prior history of drug abuse.

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[40] John Fauber, "Painkiller Boom Fueled by Networking," Milwaukee Wisc. J. Sentinel, Feb. 18, 2012.

[41] 2016 CDC Guideline at 13, 25.

55. Six of the panel members, including Dr. Portenoy, received financial backing from Purdue, and another eight received funding from other opioid manufacturers. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the guidelines were influenced by contributions that drug companies, including Purdue, made to the sponsoring organizations and committee members.

56. The 2009 AAPM/APS Guidelines were reprinted in the *Journal of Pain*, were distributed by Purdue sales representatives to prescribers, and have been relied upon by Utah prescribers in their practices. The guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids. According to Google Scholar, the guidelines have now been cited nearly 1,700 times in academic literature.

2. FSMB Guidelines

57. The Federation of State Medical Boards ("FSMB") is an association of the various state medical boards in the United States. The FSMB has financed opioid- and pain specific programs through grants from pharmaceutical manufacturers, including more than $800,000 from Purdue between 2001 and 2008.

58. In 1998, the FSMB developed its Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("FSMB Guidelines"), which the FSMB acknowledged were produced "in collaboration with" pharmaceutical companies and allied groups such as the APS.[42] The FSMB Guidelines described opioids as "essential" for treatment of chronic

[42] FSMB, *Position of the FSMB in Support of Adoption of Pain Management Guidelines*, (1998),

pain, including as a first-line option; failed to mention risks of respiratory depression and overdose; addressed addiction only to define the term as separate from physical dependence; and stated that an "inadequate understanding" of addiction can lead to "inadequate pain control."

59. A 2004 iteration of the FSMB Guidelines and the 2007 book adapted from them, *Responsible Opioid Prescribing*, repeated the 1998 version's claims. The book also claimed that opioids would improve patients' function and endorsed the dangerous, now-discredited concept of pseudoaddiction, which had suggested that signs of addiction may reflect undertreated pain that should be addressed with more opioids. Through at least 2015, the FSMB website described *Responsible Opioid Prescribing* as the "leading continuing medical education (CME) activity for prescribers of opioid medications." In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationwide through state medical boards and non-profit organizations. *Responsible Opioid Prescribing* was sponsored by Purdue, among other opioid manufacturers, and Purdue had editorial input into its contents.

3. American Pain Foundation

60. "A Policymaker's Guide to Understanding Pain & Its Management," an October 2011 American Pain Foundation pamphlet "made possible by support from Purdue Pharma LP," asserted that "[l]ess than 1 percent of children treated with opioids become addicted" and that pain was generally "undertreated" due to "misconceptions about opioid addiction."[43]

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https://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/1998_grpol_Pain_Management_Guidelines.pdf.

[43] *A Policymaker's Guide to Understanding Pain & Its Management*, Am. Pain Found. 6 (Oct. 2011),

Likewise, in 2002 testimony to the Senate, the American Pain Foundation claimed that addiction is rare, limited to certain extreme cases, and "no additional legislation is needed to attack the diversion and abuse of all opioid pain medications."[44]

C. Purdue's direct marketing understated the risk of addiction.

61. Purdue produced and provided directly to doctors and patients marketing materials that intentionally and fraudulently made similar misstatements.

62. Purdue trained sales representatives to minimize the risk of addiction to Purdue products when discussing opioids with doctors, but emphasize the risks of using competing products. For instance, Purdue sales representatives were instructed to tell doctors that opioids' addiction risk was "less than 1 percent."[45] [redacted] In addition, materials that Purdue produced, sponsored, or controlled omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would favor opioids over other therapies such as over-the-counter acetaminophen

http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

[44] *Testimony by the American Pain Foundation*: *Senate Health, Education, Labor and Pensions Committee Hearing to Examine the Effects of the Painkiller OxyContin, Focusing on Risks and Benefits*, 2 (Feb. 12, 2002) (statement of John D. Giglio, Executive Director American Pain Foundation).

[45] U.S. Gov't Accountability Office, GAO-04-110, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem* 22 (Dec. 2003), https://www.govinfo.gov/content/pkg/GAOREPORTS-GAO-04-110/pdf/GAOREPORTS-GAO-04-110.pdf.

or nonsteroidal anti-inflammatory drugs (or NSAIDs, like ibuprofen), which do not pose a risk of addiction. None of these claims were corroborated by scientific evidence.

63. Purdue sponsored training sessions where doctors were given similar misleading information regarding the risks of opioid addiction. For example, Purdue sponsored training sessions in the late 1990s and early 2000s where opioid addiction was described as "exquisitely rare."[46]

64. All of these statements were contrary to scientific facts known to Respondents. The CDC has directly contradicted Purdue's representations that opioid addiction is rare when opioids are used properly. The CDC has stated that there is "extensive evidence" of the possible harms of opioids, including opioid use disorder and overdose, and stated that "[o]pioid pain medication use presents serious risks" including addiction; and highlighted that using opioids to treat chronic pain "substantially increases" the risk of addiction.[47] A 2016 CDC guideline discusses studies that found that as many as 26% of long-term users of opioids experience problems with addiction or dependence.[48]

65. Moreover, in August 2016, the U.S. Surgeon General published an open letter to physicians nationwide, worrying that "heavy marketing to doctors" had led many to be "taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[49] This letter also noted the "devastating" results that followed from this misinformation.[50]

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[46] Barry Meier, *Pain Killer: A "wonder" drug's trail of addiction and death* 190 (2003).

[47] Deborah Dowell, Tamara Haegerich, & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain –United States, 2016*, 65 Morbidity and Mortality Weekly Report 1 (2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

[48] *Id.*

[49] Letter from U.S. Surgeon General Vivek H. Murthy (Aug. 2016), https://perma.cc/VW95-CUYC.

[50] *Id.*

66. Findings by the Food and Drug Administration ("FDA") similarly belie Purdue's assertions that opioids are safe for treating chronic pain. These findings show that (1) "most opioid drugs have 'high potential for abuse'"; (2) treatment of chronic pain with opioids poses "known serious risks," including "addiction, abuse, and misuse ... overdose and death" even when used "at recommended doses"; and (3) opioids should be used only "in patients for whom alternative treatment options" have failed.[51] Additionally, several published clinical studies finding double-digit rates of prescription drug abuse in chronic pain patients controvert Purdue's claims that addiction rates are only one percent.[52]

67. As recently as June 2017, the New England Journal of Medicine published an analysis finding that Purdue's introduction of OxyContin into the marketplace coincided with a significant increase in misleading dissemination of the claim that addiction to opioids is rare. Moreover, the authors of the June 2017 analysis concluded that "[w]e believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy."[53]

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[51] Food and Drug Admin., Letter from Janet Woodcock, M.D., Dir. of Center for Drug Evaluation and Research, to Andrew Kolodny, M.D. Responding to Petition Submitted by Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), http://www.supportprop.org/wpcontent/uploads/2014/12/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf.

[52] Caleb J. Banta-Green et al., *Opioid Use Behaviors, Mental Health and Pain— Development of a Typology of Chronic Pain Patients*, 104 Drug and Alcohol Dependence 34 (Sept. 2009), http://dx.doi.org/10.1016/j.drugalcdep.2009.03.021; Joseph A. Boscarino et al., *Risk Factors for Drug Dependence Among Out-Patients on Opioid Therapy in a Large US Health-Care System*, 105 Addiction 1776 (Oct. 2010), http://dx.doi.org/10.1111/j.1360-0443.2010.03052.x; Jette Højsted et al., *Classification and Identification of Opioid Addiction in Chronic Pain Patients, 14 European J. of Pain 1014 (Nov. 2010), http://dx.doi.org/10.1016/j.ejpain.2010.04.006.*

[53] Pamela T. M. Leung et al., *A 1980 Letter on the Risk of Opioid Addiction*, 376 New England J. of Med. 2194
(June 1, 2017), http://www.dx.doi.org/10.1056/NEJMc1700150.

68. Additionally, Respondents pushed patients to stay on Purdue's opioids through the use of savings cards, or Purdue's Rx loyalty program. [redacted]

D. Purdue falsely claimed that there was no risk in increasing opioid doses to treat chronic pain.

69. Purdue also falsely claimed that doctors and patients could increase opioid doses indefinitely without added risk. Guidelines edited and sponsored by Purdue and another opioid manufacturer, Endo[54]—titled "Treatment Options: A Guide for People Living with Pain" (2006) and "A Policymaker's Guide to Understanding Pain & Its Management" (2011)—claim that (a) some patients "need" a larger opioid dose, regardless of the dose prescribed; (b) opioids have "no ceiling dose" and are therefore the most appropriate

[54] Am. Pain Found., *Annual Report* (2010), https://www.documentcloud.org/documents/277604-apf-2010-annualreport.

treatment for severe pain; and (c) dosage escalations, even unlimited ones, are "sometimes necessary."[55]

70. As recently as June 2015, Purdue's "In the Face of Pain" website was encouraging patients to find another doctor if the patient's doctor refused to prescribe opioids in doses that were "sufficient" in the patient's opinion. Also in 2015, Purdue presented a paper at the College on the Problems of Drug Dependence, challenging the correlation between opioid dose and overdose.[56] And in 2016, Purdue's Dr. Haddox falsely claimed that evidence does not show that Purdue's opioids are being abused in large numbers.

71. Purdue made these statements despite strong contrary scientific evidence. The FDA has stated that the available data "suggest a relationship between increasing opioid dose and risk of certain adverse events."[57] The CDC has stated that there is "an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages," and

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[55] Am. Pain Found., *Treatment Options: A guide for people living with pain* (2006), https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf; Am. Pain Found., *A Policymaker's Guide to Understanding Pain & Its Management* (Oct. 2011), http://s3.documentcloud.org/documents/277603/apfpolicymakers-guide.pdf.

[56] A. DeVeaugh-Geiss et al., *Is Opioid Dose a Strong Predictor of the Risk of Opioid Overdose?: Important confounding factors that change the dose-overdose relationship*, CPDD 76th Annual Scientific Meeting Program (June 2014), http://cpdd.org/wp-content/uploads/2016/07/2014CPDDprogrambook.pdf.

[57] Food and Drug Admin., Letter from Janet Woodcock, M.D., Dir. of Center for Drug Evaluation and Research, to Andrew Kolodny, M.D. Responding to Petition Submitted by Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), http://www.supportprop.org/wpcontent/uploads/2014/12/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf.

has specifically recommended that doctors "avoid increasing doses" above 90 morphine milligram equivalents ("MME") per day.[58]

72. Nonetheless, Purdue misrepresented the effects of escalating doses to further its pursuit of profit. The ability to escalate doses was critical to Purdue's efforts to market opioids for chronic pain treatment because doctors would otherwise abandon treatment when patients built up tolerance and no longer obtained pain relief. For at least some products, escalation of dose was key—of the seven available OxyContin tablet strengths, the three strongest—40 milligrams (120 MME), 60 milligrams (180 MME), and 80 milligrams (240 MME)—all exceed the CDC limit by 2.5 to 5.3 times, even taken twice per day as directed.

E. Respondents misleadingly promoted OxyContin as supplying 12 hours of pain relief when they knew that, for many patients, it did not.

73. To convince prescribers and patients to use OxyContin, Respondents misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality, OxyContin does not last for 12 hours in many patients, a fact the Respondents have known since the product's launch. While OxyContin's FDA-approved label directs 12-hour dosing, the Respondents sought that dosing frequency in order to maintain a competitive advantage over other opioids that required more frequent dosing. Yet Respondents have gone well beyond the label's instructions to take OxyContin every 12

[58] Deborah Dowell, Tamara Haegerich, & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 Morbidity and Mortality Weekly Report 1 (2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

hours by affirmatively claiming that OxyContin lasts for 12 hours and by failing to disclose that OxyContin fails to provide 12 hours of pain relief to many patients.[59]

74. Since it was launched in 1996, OxyContin has been FDA-approved for twice-daily—"Q12"—dosing frequency. It was the Respondents' decision to submit OxyContin for approval with 12-hour dosing. While the OxyContin label indicates that "[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours," that is because Purdue has conducted no such studies.

75. From the outset, the Respondents leveraged 12-hour dosing to promote OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake to take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as providing "smooth and sustained pain control all day and all night." [redacted] But the FDA has never approved such marketing claims. To the contrary, the FDA found in 2008, in response to a Citizen Petition by the Connecticut Attorney General, that a "substantial number" of chronic pain patients taking OxyContin experienced "end of dose failure"—*i.e.*, little or no pain relief at the end of the dosing period.

76. In fact, the Respondents have long known, dating to the development of OxyContin, that the drug wears off well short of 12 hours in many patients. [redacted]

[redacted]

[redacted]

77. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience distressing psychological and physical withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[60] Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

78. [redacted]

79. Without appropriate caveats, promotion of 12-hour dosing by itself is misleading because it implies that the pain relief supplied by each dose lasts 12 hours, which the Respondents knew to be untrue for many, if not most, patients. FDA approval of OxyContin for 12-hour dosing does not give the Respondents license to misrepresent the duration of pain relief it provides to patients; moreover, the Respondents had a responsibility to disclose to

[60] Harriet Ryan, "*'You Want a Description of Hell?' OxyContin's 12-Hour Problem*", Los Angeles Times, May 5, 2016, http://www.latimes.com/projects/oxycontin-part1/.

prescribers what they knew about OxyContin's actual duration, regardless of any marketing advantage.

80. [redacted]

81. Twelve-hour dosing also is featured in most OxyContin promotional pieces. The 2012 Conversion and Titration Guide, for example, contains the tag line: "Because each patient's treatment is personal / Individualize the dose / Q12 OxyContin Tablets." A 2013 brochure for prescribers titled "Identifying Appropriate Patients for OxyContin" similarly promotes the convenience of twice-daily dosing. Upon information and belief, these pieces were distributed in Utah, and neither piece discloses that the pain relief from each 12-hour dose will last well short of 12 hours for many patients.

82. Respondents were also aware of some physicians' practice of prescribing OxyContin more frequently than 12 hours—a common occurrence. Respondents' promoted solution to this problem was to increase the dose, rather than the frequency, of prescriptions, even though higher dosing carries its own risks. For example, Purdue's 2012 Conversion and Titration Guide advises prescribers to "[i]ncrease the OxyContin dose by increasing the total daily dose, not by changing the 12-hour dosing interval." This advice was not accompanied by appropriate disclosures regarding OxyContin's shorter-than-12-hour relief in many cases. Using higher doses also means that patients will experience higher highs and lower lows, increasing their craving for their next pill.

F. Respondents overstated opioids' effect on patients' function and quality of life.

83. Respondents also claimed—without evidence—[redacted] that long-term opioid use would help to improve patients' function and quality of life and get them back to work and to their lives.

84. This false message was longstanding and directed from the top. [redacted]

85. Purdue and Purdue-sponsored materials distributed or made available in Utah reinforced this message. The 2011 Purdue sponsored publication, "A Policymaker's Guide to Understanding Pain & Its Management" (2011),[61] falsely claimed that "multiple clinical studies have shown that opioids are effective in improving daily function and quality of life for chronic pain patients." A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with chronic pain conditions—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively.

86. Purdue sponsored the Federation of State Medical Board's ("FSMB's") *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." This publication claimed that

[61] Am. Pain Found., *A Policymaker's Guide to Understanding Pain & Its Management* (Oct. 2011), http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

because pain had a negative impact on a patient's ability to function, relieving pain—alone—would "reverse that effect and improve function." However, the truth is far more complicated; functional improvements made from increased pain relief can be offset by a number of problems, including addiction. Purdue spent over [redacted] to support distribution of the book, which, upon information and belief, was sent to physicians and other prescribers in Utah.

87. Likewise, Purdue's claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. There are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long-term. [redacted]

88. [redacted]

89. On the contrary, the available evidence indicates opioids may worsen patients' health and pain. Increasing the duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

90. As one pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[62] Studies of patients with lower back pain and migraine headaches, for example, have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures. Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, stemming from greater side effects and slower returns to work.

91. Assessing existing science, the CDC Guideline found that there was "[n]o evidence show[ing] a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later"[63] and advised that "there is no good evidence that opioids improve pain or function with long-term use."[64] Similarly, the FDA has warned other opioid product manufacturers that claims of improved function and quality of life were misleading.[65] The CDC also noted that the risks of addiction and death

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[62] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonomamedicine-are-we-making-pain-patients-worse?

[63] CDC Guideline at 15.

[64] *Id.* at 20.

[65] *See,* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza

"can cause distress and inability to fulfill major role obligations."[66] In that vein, a recent study by Princeton economist Alan Krueger found that opioids may be responsible for roughly 20% of the decline in workforce participation among prime-age men and 25% of the drop for women.[67] The CDC Guideline concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[68] According to Dr. Tom Frieden, then Director of the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[69]

92. As one doctor noted, the widespread, long-term use of opioids "was an experiment on the population of the United States. It wasn't randomized, it wasn't controlled, and no data was collected until they started gathering death statistics."

G. Purdue's misleading statements were designed for maximum effect and targeted to specific audiences.

93. Purdue disseminated these misstatements to doctors through a wide array of sources, each designed to maximize impact and each targeted to a specific receptive audience.

(morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). These warning letters were available to Purdue on the FDA website.

[66] CDC Guideline at 2.

[67] Alan B. Krueger, *Where Have All the Workers Gone? An Inquiry into the Decline of the U.S. Labor Force Participation Rate*, Brookings Papers on Economic Activity Conference Draft (Aug. 26, 2017).

[68] CDC Guideline at 18.

[69] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" (Apr. 21, 2016).

94. Purdue often delivered its misstatements through "key opinion leaders," doctors in the field of pain management who were heavily funded by Purdue. Purdue frequently used opinion leaders to deliver its message because it knew that doctors often place great confidence in seemingly independent peers. At least two of Purdue's key opinion leaders live and work in Utah—Dr. Lynn Webster and Dr. Perry Fine, who served on the board of the American Pain Foundation, discussed above.

95. Dr. Lynn Webster, who works in Salt Lake City, received Purdue funding to develop and teach an online program titled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This presentation deceptively instructed that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths." The program currently is available online to Utah prescribers.[70] Upon information and belief, it has been available online for approximately six years and it has been viewed by additional Utah prescribers since it was first broadcast in September 2011.

96. Another notable opinion leader was Dr. Russell Portenoy, who held himself out as an unbiased expert on opioids but received substantial funding from Purdue. Dr. Portenoy gave, in his words, "innumerable" lectures and media appearances promoting opioids.[71] He also regularly repeated—including in a 1986 paper published in the journal of the American Pain Society, a 1996 paper written on behalf of the American Pain Society and

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[70] Emerging Solutions in Pain, "Managing Patient's Opioid Use: Balancing the Need and the Risk," http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Nov. 30, 2017).

[71] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal, Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

the American Academy of Pain, and numerous lectures—the unsubstantiated claim that the addiction risk posed by opioids was lower than one percent.[72] Dr. Portenoy later conceded that some of his statements were misleading. In December 2012, he was quoted as saying, "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, ... I guess I did."[73]

97. Between 2001 and 2010, Purdue's "In the Face of Pain" website similarly presented the statements of opinion leaders who were portrayed as independent experts. The website not only failed to disclose that Purdue had paid many of these opinion leaders for other work, but also did not identify Purdue's involvement beyond a small copyright notice at the bottom of the website.[74]

98. Purdue also often disseminated its misstatements through industry groups that presented themselves to the public as independent patient advocacy organizations, but whose content and funding came largely from Purdue. These groups included the American Pain Foundation, the American Pain Society, and the American Academy of Pain Medicine. Much like the opinion leaders, these industry groups allowed Purdue to present its misstatements as if they came from unbiased experts.

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[72] Russell Portenoy, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25 Pain 171 (May 1986), https://www.ncbi.nlm.nih.gov/pubmed/2873550; Russell Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: A review of the critical issues*, 11 J. of Pain and Symptom Mgmt. 203 (Apr. 1996), http://dx.doi.org/10.1016/0885-3924(95)00187-5; Russell Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain*, 1 Pain Research and Mgmt. 17 (1996), http://downloads.hindawi.com/journals/prm/1996/409012.pdf.

[73] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal, Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

[74] Advocacy Voices, In the Face of Pain (archived Nov. 7, 2010), https://web.archive.org/web/20101107090355/http://www.inthefaceofpain.com:80/search.aspx?cat=4#7.

99. These groups published many of the misleading "guidelines" described above, based on content and funding provided by Purdue, including: (1) "Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain" (2009);[75] (2) "A Policymaker's Guide to Understanding Pain & Its Management" (2011);[76]and (3) "Treatment Options: A Guide for People Living with Pain" (2006).[77] In 2007, the American Pain Society repeated, at a Senate Judiciary Committee hearing, Purdue's misstatements that addiction was a "rare problem" for patients using opioids for chronic pain and that there was "no causal effect ... between the marketing of [a particular opioid] and the abuse and diversion of the drug."[78]

100. Purdue also conducted conferences, training sessions, and educational programs for doctors, often with all expenses paid at resort destinations. These events were useful to Purdue because studies show that such events influence the attending practitioners' prescribing habits and views towards a drug.[79]

101. From 1996 to 2001, Purdue conducted more than 40 pain management and speaker training sessions at resorts to recruit and train physicians, nurses, and pharmacists as speakers on

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[75] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10 The J. of Pain 113 (Feb. 2009), http://dx.doi.org/10.1016/j.jpain.2008.10.008.

[76] Am. Pain Found., *A Policymaker's Guide to Understanding Pain & Its Management* (Oct. 2011), http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

[77] Am. Pain Found., *Treatment Options: A guide for people living with pain* (2006), https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

[78] *Evaluating the Propriety and Adequacy of the OxyContin Criminal Settlement: Hearing Before the S. Comm. On Judiciary*, 110th Cong. 1 (2007) (Statement of James Campbell, M.D.).

[79] Ray Moynihan, *Doctors' Education: The invisible influence of drug company sponsorship*, 336 The BMJ 416 (Feb. 23, 2008), http://dx.doi.org/10.1136/bmj.39496.430336.DB; A.C. Anand, *Professional Conferences, Unprofessional Conduct*, 67 Medical J. Armed Forces India 2 (Jan. 2011), http://dx.doi.org/10.1016/S0377-1237(11)80002-X; David McFadden et al., *The Devil Is in the Details: The pharmaceutical industry's use of gifts to physicians as marketing strategy*, 140 J. of Surgical Research 1 (2007), http://dx.doi.org/10.1016/j.jss.2006.10.010.

behalf of Purdue.[80] Purdue trained more than 5,000 people at these all-expenses-paid events.[81] In addition, the DEA has estimated that Purdue funded over 20,000 opioid pain-related educational programs between 1996 and July 2002 through direct sponsorship or financial grants.[82]

102. Purdue also used direct sales representatives to market opioids. These representatives received a large amount of their compensation in bonuses based on their individual sales figures, ensuring that they were strongly motivated to present their audiences with misleading information minimizing the risks of opioids.[83]

103. The FDA does not regulate all of the conduct in which the Respondents engaged. For example, drug labels do not address the use of opioids in treating specific conditions such as lower back pain, headaches, or fibromyalgia, three conditions for which opioids are ineffective, but for which Purdue marketed their drugs. The FDA also does not regulate unbranded advertising. Likewise, the FDA does not regulate the marketing messages or scripts relied on by sales representatives or marketing funneled through third-parties, such as the industry groups discussed above.

104. Purdue not only issued misstatements through channels thought to be the most productive, but also targeted marketing to doctors who would be most receptive to the misstatements. Purdue specifically targeted its marketing to primary care physicians, who are generally

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[80] U.S. Gov't Accountability Office, *Prescription Drugs: OxyContin abuse and diversion and efforts to address the problem* 22 (Dec. 2003), https://www.gpo.gov/fdsys/pkg/GAOREPORTS-GAO-04-110/content-detail.html.

[81] *Id.*

[82] *Id.* at 23.

[83] *Id.* at 22.

less aware of the medical literature regarding the dangers of treating chronic pain with opioids. Dr. Portenoy, speaking to an FDA advisory panel on January 30, 2002, acknowledged this fact, stating that "[g]eneralists are adopting [opioid] therapy without adequate knowledge of pain management principles."[84] On information and belief, Purdue also directly targeted susceptible patients like veterans and the elderly.

105. Purdue developed methods to specifically target physicians who were already prescribing higher-than-average numbers of opioids. Purdue purchased data from companies such as IMS Health, which provided information regarding the prescribing patterns of physicians nationwide. Through this data, Purdue could identify those prescribers who were already prescribing high amounts of opioid-containing products and target those same doctors for Purdue opioids. Purdue created a database to identify physicians with large numbers of chronic-pain patients (which also showed which physicians were simply the most frequent prescribers of opioids). This database has given Purdue extensive knowledge of where and how its drugs are being used across the country, including in Utah, and has allowed Purdue to target doctors already susceptible to its message.[85]

II. Purdue is misrepresenting its actions with regard to the opioid epidemic.

106. Purdue has also misrepresented to the public that it is taking steps to curb the opioid epidemic, rather than creating it. As recently as November 2017, Purdue stated on its website that "...too often these medications [opioids] are diverted, misused, and abused.

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[84] Food and Drug Admin., Anesthetic and Life Support Drugs Advisory Comm., Tr. of Meeting 119 (Jan. 30, 2002), http://wayback.archiveit.org/7993/20170404083838/; https://www.fda.gov/ohrms/dockets/ac/02/transcripts/3820t1.pdf.

[85] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial triumph, public health tragedy*, 99 Am. J. of Public Health 221, 222 (Feb. 2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/pdf/221.pdf.

Teenagers, in particular, are vulnerable to prescription drug abuse, which has become a national epidemic."[86] In response to the misuse of opioids, Purdue said that "Corporations have a responsibility to address this issue, and Purdue has dedicated vast resources for helping to prevent drug abuse..."[87]

107. Purdue also stated in November 2017 that it is "committed to being part of the solution to prescription drug abuse" and that it "offers an array of programs focused on education, prevention, and deterrence and through partnerships with (1) healthcare professionals, (2) families and communities, and law enforcement and government" to combat the "widespread abuse of opioid prescription pain medications [that] can lead to tragic consequences, including addiction, overdose, and death."[88]

108. Also in November 2017, Purdue discussed the opioid epidemic and its response to it, stating that "The nation is experiencing a public health crisis involving licit and illicit opioids. Purdue endorses the following policies that support a comprehensive approach to reducing addiction, abuse, diversion, and overdose related to opioids."[89] The policies employed by Purdue include limiting the duration of a patient's first opioid prescription; use of prescription drug monitoring programs; requiring demonstrated competence for

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[86] Purdue Pharma, *Combating Opioid Abuse*, http://webcache.googleusercontent.com/search?q=cache:yQnPlZfguWAJ:www.purduepharma.com/healthcareprofessionals/responsible-use-of-opioids/combating-opioid-abuse/+&cd=1&hl=en&ct=clnk&gl=us.

[87] *Id.*

[88] *Id.*

[89] Purdue Pharma, *Public Policies to Address the Opioid Crisis*, http://www.purduepharma.com/about/purduepharma-public-policy/.

opioid prescribing; and expanding the use of naloxone, an opioid reversal agent, among other things.[90]

109. However, on information and belief, these representations are untrue. For example, notwithstanding its public statements of corporate responsibility, Purdue has failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse" and "strong record of coordination with law enforcement."[91]

110. Additionally, since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. According to Purdue, physicians could be added to this database based on observed indicators of illicit prescribing, such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing volume. Purdue has said publicly that "[o]ur procedures help ensure that whenever we observe potential abuse or diversion activity, we discontinue our company's interaction with the prescriber or pharmacist and initiate an investigation."[92]

111. Yet, according to a 2016 investigation by the *Los Angeles Times*, Purdue failed to cut off these providers' opioid supply at the pharmacy level and failed to report these providers to

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[90] *Id.*

[91] Purdue Pharma L.P., *Setting the Record Straight on OxyContin's FDA-Approved Label* (May 5, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approvedlabel/; Purdue Pharma L.P., *Setting the Record Straight on Our Anti-Diversion Programs* (July 11, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversionprograms/.

[92] *Id.*

state medical boards or law enforcement — meaning Purdue continued to generate sales revenue from their prescriptions.[93]

112. The *Times'* investigation also found that "for more than a decade, Purdue collected extensive evidence suggesting illegal trafficking of OxyContin" and yet consistently failed to report suspicious dispensing or to stop supplies to the pharmacy.[94] Despite its knowledge of illicit prescribing, Purdue did not report its suspicions, for example, until years after law enforcement shut down a Los Angeles clinic that Purdue's district manager described internally as "an organized drug ring" and that had prescribed more than 1.1 million OxyContin tablets.[95]

III. Purdue knowingly and intentionally misled Utah prescribers and consumers.

113. The problems engendered by the deceptive and unfair marketing of opioids were specifically known by Purdue. Purdue was aware that its statements were misleading not only because it knew these statements were contrary to established fact, but also because it was fined and otherwise sanctioned by various government entities for its misleading marketing, and yet continued to disseminate the same marketing messages.

114. In 2007, Purdue settled federal allegations that it had introduced misbranded drugs into interstate commerce. The settlement included over $700 million in payments to the United

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[93] *See* Harriet Ryan et al., *More Than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times, July 10, 2016, http://www.latimes.com/projects/la-me-oxycontin-part2/.

[94] *Id.*

[95] *Id.*

States and guilty pleas by three of Purdue's executive officers.[96] Purdue acknowledged that "some employees made, or told other employees to make, certain statements about OxyContin to some healthcare professionals that were inconsistent with the FDA-approved prescribing information for OxyContin and the express warning it contained about risks associated with the medicine."[97]

115. On August 20, 2015, New York State concluded a multiyear investigation of Purdue and settled claims against the company related to its marketing and sales practices. Specifically, the agreement required Purdue to ensure that its sales representatives flag doctors and other professionals who were improperly prescribing and/or diverting opioids, stop calling and/or marketing to doctors on the company's "no-call list," and provide information to health care providers about FDA-approved training programs regarding the appropriate prescription of opioids. The agreement also required Purdue to cease marketing representations on its website "www.inthefaceofpain.com" implying that the website was neutral or unbiased, and to disclose the financial relationships Purdue's purported neutral experts have with the company.[98]

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[96] *Id.*; Plea Agreement at 4, *United States of America v. The Purdue Frederick Co., Inc.*, Case No. 1:07-cr-00029-JPJ(W.D. Va. May 10, 2017), http://i.bnet.com/blogs/purdue-agreed-facts.pdf.

[97] Shannon Henson, *Purdue, Employees to Pay $700M in OxyContin Case*, LAW360, (May 10, 2007, 12:00 AM), https://www.law360.com/illinois/articles/24509/purdue-employees-to-pay-700m-in-oxycontin-case.

[98] Press Release, N.Y. State Office of the Attorney General, A.G. Schneiderman Announces Settlement With Purdue Pharma That Ensures Responsible And Transparent Marketing Of Prescription Opioid Drugs By The Manufacturer (August 20, 2015), https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensuresresponsible-and-transparent.

116. In August 2017, Purdue settled, for over $20 million, claims by numerous Canadian plaintiffs that the company failed to warn about the dangers of OxyContin, including its addictive properties.[99]

117. Respondents knew that their continuing efforts to employ deceptive and unfair marketing, despite Purdue being previously sanctioned by government agencies for such actions, would contribute to the opioid epidemic in Utah, and would create access to opioids by at-risk and unauthorized users, which, in turn, would perpetuate the cycle of abuse, addiction, demand, and illegal transactions.

118. [redacted]

119. Furthermore, Purdue knew that when more patients gained access to opioids based on deceptive and false marketing, tragic, preventable injuries would result, including addiction, abuse, overdoses, and death. It was reasonably foreseeable that many of these injuries would be suffered by Utah citizens, and that the costs of these injuries would be shouldered by the State and state agencies.

120. It was foreseeable that the increased number of prescriptions for opioids resulting from Purdue's deceptive and unfair marketing would cause harm to the citizens and government

[99] Will Davidson LLP, *Purdue Pharma Agrees to OxyContin Settlement, but Is it Fair?*, Lexology (Aug. 22, 2017), https://www.lexology.com/library/detail.aspx?g=d53ee1ee-44cb-4ef5-b916-e570a385b568.

of Utah. [redacted]

121. Purdue made substantial profits over the years based on the intentionally deceptive and unfair marketing of opioids in Utah.

122. Purdue's deceptive and unfair marketing of prescription opioids to Utah citizens showed a reckless disregard for the safety of Utah and its citizens. Its conduct poses a continuing threat to the health, safety, and welfare of Utah and its citizens.

123. Purdue's misleading marketing and failure to prevent opioid diversion in and around Utah has contributed to a range of social problems, including violence and delinquency, that were foreseeable to Respondents. These foreseeable adverse social outcomes include child neglect, family dysfunction, babies born addicted to opioids, criminal behavior, poverty, property damage, unemployment, and social despair. As a result, more and more of Utah's resources and those of its counties and municipalities are devoted to addiction-related problems. Meanwhile, the prescription opioid crisis diminishes Utah's available workforce, decreases productivity, increases poverty, and consequently requires greater State and local expenditures.

124. Prescription opioid abuse costs the State approximately $238 million in healthcare costs, not to mention additional social services and education expenses.[100] And, it adds an estimated $169 per capita in costs to Utah's healthcare system, loss in productivity, and criminal justice costs. Mortality costs brings the total to approximately $1,827 per Utahn.

IV. The Sackler Respondents are personally responsible.

125. Respondent Richard Sackler and Respondent Kathe Sackler each personally directed the unfair, deceptive and otherwise unlawful conduct alleged herein. Their actions were taken as members of the Purdue Board of Directors as well as individually as Purdue executive officers and owners of, as the company describes it, [redacted]

A. The Sackler Respondents' actions as members of the board

126. Purdue's Board of Directors is very hands-on, described in the company's own planning documents as [redacted]

[100] Matric Global Advisors, *Health Care Costs from Opioid Abuse: A state-by-state analysis*, 5 (2015), http://drugfree.org/wp-content/uploads/2015/04/Matrix_OpioidAbuse_040415.pdf (prescription opioid abuse costs the citizens and State of Utah approximately $238 million in healthcare costs each year); Kohei Hasegawa et al., *Epidemiology of Emergency Department Visits for Opioid Overdose: A population-based study*, 89 Mayo Clinic Proceedings 462, 465, 467 (2014) (there are about two times as many opioid overdoses in Emergency Departments among publicly-insured individuals than among individuals with private insurance and publicly-insured individuals are approximately twice as likely to have a second visit to the Emergency Departments for opioid overdose as are privately-insured individuals); The Nat'l Ctr. on Addiction and Substance Abuse, *Shoveling Up II: The impact of substance abuse on federal, state, and local budgets*, 27 (May 2009), http://www.centeronaddiction.org/addictionresearch/reports/shoveling-ii-impact-substance-abuse-federal-state-and-local-budgets (State governments spend 27%of the amount they spend on healthcare to fund the social services related to substance abuse.); The Nat'l Ctr. On Addiction and Substance Abuse, *Shoveling Up II: The impact of substance abuse on federal, state, and local budgets*, 27 (May 2009), http://www.centeronaddiction.org/addiction-research/reports/shoveling-ii-impactsubstance-abuse-federal-state-and-local-budgets (State governments spend 77% of the amount they spend on healthcare on the K–12 education expenses associated with substance abuse.).

127. [redacted]

[redacted]

128. [redacted]

129. The Sackler Respondents were both longstanding members of Purdue's Board of Directors. As such, they were informed of and approved the decisions related to Purdue's marketing and compliance operations that were at the core of Purdue's business. However, as laid out below, Richard and Kathe Sackler exercised a level of involvement and control, particularly in the unlawful conduct described in this Citation, that surpassed even that of other Sackler Board member-owners. In addition, as also detailed below, each of the Sackler Respondents served for many years as executive officers of Purdue, taking many actions personally to carry out the unfair, deceptive and otherwise unlawful activity that led to Utah's opioid epidemic.

B. Richard Sackler

130. [redacted]

131. Accordingly, Respondent Richard Sackler personally oversaw, directed, made and approved many of the key decisions regarding Purdue's opioids and he is legally responsible for their outcomes in Utah. [redacted]

[redacted]

132. Respondent Richard Sackler spent 43 years at Purdue in his various capacities, including the head of marketing, President, Co-Chairman of the Board, and board member. Upon information and belief, as head of Purdue's marketing department and then President and Co-Chairman of Purdue's Board, with a demonstrated interest and involvement in Purdue's sales efforts and promotional messaging, Respondent Richard Sackler would have been aware of and approved all of Purdue's marketing themes and strategies.

133. Respondent Richard Sackler has been characterized in the press as having an appetite for micromanagement. [redacted] Throughout his tenure, Respondent Richard Sackler either had knowledge of Purdue's marketing misrepresentations, or was recklessly indifferent to their truth or falsity, [redacted]

[redacted]

101 [redacted]

[redacted]

134. This detailed involvement began even more than a year before Purdue launched OxyContin. [redacted] Upon information and belief, Defendant Richard Sackler and his team at Purdue decided not to disclose the study to the FDA.

135. [redacted]

136. [redacted]

137. Thereafter, Richard Sackler became involved—deeply—in every aspect of Purdue's marketing operations. [redacted]

138. [redacted]

139. [redacted]

[redacted]

[102] [redacted]

[redacted]

140. [redacted]

141. [redacted]

142. [redacted]

143. [redacted]

144. [redacted]

145. [redacted]

146. [redacted]

147. [redacted]

148. [redacted]

[redacted]

149. [redacted]

150. In January of 2018, however, Respondent Richard Sackler received a patent for "a method of medication-assisted treatment for opioid addiction."[103] In Respondent Richard Sackler, it seems that a change in the bottom line may have inspired a change of heart.

[103] U.S. Patent No. 9,861,628

C. Kathe Sackler

151. Respondent Kathe Sackler is a current board member of Purdue, and has been a member of the board of directors of Purdue since the 1990s. She also spent a number of years as Purdue's Senior Vice President. Upon information and belief, she held the position of Senior Vice President from at least 2004-2014.

152. Respondent Kathe Sackler was also personally involved in Purdue's operations from the early days of planning the launch of OxyContin. [redacted]

153. [redacted]

[redacted]

154. [redacted]

155. [redacted]

156. [redacted]

[redacted]

[redacted]

157. [redacted]

158. [redacted]

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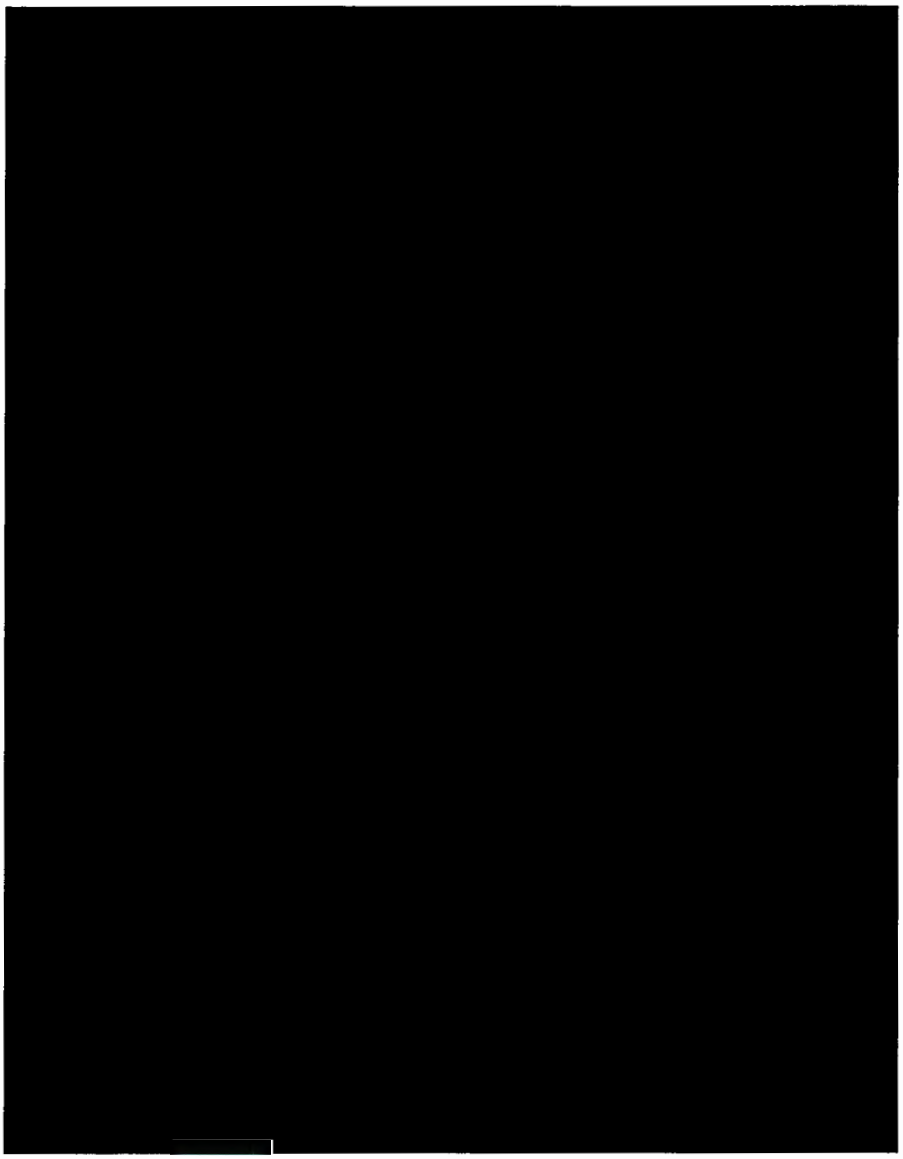

159. [redacted]

160. [redacted] But Richard Sackler and Purdue did not give up on this new strategy. [redacted] Richard invented one, obtaining the patent for an addiction treatment drug that he then transferred to Purdue. In true form, the Sackler Respondents and Purdue are thus poised to further profit from the crisis they created.

RESPONDENTS' CONDUCT VIOLATED THE CONSUMER SALES PRACTICES ACT

161. At the Sackler Respondents' direction, Purdue has continued to promote, directly and indirectly, deceptive marketing messages that misrepresent, and fail to include material facts about, the dangers of opioid usage in Utah, despite knowing that these marketing messages are false, in order to increase their sales, revenue, and compensation.

COUNT I

162. The Division realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

163. The CSPA prohibits, in connection with a consumer transaction, deceptive consumer sales practices that mislead consumers about the nature of the product they are receiving. Utah Code § 13-11-1, *et seq*. This Count is brought in the public interest under the CSPA, Utah Code § 13-11-4(1).

164. As is described herein, Respondents mislead consumers about the nature of their products by disseminating marketing material and messages that overstated the benefits of opioids and understated their risks, and by omitting or concealing material facts.

COUNT II

165. The Division realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

166. In marketing and selling prescription opioids, Respondents have knowingly or intentionally and persistently committed deceptive acts or practices, in violation of the CSPA. Utah Code § 13-11-1, *et seq.*

167. Respondents violated the CSPA by knowingly or intentionally, and fraudulently indicating that opioids had sponsorship, approval, performance characteristics, uses, or benefits, when they did not, in violation of Utah Code § 13-11-4(2)(a).

168. Respondents violated the CSPA by knowingly or intentionally, and fraudulently omitting or concealing material facts and failing to correct prior misrepresentations and omissions about the risks and benefits of opioids. Respondents' omissions rendered even their seemingly truthful statements about opioids deceptive.

169. Respondents violated the CSPA by knowingly or intentionally, and fraudulently indicating that opioids were of a particular standard, quality, grade, style, or model, when they were not, in violation of Utah Code § 13-11-4(2)(b).

170. Respondents violated the CSPA by knowingly or intentionally, and fraudulently indicating that opioids had been supplied in accordance with Purdue's previous representations, when they had not, in violation of Utah Code § 13-11-4(2)(e).

COUNT III

171. The Division realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

172. Respondents have knowingly or intentionally, and fraudulently marketed drugs through misstatements and omissions of facts regarding the safety and efficacy of their drugs, and they have failed adequately to guard against misstatements and omissions concerning opioids made by their employees and agents. Respondents knew or had reason to know

that their misstatements, omissions, and failure to guard against misstatements and omissions made by their employees and agents would harm Utah's citizens.

173. By manufacturing and marketing opioids in the manner described above, or by directing others to do so, Respondents have also committed unconscionable acts or practices in violation of Utah Code § 13-11-5. Specifically, Respondents have violated their statutory duties to Utah and Utah citizens to report suspicious prescribers in Utah communities that were known to Respondents, have misused their position of trust in the community, and have preyed on Utah's most vulnerable residents for profit.

174. For purposes of penalty calculations, each instance where Respondents have misrepresented a material fact or suppressed, concealed, or omitted any material fact regarding the prescription opioids they manufactured or marketed constitutes a separate violation of the CSPA. The Division intends to calculate the administrative fines after the liability portion of the case has concluded.

THIS CITATION ISSUED this 30 day of January, 2019.

Daniel R. S. O'Bannon

UTAH DIVISION OF CONSUMER PROTECTION

CERTIFICATE OF SERVICE

I certify that I have this day served the foregoing document on the parties of record in this proceeding set forth below sending courtesy copies to the following, counsel for Respondents, by email:

Mark Cheffo Mark.Cheffo@dechert.com Will Sachse Will.Sachse@dechert.com	Sara Roitman Sara.Roitman@dechert.com Paul LaFata Paul.LaFata@dechert.com Elisabeth McOmber emcomber@swlaw.com

Dated this 30th day of January, 2019.

/s/ Kevin McLean

Assistant Attorney General
Counsel for the Division of Consumer Protection

NOTICE
IMPORTANT - READ CAREFULLY

This citation may be contested by filing a request for review, in writing, within twenty (20) days of receipt of this citation. Following receipt of a request for review, an informal hearing will be scheduled before the State of Utah, Department of Commerce, Division of Consumer Protection pursuant to Utah Code § 63G-4-203, Procedures for Informal Adjudicative Proceedings. The purpose for the hearing is a review of the citation for factual and legal sufficiency and other questions to be determined by the presiding officer.

A citation that is not contested becomes the final default order of the Division. A defaulted party may make a motion to the presiding officer to set aside a default. Utah Code § 63G-4-209(3). The defaulted party may seek agency review pursuant to Utah Code § 63G-4-301, or reconsideration pursuant to Utah Code § 63G-4-302, only of the presiding officer's decision on the motion to set aside the default. *See* Utah Code § 63G-4-209(3)(c).

In addition to any fines that may be levied, a cease and desist order may be entered against you. An intentional violation of a final cease and desist order is a third degree felony. Utah Code § 13-2-6(2).

To request a review of the citation, mail your written request to:

Daniel R. S. O'Bannon – Director
Utah Division of Consumer Protection
PO Box 146704
Salt Lake City, UT 84114-6704

The presiding officer designated by the Director of the Division of Consumer Protection to conduct the hearing in your case is:

Bruce Dibb, Administrative Law Judge
Heber M. Wells Bldg., 2nd Floor
160 East 300 South
Salt Lake City, UT 84114
Telephone: (801) 531-6706

Please be advised that all inquiries, correspondence, or other contacts concerning this citation, with the exception of any written request for review as set out above, should be directed to the following, counsel for The Division of Consumer Protection:

Robert Wing or Kevin McLean
Assistant Attorneys General
Utah Attorney General's Office
160 East 300 South, 5th Floor
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Salt Lake City, UT 84114-0872
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1. **How can I talk to someone at the Division about this citation?** The name of the investigator assigned to your case appears at the end of your citation. If you call the Division, 801-530-6601 and press 0, the receptionist can help transfer you to the assigned investigator.
2. **Can I resolve the citation without a hearing?** Contact the investigator assigned to your case if you are interested in a settlement to see if a settlement is possible in your case.
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4. **How long do I have to respond to the citation?** You have 20 calendar days from issuance of the citation to submit a Request for Review.
5. **What happens after I submit a Request for Review?** The presiding officer will send you a Notice of Administrative Hearing specifying a time, date, and location of a hearing before the Division.
6. **Who will preside over the case?** The name of the presiding officer for the hearing will be on your Notice of Administrative Hearing. Please address the presiding officer by name (e.g., "Judge Smith"). You may contact the presiding officer with any technical or procedural questions, but the presiding officer may not discuss the merits of the case with you.
7. **What if I have a scheduling conflict with the scheduled hearing time?** Failure to attend a hearing may result in a default and entry of judgment against you. You may ask the presiding officer assigned to your case, in writing, to reschedule the hearing if you have a conflict or require more time to prepare. A request for additional time is within the discretion of the presiding officer and may not be granted, particularly if requested only shortly before the scheduled hearing.
8. **What should I expect at a hearing?** An administrative law judge will act as the presiding officer and direct the proceeding. The hearing room has two tables for the parties, with the presiding officer sitting at the front of the hearing room. Generally you (and your counsel, if applicable) will sit at one of the tables and Division staff will sit at the other table. Beginning with the Division, both sides will have an opportunity to present witnesses, evidence, and argument in support of why the citation should or should not stand.
9. **What kind of evidence can I present?** All parties may testify, present evidence, and comment on the issues. In presenting evidence, any party may examine witnesses and submit exhibits. At the request of either party, or at his or her own initiative, the presiding officer may also choose to examine a witness. Any party may ask to present a witness by telephone. The presiding officer may exclude any evidence he or she deems irrelevant, immaterial, or unduly repetitious or improper.
10. **How can I determine what evidence the Division has?** Discovery is prohibited in informal hearings, but parties may request information contained in the agency's files to the extent permitted by law. You may contact the assigned investigator to request access to this information.
11. **What is the burden of proof for the Division at a hearing?** Generally the Division is responsible to prove its case against you by substantial evidence.
12. **Must I have an attorney?** You may represent yourself or be represented through an attorney. You may also represent a business that you own or manage.

You should not rely on this letter alone for instructions regarding hearings. The hearing is governed by law (including the Administrative Procedures Act, *see* Utah Code § 63G-4 *et al.*, Utah Division of Consumer Protection, *see* Utah Code § 13-2 *et al.*, and Department of Commerce Administrative Procedures Act Rules, *see* Utah Admin. Code R151-4.) You may access these laws and rules at le.uteth.gov and rules.utah.gov.

DIVISION OF CONSUMER PROTECTION
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REQUEST FOR REVIEW

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Requests for review must be received by the division within 20 calendar days of issuance of the citation. Utah Code § 13-2-6(3). If you fail to make a timely request, the citation shall become the final order of the division. If you represent multiple respondents, please submit a separate request for each respondent.

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Select only one of the following:

❑	I admit to the statutory violation(s) described in the citation. The presiding officer will enter an order, assess a fine, and issue a cease and desist order.
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Signature	Date of Signature

REDACTED CITATION 2 - PUBLIC

(Information that was publicly disclosed in another forum has been revealed.)

Utah Division of Consumer Protection
160 East 300 South, Second Floor
PO Box 146704
Salt Lake City, UT 84114-6704
PH. (801) 530-6601/FAX (801) 530-6001

**BEFORE THE DIVISION OF CONSUMER PROTECTION
OF THE DEPARTMENT OF COMMERCE
OF THE STATE OF UTAH**

IN THE MATTER OF: **PURDUE PHARMA L.P., a Delaware limited partnership; PURDUE PHARMA INC., a New York corporation; THE PURDUE FREDERICK COMPANY, a Delaware corporation; RICHARD SACKLER, M.D., individually and as an owner, officer, director, member, principal, manager, and/or key employee of the above named entities; and KATHE SACKLER, M.D., individually and as an owner, officer, director, member, principal, manager, and/or key employee of the above named entities;** **Respondents.**	**ADMINISTRATIVE CITATION** **DCP Legal File No. CP-2019-___** **DCP Case No. _____**

PURSUANT TO THE AUTHORITY granted by Utah Code § 13-2-6, which empowers the Division of Consumer Protection ("Division") to issue a citation upon reasonable cause to believe a person has violated or is violating any statute listed in Utah Code § 13-2-1, it appears, upon information and belief, that Respondents have violated the *Utah Consumer Sales Practices Act* (CSPA), Utah Code § 13-11-1 *et seq.* In particular, the Division alleges:

RESPONDENTS

1. Respondent Purdue Pharma L.P. is a limited partnership organized and existing under the laws of the State of Delaware with its principal place of business located in Stamford,

Connecticut. During all relevant times, Purdue Pharma L.P. has manufactured substantial amounts of prescription opioids that have been, and continue to be, distributed and sold in Utah. Purdue Pharma L.P. has engaged in consensual commercial dealings with Utah and its citizens and has purposefully availed itself of the advantages of conducting business with and within Utah.

2. Respondent Purdue Pharma Inc. is a corporation organized and existing under the laws of New York State with its principal place of business located in Stamford, Connecticut. During all relevant times, Purdue Pharma Inc. has manufactured substantial amounts of prescription opioids that have been, and continue to be, distributed and sold in Utah. Purdue Pharma Inc. has engaged in consensual commercial dealings with Utah and its citizens and has purposefully availed itself of the advantages of conducting business with and within Utah.

3. Respondent The Purdue Frederick Company is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located in Stamford, Connecticut. During all relevant times, The Purdue Frederick Company has manufactured substantial amounts of prescription opioids that have been, and continue to be, distributed and sold in Utah. The Purdue Frederick Company has engaged in consensual commercial dealings with Utah and its citizens and has purposefully availed itself of the advantages of conducting business with and within Utah.

4. Purdue Pharma L.P., Purdue Pharma Inc. and The Purdue Frederick Company will be referred to collectively as "Purdue."

5. Respondent Richard Sackler, M.D. is an individual with a residence in Connecticut and at least one residence in Alta, Utah, now titled in the name of Superior View LLC c/o Richard Sackler, MD, with an assessed value of over $3 million. [redacted]

[redacted]

Upon information and belief, Respondent Richard Sackler joined Purdue in 1971 as an assistant to his father, Raymond Sackler. Richard Sackler served as head of Purdue's Marketing Department and of its Research and Development Department, before serving as President of Purdue from 1999-2003, where he oversaw the early marketing of OxyContin. From 2003 to approximately 2014, he served as Co-Chairman of the Purdue Board. Richard Sackler was a Board Member of Purdue until July of 2018 when a wave of litigation was filed against Purdue. Upon information and belief, Richard Sackler has long held an ownership interest in Purdue and continues to hold an ownership interest in Purdue. Richard Sackler is the listed inventor on a number of patents assigned to Purdue, including a patent for "drug substitution therapy in drug-dependent human subjects," known in lay terms as addiction treatment. In other words, having caused the opioid epidemic, Richard Sackler, through his companies, is poised to profit further from the aftermath.

6. Respondent Kathe Sackler, M.D. is an individual with a residence in Connecticut. She is the daughter of Mortimer Sackler, one of the three original founders of Purdue, and she has served as a member of the board of directors of Purdue since the 1990s. In addition to her role on the Board, Kathe Sackler served as the Senior Vice President of Purdue.

7. Richard Sackler and Kathe Sackler, M.D. will, at times, be referred to collectively as the "Sackler Respondents."

8. Utah has personal jurisdiction over Respondents Richard and Kathe Sackler because they personally directed Purdue to conduct the deceptive or unfair acts or practices alleged herein that took place in Utah. The Sackler Respondents are "suppliers" within the

meaning of the CSPA because, through their direct involvement in Purdue's business, they indirectly solicited and engaged in the sales of opioids in Utah; by express statutory provision, they need not deal directly with their customers. Utah Code § 13-11-3(6). Through their decisions and directives at Purdue, the Sackler Respondents knowingly caused the unlawful promotion and sales of Purdue's opioids in Utah. Business activities that the Sackler Respondents directed include Purdue's employment of a substantial number of sales representatives nationwide, including in Utah, to visit doctors in their local offices for the purpose of delivering deceptive marketing messages and encouraging such doctors to write prescriptions for Purdue's opioid products. They determined the methods by which prescribers were targeted by Purdue's sales representatives, how often the doctors were visited, and what messages and strategies were used with them. Among other things, the Sackler Respondents directed Purdue's sales representatives, including those in Utah, to promote the use of opioids at high doses and for long periods of time, which was unfair and misleading, and which increased Purdue's revenue, but magnified the risk to the State of Utah and its residents.

9. Respondents are subject to the Division's jurisdiction because the actionable conduct was committed wholly or partly within Utah; because conduct committed outside Utah constituted an attempt to commit a violation within Utah; and because transactional resources located within Utah used by Respondents directly or indirectly facilitated a violation or attempted violation. Utah Code § 13-2-6(4).

BACKGROUND AND INFORMATION

10. Opioid abuse and addiction is a national public health crisis. According to the Centers for Disease Control ("CDC"), over 70,000 Americans died of a drug overdose in 2017, of

which 67.8 percent (47,600) involved opioids. The number of deaths and the prevalence of opioids were both worse in 2017 than a year prior.[1]

11. Utah is not immune from the effects of this opioid crisis. According to the CDC, Utah lost 1,884 people to drug overdose deaths between 2014 and 2016, and the "main driver" of these deaths was prescription and illicit opioids.[2] In 2017, there were 456 opioid-related overdose deaths in Utah—a rate of 15.5 deaths per 100,000, which is higher than the national rate of 14.9 deaths per 100,000.[3]

12. The Respondents' misconduct, including its consistent, intentional failure to comply with its legal obligations, has led to an epidemic of prescription opioid abuse in Utah. This epidemic resulted in a nearly 600% increase in prescription opioid-related deaths in Utah between 1999 and 2007,[4] 466 prescription opioid-related deaths in Utah in 2016 alone,[5] and millions drained annually from State resources.

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[1] Ctr. for Disease Control & Prevention, *Drug Overdose Deaths*, https://www.cdc.gov/drugoverdose/data/statedeaths.html According to the CDC, over 63,000 Americans died of a drug overdose in 2016, of which 66.4 percent (42,249) reportedly involved opioids. (Ctr. for Disease Control & Prevention, Morbidity and Mortality Weekly Report, March 30, 2016, *Overdose Deaths*, 2015-2016, https://www.cdc.gov/mmwr/volumes/67/wr/mm6712a1.htm?s_cid=mm6712a1_w.)

[2] Ctr. for Disease Control & Prevention, *Drug Overdose Deaths*, https://www.cdc.gov/drugoverdose/data/statedeaths.html (Number and age-adjusted rates of drug overdose deaths by state, US 2014, 2015, 2016).

[3] Ctr. for Disease Control & Prevention, Morbidity and Mortality Report, December 28, 2018, *Drug and Opioid-Involved Overdose Deaths - United States*, 2015-2017, https://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm?s_cid=mm675152e1_w#T1_down.

[4] Ctr. Disease Control & Prevention, Morbidity and Mortality Weekly Report, Feb. 19, 2010 59(06), *Adult Use of Prescription Opioid Pain Medications --- Utah, 2008*, https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5906a1.htm?s_cid=mm5906a1_w.

[5] *Utah Opioid Summary*, Nat'l Inst. on Drug Abuse, https://www.drugabuse.gov/drugs-abuse/opioids/opioidsummaries-by-state/utah-opioid-summary.

13. This epidemic has drained State resources from the criminal justice,[6] social services and welfare,[7] education,[8] and healthcare systems.[9] Prescription opioid abuse costs the citizens and State of Utah approximately $238 million in healthcare costs each year.[10]

14. Prescription opioids are powerful pain-reducing medications. They include non-synthetic derivatives of the opium poppy (also called "opiates," such as codeine and morphine), partially-synthetic derivatives (such as hydrocodone and oxycodone), and fully-synthetic derivatives (such as fentanyl and methadone).

15. While opioids can dampen the perception of pain, they also can create an addictive, euphoric high. At higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy

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[6] *The High Price of the Opioid Crisis*, Pew Charitable Trusts July 2017, http://www.pewtrusts.org/~/media/assets/2017/07/highpriceofopioidcrisis_infographic_final.pdf?la=en. In 2013, $7.6 billion was spent nationally on criminal justice costs associated with prescription opioid abuse, and 96% of the costs fell to state and local governments.

[7] The Nat'l Ctr. on Addiction and Substance Abuse, *Shoveling Up II: The impact of substance abuse on federal, state, and local budgets* 27 (2009), http://www.centeronaddiction.org/addictionresearch/reports/shoveling-iiimpact-substance-abuse-federal-state-and-local-budgets. In 2005, state governments spent 27% of the amount they spend on healthcare to fund the social services related to substance abuse.

[8] *Id.* at 24. In 2005, approximately 12.2% of federal government education spending "was spent coping with the impact of substance abuse and addiction."

[9] Matric Global Advisors, *Health Care Costs from Opioid Abuse: A state-by-state analysis* 5 (2015), http://drugfree.org/wp-content/uploads/2015/04/Matrix_OpioidAbuse_040415.pdf; Kohei Hasegawa et al., *Epidemiology of Emergency Department Visits for Opioid Overdose: A population-based study*, 89 Mayo Clinic Proceedings 462, 465, 467 (2014) (there are about two times as many opioid overdoses in Emergency Department among publicly-insured individuals than among individuals with private insurance and publicly-insured individuals are approximately twice as likely to have a second visit to the Emergency Departments for opioid overdose as are privately-insured individuals); Cong. Research Serv.,*Medicaid's Federal Medical Assistance Percentage (FMAP)* 14–15 (2016), https://fas.org/sgp/crs/misc/R43847.pdf (the State of Utah pays for approximately 30% of publicly funded healthcare expenses).

[10] Matric Global Advisors, *Health Care Costs from Opioid Abuse: A state-by-state analysis* 5 (2015), http://drugfree.org/wp-content/uploads/2015/04/Matrix_OpioidAbuse_040415.pdf.

will experience withdrawal symptoms—including severe anxiety, nausea, headaches, tremors, delirium, and pain—which are often prolonged, if opioid use is delayed or discontinued. When using opioids continuously, patients grow tolerant to their analgesic effects (i.e. to relief of pain)—requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose. Prescription opioids are no less addictive than heroin. No other medication routinely used for a nonfatal condition kills patients so frequently.[11] When used long-term to treat chronic pain conditions, those risks are amplified.

16. The Respondents have intentionally engaged, and continue to engage, in an aggressive marketing campaign to overstate the benefits and misstate and conceal the risks of treating chronic pain with opioids in order to increase their profits. Utah law prohibits suppliers from using misleading or deceptive practices to market their products. Nonetheless, Purdue disseminated misstatements through multiple channels, representing opioids as beneficial in treating chronic pain long-term, and as having a low risk of addiction. This campaign included websites, promotional materials distributed in Utah, conferences available to Utah prescribers, dinner programs held in Utah for Utah prescribers, guidelines for doctors, thousands of personal visits between Respondents' sales representatives and Utah prescribers in their medical offices, and other such modes of communication. Purdue also helped cultivate a narrative that pain was undertreated and pain treatment should be a higher priority for health care providers. This paved the way for increased prescribing of opioids for chronic pain.

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[11] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, *Reducing the Risks of Relief, the CDC Opioid-Prescribing Guideline*, at 1503 (Apr. 21, 2016).

17. In addition, Purdue paid at least two Utah doctors to be "key opinion leaders." They wrote promotional materials supporting opioids as the best approach to pain management, and prescribed lethal amounts of opioids to Utah residents from their Salt Lake City offices.[12]

18. Purdue's marketing campaign enabled Purdue to overcome the longstanding medical consensus that opioids were unsafe for the treatment of chronic pain. Purdue's campaign resulted in a significant increase in the number of opioids prescribed nationwide. In fact, between 1999 and 2015, the number of opioids prescribed nationwide tripled.[13] Not surprisingly, deaths from prescription opioid use quadrupled between 1999 and 2011.[14] Between 2002 and 2015, the number of opioid prescriptions dispensed in Utah increased by over one million. In 2015, Utah prescribers wrote 73.1 opioid prescriptions per 100 persons, compared to the national average of 70 opioid prescriptions per 100 persons.[15]

19. The increase in opioid prescriptions to treat chronic pain correlates with an increase in the number of people becoming addicted to opioids and seeking prescription opioids for non-medical purposes.[16] Nationally, the number of people who take prescription opioids for

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[12] Deseret News, *The untold story of how Utah doctors and Big Pharma helped drive the national opioid epidemic*, (Oct. 26, 2017), https://www.deseretnews.com/article/900002328/the-untold-story-of-how-utah-doctors-and-bigpharma-helped-drive-the-national-opioid-epidemic.html.

[13] Guy, Gery et al., *Vital Signs: Changes in Opioid Prescribing in the United States, 2006* – 2015, CDC Morbidity and Mortality Weekly Report (MMWR), July 7, 2017, https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm

[14] Li Hui Chen et al., *Drug-poisoning Deaths Involving Opioid Analgesics: United States, 1999–2011*, 166 Nat'l Ctr.for Health Statistics Data Brief (Sept. 2014), https://www.cdc.gov/nchs/data/databriefs/db166.pdf.

[15] National Institute on Drug Abuse, Opioid-Related Overdose Deaths, https://www.drugabuse.gov/drugsabuse/opioids/opioid-summaries-by-state/utah-opioid-summary.

[16] Chronic pain is often defined as any pain lasting more than 12 weeks. National Institutes of Health, NIH.

non-medical purposes is now greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.[17] In Utah alone, data from the Substance Abuse and Mental Health Services Administration indicates that from 2012-2014, between 7.3% and 8.54% of 18 - 25 year-olds used prescription opioids for non-medical purposes.[18]

20. This increase in addiction and non-medical demand has corresponded with an increase in "diversion." Diversion occurs when the prescription opioid supply chain breaks and the drugs are transferred from legitimate channels to illegitimate ones.

21. The legitimate supply chain for prescription opioids begins with the manufacture and packaging of the pills. Manufacturers, including Purdue, then transfer the pills to distribution companies. Distributors then supply opioids to pharmacies and other healthcare providers, which then dispense the drugs to consumers. Diversion to illicit use can occur anywhere in the supply chain, from a distribution truck or pharmacy robbery, to a curious teenager taking pills a parent inadvertently left accessible.

MedlinePlus, Spring, 2011, https://medlineplus.gov/magazine/issues/spring11/articles/spring11pg5-6.html.

[17] Substance Abuse and Mental Health Servs. Admin., *Results from the 2015 National Survey on Drug Use and Health: Detailed Tables*, https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015.pdf.

[18] Substance Abuse and Mental Health Servs. Admin., *2012-2014 National Survey on Drug Use and Health Substate Age Group Tables* 143 (2015), https://www.samhsa.gov/data/sites/default/files/NSDUHsubstateAgeGroupTabs2014/NSDUHsubstateAgeGroupTabs2014.pdf (in Utah, though statistics varied according to substate region, 4.15% of people age 12-15, and 3.03% of people 26+, engage in the non-medical use of prescription pain relievers).

22. Of the 2.2 million opioid prescriptions issued in Utah in 2015 (nearly one prescription per Utah resident), studies suggest that as many as 281,600 of those prescriptions were diverted to non-medical uses.[19]

23. The extent to which opioids are diverted into illicit use is even more concerning because Utah has the second highest high-dose opioid prescription rate in the United States.[20]

24. In 2017, Carbon County had the highest opioid prescribing rate in Utah, at 154.1 prescriptions per 100 residents.[21] The county with the next highest prescribing rate was Sevier, with 108.2 prescriptions per 100 residents. By comparison, the rates in Salt Lake and Tooele Counties were 63.2 and 64.0 prescriptions per 100 residents, respectively.

25. One result is that the economic impacts of the opioid epidemic seen nation and state–wide, are even more pronounced in some of the communities least equipped to address them.

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[19] *Opioid Pain Reliever Prescriptions*, Nat'l Inst. on Drug Abuse, https://www.drugabuse.gov/drugsabuse/opioids/opioid-summaries-by-state/utah-opioid-summary. The studies estimate that the percentage of prescription opioids that are diverted to illegitimate purposes ranges from 1.9 percent to 12.8 percent of total prescriptions. B.L. Wilsey et al., *Profiling Multiple Provider Prescribing of Opioids, Benzodiazepines, Stimulants, and Anorectics*, 112 Drug and Alcohol Dependence 99 (2010) (estimating that 12.8% of prescriptions are diverted); N. Katz et al., *Usefulness of Prescription Monitoring Programs for Surveillance– Analysis of Schedule II Opioid Prescription Data in Massachusetts, 1996–2006*, 19 Pharmacoepidemiology and Drug Safety 115 (2010) (estimating the diversion rate at 7.7% when defining likely diversion as patients that obtain opioids from at least 3 prescribers and at least 3 pharmacies in a year); D.C. McDonald & K.E. Carlson, *Estimating the Prevalence of Opioid Diversion by "Doctor Shoppers" in the United States*, 8 PLOS ONE (2013) (estimating the diversion rate at 1.9% of all prescriptions and 4% of total grams dispensed).

[20] *Annual Surveillance Report of Drug-Related Risks and Outcomes: United States, 2017*, Ctr. Disease Control & Prevention, 10 https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf.

[21] Centers for Disease Control and Prevention, U.S. County Prescribing Rates (2017), https://www.cdc.gov/drugoverdose/maps/rxcounty2017.html.

Carbon County ranks 11th in the nation for the highest per-capita opioid costs, coming in at a staggering $6,365.[22]

26. According to Purdue's reporting through Open Payments, Purdue has given Utah prescribers almost $200,000 in gifts and other payments during the five-year period between 2013-2017. According to Purdue's marketing records, from 2006-2017, Respondents employed [redacted] sales representatives in Utah to visit Utah prescribers in their medical offices and deliver direct marketing messages, both verbal and written. [redacted] Utah prescribers prescribed more opioids for their patients than they otherwise would have.[23]

27. Utah ranked 7th in the United States for prescription drug poisoning deaths from 2013-2015, "which . . . outpaced deaths due to firearms, falls, and motor vehicle crashes."[24]

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[22] Alex Brill & Scott Ganz, *The Geographic variation in the Cost of the Opioid Crisis*, American Enterprise Institute 8 (Mar. 2018).

[23] *See also* Scott E. Hadland, Arladne Rivera-Aguirre, Brandon D.L. Marshall, Magdalena Cerda, *Association of Pharmaceutical Industry Marketing of Opioid Products With Mortality From Opioid-Related Overdoses*, JAMA (Jan.. 18, 2019); Fn. 9 -11 supra.

[24] Utah Department of Health, *Prescription Drug Overdoses*, http://health.utah.gov/vipp/topics/prescription-drugoverdoses/.

28. Respondents' actions have caused significant harm to the State and its agencies, including the costs of (a) medical care, therapeutic and prescription drugs, and other treatments for patients suffering from opioid-related addiction, overdoses, or disease, or from medical conditions exacerbated by opioid abuse; (b) treatment of infants born with opioid-related addiction or medical conditions; (c) law enforcement and public safety measures necessitated by the opioid crisis; (d) opioid-related counseling and rehabilitation services; (e) welfare for children whose parents suffer from opioid-related disease or incapacitation; (f) expenditures under Medicaid for purchases of prescription opioids for non-medical, illegitimate, or other improper purposes; and (g) emergency room care. These costs continue to mount.

29. In this administrative petition, the State describes these harms not to recover them, but so that they may be weighed in determining the civil penalties appropriate for Purdue's conduct.

OPIOID PAINKILLERS AND RESPONDENTS' DECEPTIVE MARKETING

30. Prescription opioids are powerful pain-reducing medications that include non-synthetic, partially-synthetic, and fully-synthetic derivatives of the opium poppy. While these drugs can have benefits when used properly, and under appropriate medical supervision, they also pose serious risks. In March of 2016, the FDA emphasized the "known serious risk[] of . . . addiction"—"even at recommended doses"—of all opioids."[25] In particular, government agencies have warned that "continuing opioid therapy for 3 months

[25] *FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics,* FDA (Sep. 10, 2013); *see also FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death,* FDA (Mar. 22, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

substantially increases risk for opioid use disorder,"[26] and that opioid risks include "misuse, addiction, overdose and death, especially with long term use."[27]

31. Given these risks, the marketing, distribution, and sale of prescription opioids are heavily regulated under Utah and federal law. Utah's Pharmacy Practice Act, Utah Code § 58-17b-101, *et seq.*, Utah's Controlled Substances Act, Utah Code § 58-37-1, *et seq.*, and numerous professional regulations related to persons who handle, prescribe, and dispense controlled substances provide strict controls and requirements throughout the opioid distribution chain. These provisions of Utah law also incorporate and reference federal law regarding the marketing, distribution, and sale of prescription opioids, including the Federal Controlled Substances Act, 21 U.S.C. § 801, *et seq.*, and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321, *et seq.*

32. As discussed below, despite the dangers of prescription opioids, the Respondents fraudulently marketed them through misleading statements that mischaracterized the true magnitude of those risks and overstated the benefits of opioids in a deliberate effort to increase profits by deceiving prescribers, who reasonably relied on such representations. The Respondents' actions created an inflated market for prescription opioids, which caused injury to healthcare programs and other third-party payors of healthcare costs, including the costs of opioid prescriptions, and led to massive diversion of these drugs from legitimate to illegitimate channels. As a result of the Respondents' wrongful acts, Utah and its citizens suffered injuries and damages.

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[26] 2016 CDC Guideline at 21.

[27] CDC Opioid Overdose, Prescription Opioid Data, *https://www.cdc.gov/drugoverdose/data/prescribing.html.*

I. Purdue made misleading statements about the risks and benefits of opioids.

33. In the mid-1990s, at about the time Purdue introduced its drug OxyContin to the marketplace, the medical community was aware of both the risks of opioids and the relative ineffectiveness of long-term opioid use. Dr. Russell Portenoy, whose theories were later adopted by Purdue, acknowledged the prevailing medical understanding regarding use of opioids long-term for non-cancer pain:

> The traditional approach to chronic non-malignant pain does not accept the longterm administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effect over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutatory mood changes, but adverse effects will inevitably occur thereafter.[28]

Thus, in 1994, conventional wisdom predicted that opioids would appear effective in the short term, but prove ineffective over time with increasing negative effects.

34. The medical community knew that published reports associated opioid use "with heightened pain and functional impairment, neuropsychological toxicity, prevarication about drug use, and poor treatment response."[29] Dr. Portenoy noted: "the problematic nature of opioid therapy in some patients is unquestionable, and the potential adverse impact of all possible outcomes related to treatment, including physical dependence, deserves to be addressed."[30]

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[28] Russell Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt, 247 (1994).

[29] Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: A Review of the Critical Issues*, 11 J. Pain & Symptom Mgmt. 203, 206 (1996).

[30] *Id.*

35. Dr. Portenoy argued in favor of expanding the use of opioids, pointing to evidence from opioid use among cancer patients. He posited that there was a population of patients without cancer who could benefit from long-term opioid use. Even then, he admitted, "controlled trials suggest favorable outcomes, but are very limited. The generalizability of these data are questionable due to the brief periods of treatment and follow-up."[31]

36. Dr. Portenoy claimed that the lack of evidence should not deter doctors from prescribing opioids, arguing there was a lack of data that non-malignant pain generally, or any patient subgroup with non-malignant pain (such as those with neuropathic pain, low back pain, headache, or idiopathic pain), are inherently unresponsive to opioid drugs. Consequently, he believed, opioid therapy could not be withheld based on the assumption that any particular pain or patient group will inevitably fail to benefit.[32]

37. Purdue seized on, and intentionally distorted, Dr. Portenoy's work, emphasizing the benefits of opioids for chronic pain, but failing to convey the limitations of existing research and the cautions for their use. Where Portenoy proposed a clinical experiment with "appropriate monitoring," Purdue, through its marketing, expanded the "empirical treatment" to thousands of busy primary care physicians, nurse practitioners, physician assistants, and other prescribers, none of whom had Dr. Portenoy's expertise.

38. Purdue's business and marketing model nationalized an experiment in the absence of good evidence. Purdue hired other health care professionals that Purdue identified as "key opinion leaders" and, through an extensive marketing scheme, set about convincing the rest of the medical establishment, patients, and policy makers to participate willingly in the

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[31] *Id.*

[32] *Id.*

experiment. Purdue did so by deceptively presenting the experimental hypotheses as facts – that (a) opioids would be more effective than alternatives at treating chronic non-cancer pain long-term; and (b) the risks of addiction and associated problems were both slight and manageable. Purdue's factual claims were unsubstantiated and, unfortunately for the many Utahns who have suffered as a result, untrue.

39. Purdue has made statements through its sales representatives visiting Utah doctors, websites, promotional materials, conferences, guidelines for doctors, and other modes of communication that suggested that the risk of opioid addiction when used for chronic pain was low — statements directly contrary to established scientific evidence.

40. Purdue's marketing claims also differ from the safety warnings that Purdue must place on many of its opioid products. In fact, Purdue has been repeatedly fined or otherwise sanctioned for its misleading statements in marketing opioids.

A. Purdue seeded the science of opioid efficacy and risk with flawed and biased research.

41. Rather than rigorously test the safety and efficacy of opioids for long-term use, Purdue created scientific support for its marketing claims by sponsoring studies that were methodologically flawed, and biased, and which drew inappropriate conclusions from prior evidence. It then published studies with favorable outcomes and suppressed the problematic ones. The result was a body of literature whose primary purpose was to promote the use of opioids for chronic pain but which was passed off as legitimate scientific research. Subsequent studies then cited—and continue to cite—this research to insidious effect. The body of evidence on which physicians rely to prescribe opioids now fully incorporates Purdue's skewed science.

42. For example, Purdue-sponsored studies, and the Purdue marketing materials that cited them, regularly made claims that the risk of psychological dependence or addiction is low absent a history of substance abuse. One such study, published in the journal *Pain* in 2003 and widely referenced since (with nearly 600 citations in Google Scholar),[33] ignored previous Purdue-commissioned research showing addiction rates between 8% and 13%—far higher than Purdue acknowledged was possible in its mainstream marketing. Purdue relegated those earlier studies to less prominent headache journals, where it knew they would be less widely read.[34]

43. Instead, to support the claim that OxyContin rarely was addictive, the *Pain* article reached back to a 1980 letter to the editor—not an article, but a letter—in the *New England Journal of Medicine*.[35] That letter, the "Porter-Jick Letter," appeared as follows:

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[33] C. Peter N. Watson et al., *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial in painful diabetic neuropathy,* 105 Pain 71 (2003).

[34] Lawrence Robbins, *Long-Acting Opioids for Severe Chronic Daily Headache*, 10(2) Headache Quarterly 135
(1999); Lawrence Robbins, *Works in Progress: Oxycodone CR, a Long-Acting Opioid, for Severe Chronic Daily Headache*, 19 Headache Quarterly 305 (1999).

[35] J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302(2) New England Journal of Medicine 123 (1980).

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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44. The Porter-Jick Letter does not reflect any study, but simply describes a review of the charts of hospitalized patients who had received opioids. The Porter-Jick Letter notes that the review found almost no references to signs of addiction, though there is no indication that staff were instructed to assess or document signs of addiction. And because the opioids were administered in a hospital, there was no risk of patients taking more or higher doses than were prescribed.

45. The Porter-Jick Letter has become a mainstay in scientific literature, with more than 1,000 citations in Google Scholar. Purdue, for example, has cited it in support of Purdue's patently false marketing claim that "less than 1%" of opioid patients become addicted, most prominently in its 1998 "I Got My Life Back" video. Yet Purdue failed to disclose either the nature of the citation (a letter, not a study) or any of its serious limitations. Dr. Jick later complained that drug companies "pushing out new pain drugs" had misused the Letter—citing it to conclude that their opioids were not addictive, even though "that's not in any

shape or form what we suggested in our letter."[36] In June 2017, the *New England Journal of Medicine*, citing a new analysis of the Porter-Jick Letter's citation history, added this editor's note to its online version of the Letter: "For reasons of public health, readers should be aware that this letter has been 'heavily and uncritically cited' as evidence that addiction is rare with opioid therapy."

46. Purdue published other research supporting chronic opioid therapy that was just as flawed as the 2003 *Pain* article. One such Purdue-sponsored study, which featured two Purdue-employed authors and appeared in the Journal of Rheumatology in 1999, misleadingly suggested that OxyContin was safe and effective as a long-term treatment for osteoarthritis.[37] Patients were given OxyContin only for 30 days. Only 106 of the 167 patients continued the study after their appropriate dose was determined, and most who left did so due to ineffective pain control or side effects from the drug. While acknowledging the short-term nature of the trial, the authors still drew the unsupported conclusion that "[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids longterm."

47. [redacted]

[36] National Public Radio, *Doctor Who Wrote 1980 Letter on Painkillers Regrets That It Fed The Opioid Crisis*, (June 16, 2017), http://www.npr.org/sections/healthshots/2017/06/16/533060031/.

[37] Jacques R. Caldwell et al., *Treatment of Osteoarthritis Pain with Controlled Release Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial*, 26:4 Journal of Rheumatology 862-868 (1999).

[redacted]

48. Another Purdue-authored study, published in the *Clinical Journal of Pain* in 1999, misleadingly implied that OxyContin was safe and effective as a long-term treatment of back pain.[38] This study, too, had a high dropout rate and, though it concerned a chronic condition, it followed patients on OxyContin only between four and seven days. The study was not set up to consider long-term risks, including the risk of addiction, but blithely concluded that "common opioid side effects can be expected to become less problematic for the patient as therapy continues."

B. Purdue worked with professional associations to create treatment guidelines that overstated the benefits and understated the risks of opioids.

49. Treatment guidelines were particularly important to Purdue in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but also are cited

[38] Martin E. Hale et al., *Efficacy and Safety of Controlled-Release Versus Immediate-Release Oxycodone: Randomized, Double-Blind Evaluation in Patients with Chronic Back Pain*, 15(3) Clinical Journal of Pain 179-183 (Sept. 1999).

throughout the scientific literature and referenced by third-party payors in determining whether they should cover prescriptions. Purdue financed and collaborated with two groups, in particular, on guidelines that have been, and continue to be, broadly influential in Utah and nationwide.

1. AAPM/APS Guidelines

50. The American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") each received substantial funding from Purdue. In 1997, AAPM and APS issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," that endorsed using opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was, at the time, a paid speaker for Purdue and later became a senior executive for the company. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained, though it lingers on elsewhere on the internet.

51. AAPM and APS also issued a 2001 set of recommendations, titled "Definitions Related to the Use of Opioids for the Treatment of Pain," that advanced the unsubstantiated concept of "pseudoaddiction." The term, coined by Dr. Haddox in a 1989 journal article, reflects the idea that signs of addiction may actually be the manifestation of undertreated pain and will resolve once the pain is effectively treated—i.e., with more or higher doses of opioids.[39] The 2001 AAPM/APS recommendations claimed "clock-watch[ing]," "drug

[39] David E. Weismann & J. David Haddox, *Opioid Pseudoaddiction—an Iatrogenic Syndrome*, 36 Pain 363-366 (1989).

seeking," and "[e]ven such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain [pain] relief."

52. Notes taken by Purdue's sales representatives in Utah show that the sales representatives discussed the false concept of pseudoaddiction with Utah doctors. Dr. Lynn Webster, a key opinion leader in Salt Lake City who was funded by Purdue, admitted in 2012 that pseudoaddiction was "already something we are debunking as a concept" and became "too much of an excuse to give patients more medication. It led us down a path that caused harm."[40]

53. The 2016 CDC Guideline rejects the concept of pseudoaddiction, explaining that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use" and that physicians should "reassess[] pain and function within 1 month" to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[41]

54. In 2009, AAPM and APS issued comprehensive opioid prescribing guidelines ("2009 AAPM/APS Guidelines"), drafted by a 21-member panel, that promoted opioids as "safe and effective" for treating chronic pain. The panel made what it termed "strong recommendations" despite "low quality evidence," and concluded that the risk of addiction is manageable for patients, even patients with a prior history of drug abuse.

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[40] John Fauber, "Painkiller Boom Fueled by Networking," Milwaukee Wisc. J. Sentinel, Feb. 18, 2012.

[41] 2016 CDC Guideline at 13, 25.

55. Six of the panel members, including Dr. Portenoy, received financial backing from Purdue, and another eight received funding from other opioid manufacturers. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the guidelines were influenced by contributions that drug companies, including Purdue, made to the sponsoring organizations and committee members.

56. The 2009 AAPM/APS Guidelines were reprinted in the *Journal of Pain*, were distributed by Purdue sales representatives to prescribers, and have been relied upon by Utah prescribers in their practices. The guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids. According to Google Scholar, the guidelines have now been cited nearly 1,700 times in academic literature.

2. FSMB Guidelines

57. The Federation of State Medical Boards ("FSMB") is an association of the various state medical boards in the United States. The FSMB has financed opioid- and pain specific programs through grants from pharmaceutical manufacturers, including more than $800,000 from Purdue between 2001 and 2008.

58. In 1998, the FSMB developed its Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("FSMB Guidelines"), which the FSMB acknowledged were produced "in collaboration with" pharmaceutical companies and allied groups such as the APS.[42] The FSMB Guidelines described opioids as "essential" for treatment of chronic

[42] FSMB, *Position of the FSMB in Support of Adoption of Pain Management Guidelines*, (1998),

pain, including as a first-line option; failed to mention risks of respiratory depression and overdose; addressed addiction only to define the term as separate from physical dependence; and stated that an "inadequate understanding" of addiction can lead to "inadequate pain control."

59. A 2004 iteration of the FSMB Guidelines and the 2007 book adapted from them, *Responsible Opioid Prescribing*, repeated the 1998 version's claims. The book also claimed that opioids would improve patients' function and endorsed the dangerous, now-discredited concept of pseudoaddiction, which had suggested that signs of addiction may reflect undertreated pain that should be addressed with more opioids. Through at least 2015, the FSMB website described *Responsible Opioid Prescribing* as the "leading continuing medical education (CME) activity for prescribers of opioid medications." In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationwide through state medical boards and non-profit organizations. *Responsible Opioid Prescribing* was sponsored by Purdue, among other opioid manufacturers, and Purdue had editorial input into its contents.

3. American Pain Foundation

60. "A Policymaker's Guide to Understanding Pain & Its Management," an October 2011 American Pain Foundation pamphlet "made possible by support from Purdue Pharma LP," asserted that "[l]ess than 1 percent of children treated with opioids become addicted" and that pain was generally "undertreated" due to "misconceptions about opioid addiction."[43]

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https://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/1998_grpol_Pain_Management_Guidelines.pdf.

[43] *A Policymaker's Guide to Understanding Pain & Its Management*, Am. Pain Found. 6 (Oct. 2011),

Likewise, in 2002 testimony to the Senate, the American Pain Foundation claimed that addiction is rare, limited to certain extreme cases, and "no additional legislation is needed to attack the diversion and abuse of all opioid pain medications."[44]

C. Purdue's direct marketing understated the risk of addiction.

61. Purdue produced and provided directly to doctors and patients marketing materials that intentionally and fraudulently made similar misstatements.

62. Purdue trained sales representatives to minimize the risk of addiction to Purdue products when discussing opioids with doctors, but emphasize the risks of using competing products. For instance, Purdue sales representatives were instructed to tell doctors that opioids' addiction risk was "less than 1 percent."[45] [redacted] In addition, materials that Purdue produced, sponsored, or controlled omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would favor opioids over other therapies such as over-the-counter acetaminophen

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http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

[44] *Testimony by the American Pain Foundation: Senate Health, Education, Labor and Pensions Committee Hearing to Examine the Effects of the Painkiller OxyContin, Focusing on Risks and Benefits*, 2 (Feb. 12, 2002) (statement of John D. Giglio, Executive Director American Pain Foundation).

[45] U.S. Gov't Accountability Office, GAO-04-110, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem* 22 (Dec. 2003), https://www.govinfo.gov/content/pkg/GAOREPORTS-GAO-04-110/pdf/GAOREPORTS-GAO-04-110.pdf.

or nonsteroidal anti-inflammatory drugs (or NSAIDs, like ibuprofen), which do not pose a risk of addiction. None of these claims were corroborated by scientific evidence.

63. Purdue sponsored training sessions where doctors were given similar misleading information regarding the risks of opioid addiction. For example, Purdue sponsored training sessions in the late 1990s and early 2000s where opioid addiction was described as "exquisitely rare."[46]

64. All of these statements were contrary to scientific facts known to Respondents. The CDC has directly contradicted Purdue's representations that opioid addiction is rare when opioids are used properly. The CDC has stated that there is "extensive evidence" of the possible harms of opioids, including opioid use disorder and overdose, and stated that "[o]pioid pain medication use presents serious risks" including addiction; and highlighted that using opioids to treat chronic pain "substantially increases" the risk of addiction.[47] A 2016 CDC guideline discusses studies that found that as many as 26% of long-term users of opioids experience problems with addiction or dependence.[48]

65. Moreover, in August 2016, the U.S. Surgeon General published an open letter to physicians nationwide, worrying that "heavy marketing to doctors" had led many to be "taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[49] This letter also noted the "devastating" results that followed from this misinformation.[50]

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[46] Barry Meier, *Pain Killer: A "wonder" drug's trail of addiction and death* 190 (2003).

[47] Deborah Dowell, Tamara Haegerich, & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain –United States, 2016*, 65 Morbidity and Mortality Weekly Report 1 (2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

[48] *Id.*

[49] Letter from U.S. Surgeon General Vivek H. Murthy (Aug. 2016), https://perma.cc/VW95-CUYC.

[50] *Id.*

66. Findings by the Food and Drug Administration ("FDA") similarly belie Purdue's assertions that opioids are safe for treating chronic pain. These findings show that (1) "most opioid drugs have 'high potential for abuse'"; (2) treatment of chronic pain with opioids poses "known serious risks," including "addiction, abuse, and misuse ... overdose and death" even when used "at recommended doses"; and (3) opioids should be used only "in patients for whom alternative treatment options" have failed.[51] Additionally, several published clinical studies finding double-digit rates of prescription drug abuse in chronic pain patients controvert Purdue's claims that addiction rates are only one percent.[52]

67. As recently as June 2017, the New England Journal of Medicine published an analysis finding that Purdue's introduction of OxyContin into the marketplace coincided with a significant increase in misleading dissemination of the claim that addiction to opioids is rare. Moreover, the authors of the June 2017 analysis concluded that "[w]e believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy."[53]

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[51] Food and Drug Admin., Letter from Janet Woodcock, M.D., Dir. of Center for Drug Evaluation and Research, to Andrew Kolodny, M.D. Responding to Petition Submitted by Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), http://www.supportprop.org/wpcontent/uploads/2014/12/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf.

[52] Caleb J. Banta-Green et al., *Opioid Use Behaviors, Mental Health and Pain— Development of a Typology of Chronic Pain Patients*, 104 Drug and Alcohol Dependence 34 (Sept. 2009), http://dx.doi.org/10.1016/j.drugalcdep.2009.03.021; Joseph A. Boscarino et al., *Risk Factors for Drug Dependence Among Out-Patients on Opioid Therapy in a Large US Health-Care System*, 105 Addiction 1776 (Oct. 2010), http://dx.doi.org/10.1111/j.1360-0443.2010.03052.x; Jette Højsted et al., *Classification and Identification of Opioid Addiction in Chronic Pain Patients, 14 European J. of Pain 1014 (Nov. 2010), http://dx.doi.org/10.1016/j.ejpain.2010.04.006.*

[53] Pamela T. M. Leung et al., *A 1980 Letter on the Risk of Opioid Addiction*, 376 New England J. of Med. 2194 (June 1, 2017), http://www.dx.doi.org/10.1056/NEJMc1700150.

68. Additionally, Respondents pushed patients to stay on Purdue's opioids through the use of savings cards, or Purdue's Rx loyalty program. [redacted] Staff reported to the Sackler Respondents that Purdue had conducted a sensitivity analysis on the opioid savings cards to maximize their impact and, as a result, had increased the dollar value and set the program period to be *15 months* long. [redacted] Staff also reported that Purdue had created promotional materials to support these tactics and had distributed them to the sales force. [redacted]

D. Purdue falsely claimed that there was no risk in increasing opioid doses to treat chronic pain.

69. Purdue also falsely claimed that doctors and patients could increase opioid doses indefinitely without added risk. Guidelines edited and sponsored by Purdue and another opioid manufacturer, Endo[54]—titled "Treatment Options: A Guide for People Living with Pain" (2006) and "A Policymaker's Guide to Understanding Pain & Its Management" (2011)—claim that (a) some patients "need" a larger opioid dose, regardless of the dose prescribed; (b) opioids have "no ceiling dose" and are therefore the most appropriate

[54] Am. Pain Found., *Annual Report* (2010), https://www.documentcloud.org/documents/277604-apf-2010-annualreport.

treatment for severe pain; and (c) dosage escalations, even unlimited ones, are "sometimes necessary."[55]

70. As recently as June 2015, Purdue's "In the Face of Pain" website was encouraging patients to find another doctor if the patient's doctor refused to prescribe opioids in doses that were "sufficient" in the patient's opinion. Also in 2015, Purdue presented a paper at the College on the Problems of Drug Dependence, challenging the correlation between opioid dose and overdose.[56] And in 2016, Purdue's Dr. Haddox falsely claimed that evidence does not show that Purdue's opioids are being abused in large numbers.

71. Purdue made these statements despite strong contrary scientific evidence. The FDA has stated that the available data "suggest a relationship between increasing opioid dose and risk of certain adverse events."[57] The CDC has stated that there is "an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages," and

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[55] Am. Pain Found., *Treatment Options: A guide for people living with pain* (2006), https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf; Am. Pain Found., *A Policymaker's Guide to Understanding Pain & Its Management* (Oct. 2011), http://s3.documentcloud.org/documents/277603/apfpolicymakers-guide.pdf.

[56] A. DeVeaugh-Geiss et al., *Is Opioid Dose a Strong Predictor of the Risk of Opioid Overdose?: Important confounding factors that change the dose-overdose relationship*, CPDD 76th Annual Scientific Meeting Program (June 2014), http://cpdd.org/wp-content/uploads/2016/07/2014CPDDprogrambook.pdf.

[57] Food and Drug Admin., Letter from Janet Woodcock, M.D., Dir. of Center for Drug Evaluation and Research, to Andrew Kolodny, M.D. Responding to Petition Submitted by Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), http://www.supportprop.org/wpcontent/uploads/2014/12/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf.

has specifically recommended that doctors "avoid increasing doses" above 90 morphine milligram equivalents ("MME") per day.[58]

72. Nonetheless, Purdue misrepresented the effects of escalating doses to further its pursuit of profit. The ability to escalate doses was critical to Purdue's efforts to market opioids for chronic pain treatment because doctors would otherwise abandon treatment when patients built up tolerance and no longer obtained pain relief. For at least some products, escalation of dose was key—of the seven available OxyContin tablet strengths, the three strongest—40 milligrams (120 MME), 60 milligrams (180 MME), and 80 milligrams (240 MME)—all exceed the CDC limit by 2.5 to 5.3 times, even taken twice per day as directed.

E. Respondents misleadingly promoted OxyContin as supplying 12 hours of pain relief when they knew that, for many patients, it did not.

73. To convince prescribers and patients to use OxyContin, Respondents misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality, OxyContin does not last for 12 hours in many patients, a fact the Respondents have known since the product's launch. While OxyContin's FDA-approved label directs 12-hour dosing, the Respondents sought that dosing frequency in order to maintain a competitive advantage over other opioids that required more frequent dosing. Yet Respondents have gone well beyond the label's instructions to take OxyContin every 12

[58] Deborah Dowell, Tamara Haegerich, & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 Morbidity and Mortality Weekly Report 1 (2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

hours by affirmatively claiming that OxyContin lasts for 12 hours and by failing to disclose that OxyContin fails to provide 12 hours of pain relief to many patients.[59]

74. Since it was launched in 1996, OxyContin has been FDA-approved for twice-daily—"Q12"—dosing frequency. It was the Respondents' decision to submit OxyContin for approval with 12-hour dosing. While the OxyContin label indicates that "[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours," that is because Purdue has conducted no such studies.

75. From the outset, the Respondents leveraged 12-hour dosing to promote OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake to take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as providing "smooth and sustained pain control all day and all night." [redacted] But the FDA has never approved such marketing claims. To the contrary, the FDA found in 2008, in response to a Citizen Petition by the Connecticut Attorney General, that a "substantial number" of chronic pain patients taking OxyContin experienced "end of dose failure"—*i.e.*, little or no pain relief at the end of the dosing period.

76. In fact, the Respondents have long known, dating to the development of OxyContin, that the drug wears off well short of 12 hours in many patients. [redacted]

[59] [redacted]

[redacted]

77. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience distressing psychological and physical withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[60] Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

78. [redacted]

79. Without appropriate caveats, promotion of 12-hour dosing by itself is misleading because it implies that the pain relief supplied by each dose lasts 12 hours, which the Respondents knew to be untrue for many, if not most, patients. FDA approval of OxyContin for 12-hour dosing does not give the Respondents license to misrepresent the duration of pain relief it provides to patients; moreover, the Respondents had a responsibility to disclose to

[60] Harriet Ryan, "*'You Want a Description of Hell?' OxyContin's 12-Hour Problem*", Los Angeles Times, May 5, 2016, http://www.latimes.com/projects/oxycontin-part1/.

prescribers what they knew about OxyContin's actual duration, regardless of any marketing advantage.

80. [redacted]

81. Twelve-hour dosing also is featured in most OxyContin promotional pieces. The 2012 Conversion and Titration Guide, for example, contains the tag line: "Because each patient's treatment is personal / Individualize the dose / Q12 OxyContin Tablets." A 2013 brochure for prescribers titled "Identifying Appropriate Patients for OxyContin" similarly promotes the convenience of twice-daily dosing. Upon information and belief, these pieces were distributed in Utah, and neither piece discloses that the pain relief from each 12-hour dose will last well short of 12 hours for many patients.

82. Respondents were also aware of some physicians' practice of prescribing OxyContin more frequently than 12 hours—a common occurrence. Respondents' promoted solution to this problem was to increase the dose, rather than the frequency, of prescriptions, even though higher dosing carries its own risks. For example, Purdue's 2012 Conversion and Titration Guide advises prescribers to "[i]ncrease the OxyContin dose by increasing the total daily dose, not by changing the 12-hour dosing interval." This advice was not accompanied by appropriate disclosures regarding OxyContin's shorter-than-12-hour relief in many cases. Using higher doses also means that patients will experience higher highs and lower lows, increasing their craving for their next pill.

F. Respondents overstated opioids' effect on patients' function and quality of life.

83. Respondents also claimed—without evidence—[redacted] that long-term opioid use would help to improve patients' function and quality of life and get them back to work and to their lives.

84. This false message was longstanding and directed from the top. [redacted]

85. Purdue and Purdue-sponsored materials distributed or made available in Utah reinforced this message. The 2011 Purdue sponsored publication, "A Policymaker's Guide to Understanding Pain & Its Management" (2011),[61] falsely claimed that "multiple clinical studies have shown that opioids are effective in improving daily function and quality of life for chronic pain patients." A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with chronic pain conditions—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively.

86. Purdue sponsored the Federation of State Medical Board's ("FSMB's") *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." This publication claimed that

[61] Am. Pain Found., *A Policymaker's Guide to Understanding Pain & Its Management* (Oct. 2011), http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

because pain had a negative impact on a patient's ability to function, relieving pain—alone—would "reverse that effect and improve function." However, the truth is far more complicated; functional improvements made from increased pain relief can be offset by a number of problems, including addiction. Purdue spent over [redacted] to support distribution of the book, which, upon information and belief, was sent to physicians and other prescribers in Utah.

87. Likewise, Purdue's claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. There are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long-term. [redacted]

88. [redacted]

89. On the contrary, the available evidence indicates opioids may worsen patients' health and pain. Increasing the duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

90. As one pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[62] Studies of patients with lower back pain and migraine headaches, for example, have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures. Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, stemming from greater side effects and slower returns to work.

91. Assessing existing science, the CDC Guideline found that there was "[n]o evidence show[ing] a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later"[63] and advised that "there is no good evidence that opioids improve pain or function with long-term use."[64] Similarly, the FDA has warned other opioid product manufacturers that claims of improved function and quality of life were misleading.[65] The CDC also noted that the risks of addiction and death

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[62] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonomamedicine-are-we-making-pain-patients-worse?

[63] CDC Guideline at 15.

[64] *Id.* at 20.

[65] *See,* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza

"can cause distress and inability to fulfill major role obligations."[66] In that vein, a recent study by Princeton economist Alan Krueger found that opioids may be responsible for roughly 20% of the decline in workforce participation among prime-age men and 25% of the drop for women.[67] The CDC Guideline concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[68] According to Dr. Tom Frieden, then Director of the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[69]

92. As one doctor noted, the widespread, long-term use of opioids "was an experiment on the population of the United States. It wasn't randomized, it wasn't controlled, and no data was collected until they started gathering death statistics."

G. Purdue's misleading statements were designed for maximum effect and targeted to specific audiences.

93. Purdue disseminated these misstatements to doctors through a wide array of sources, each designed to maximize impact and each targeted to a specific receptive audience.

(morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). These warning letters were available to Purdue on the FDA website.

[66] CDC Guideline at 2.

[67] Alan B. Krueger, *Where Have All the Workers Gone? An Inquiry into the Decline of the U.S. Labor Force Participation Rate*, Brookings Papers on Economic Activity Conference Draft (Aug. 26, 2017).

[68] CDC Guideline at 18.

[69] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" (Apr. 21, 2016).

94. Purdue often delivered its misstatements through "key opinion leaders," doctors in the field of pain management who were heavily funded by Purdue. Purdue frequently used opinion leaders to deliver its message because it knew that doctors often place great confidence in seemingly independent peers. At least two of Purdue's key opinion leaders live and work in Utah—Dr. Lynn Webster and Dr. Perry Fine, who served on the board of the American Pain Foundation, discussed above.

95. Dr. Lynn Webster, who works in Salt Lake City, received Purdue funding to develop and teach an online program titled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This presentation deceptively instructed that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths." The program currently is available online to Utah prescribers.[70] Upon information and belief, it has been available online for approximately six years and it has been viewed by additional Utah prescribers since it was first broadcast in September 2011.

96. Another notable opinion leader was Dr. Russell Portenoy, who held himself out as an unbiased expert on opioids but received substantial funding from Purdue. Dr. Portenoy gave, in his words, "innumerable" lectures and media appearances promoting opioids.[71] He also regularly repeated—including in a 1986 paper published in the journal of the American Pain Society, a 1996 paper written on behalf of the American Pain Society and

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[70] Emerging Solutions in Pain, "Managing Patient's Opioid Use: Balancing the Need and the Risk," http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Nov. 30, 2017).

[71] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal, Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

the American Academy of Pain, and numerous lectures—the unsubstantiated claim that the addiction risk posed by opioids was lower than one percent.[72] Dr. Portenoy later conceded that some of his statements were misleading. In December 2012, he was quoted as saying, "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, ... I guess I did."[73]

97. Between 2001 and 2010, Purdue's "In the Face of Pain" website similarly presented the statements of opinion leaders who were portrayed as independent experts. The website not only failed to disclose that Purdue had paid many of these opinion leaders for other work, but also did not identify Purdue's involvement beyond a small copyright notice at the bottom of the website.[74]

98. Purdue also often disseminated its misstatements through industry groups that presented themselves to the public as independent patient advocacy organizations, but whose content and funding came largely from Purdue. These groups included the American Pain Foundation, the American Pain Society, and the American Academy of Pain Medicine. Much like the opinion leaders, these industry groups allowed Purdue to present its misstatements as if they came from unbiased experts.

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[72] Russell Portenoy, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25 Pain 171 (May 1986), https://www.ncbi.nlm.nih.gov/pubmed/2873550; Russell Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: A review of the critical issues*, 11 J. of Pain and Symptom Mgmt. 203 (Apr. 1996), http://dx.doi.org/10.1016/0885-3924(95)00187-5; Russell Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain*, 1 Pain Research and Mgmt. 17 (1996), http://downloads.hindawi.com/journals/prm/1996/409012.pdf.

[73] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal, Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

[74] Advocacy Voices, In the Face of Pain (archived Nov. 7, 2010), https://web.archive.org/web/20101107090355/http://www.inthefaceofpain.com:80/search.aspx?cat=4#7.

99. These groups published many of the misleading "guidelines" described above, based on content and funding provided by Purdue, including: (1) "Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain" (2009);[75] (2) "A Policymaker's Guide to Understanding Pain & Its Management" (2011);[76]and (3) "Treatment Options: A Guide for People Living with Pain" (2006).[77] In 2007, the American Pain Society repeated, at a Senate Judiciary Committee hearing, Purdue's misstatements that addiction was a "rare problem" for patients using opioids for chronic pain and that there was "no causal effect ... between the marketing of [a particular opioid] and the abuse and diversion of the drug."[78]

100. Purdue also conducted conferences, training sessions, and educational programs for doctors, often with all expenses paid at resort destinations. These events were useful to Purdue because studies show that such events influence the attending practitioners' prescribing habits and views towards a drug.[79]

101. From 1996 to 2001, Purdue conducted more than 40 pain management and speaker training sessions at resorts to recruit and train physicians, nurses, and pharmacists as speakers on

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[75] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10 The J. of Pain 113 (Feb. 2009), http://dx.doi.org/10.1016/j.jpain.2008.10.008.

[76] Am. Pain Found., *A Policymaker's Guide to Understanding Pain & Its Management* (Oct. 2011), http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

[77] Am. Pain Found., *Treatment Options: A guide for people living with pain* (2006), https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

[78] *Evaluating the Propriety and Adequacy of the OxyContin Criminal Settlement: Hearing Before the S. Comm. On Judiciary*, 110th Cong. 1 (2007) (Statement of James Campbell, M.D.).

[79] Ray Moynihan, *Doctors' Education: The invisible influence of drug company sponsorship*, 336 The BMJ 416 (Feb. 23, 2008), http://dx.doi.org/10.1136/bmj.39496.430336.DB; A.C. Anand, *Professional Conferences, Unprofessional Conduct*, 67 Medical J. Armed Forces India 2 (Jan. 2011), http://dx.doi.org/10.1016/S0377-1237(11)80002-X; David McFadden et al., *The Devil Is in the Details: The pharmaceutical industry's use of gifts to physicians as marketing strategy*, 140 J. of Surgical Research 1 (2007), http://dx.doi.org/10.1016/j.jss.2006.10.010.

behalf of Purdue.[80] Purdue trained more than 5,000 people at these all-expenses-paid events.[81] In addition, the DEA has estimated that Purdue funded over 20,000 opioid pain-related educational programs between 1996 and July 2002 through direct sponsorship or financial grants.[82]

102. Purdue also used direct sales representatives to market opioids. These representatives received a large amount of their compensation in bonuses based on their individual sales figures, ensuring that they were strongly motivated to present their audiences with misleading information minimizing the risks of opioids.[83]

103. The FDA does not regulate all of the conduct in which the Respondents engaged. For example, drug labels do not address the use of opioids in treating specific conditions such as lower back pain, headaches, or fibromyalgia, three conditions for which opioids are ineffective, but for which Purdue marketed their drugs. The FDA also does not regulate unbranded advertising. Likewise, the FDA does not regulate the marketing messages or scripts relied on by sales representatives or marketing funneled through third-parties, such as the industry groups discussed above.

104. Purdue not only issued misstatements through channels thought to be the most productive, but also targeted marketing to doctors who would be most receptive to the misstatements. Purdue specifically targeted its marketing to primary care physicians, who are generally

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[80] U.S. Gov't Accountability Office, *Prescription Drugs: OxyContin abuse and diversion and efforts to address the problem* 22 (Dec. 2003), https://www.gpo.gov/fdsys/pkg/GAOREPORTS-GAO-04-110/content-detail.html.

[81] *Id.*

[82] *Id.* at 23.

[83] *Id.* at 22.

less aware of the medical literature regarding the dangers of treating chronic pain with opioids. Dr. Portenoy, speaking to an FDA advisory panel on January 30, 2002, acknowledged this fact, stating that "[g]eneralists are adopting [opioid] therapy without adequate knowledge of pain management principles."[84] On information and belief, Purdue also directly targeted susceptible patients like veterans and the elderly.

105. Purdue developed methods to specifically target physicians who were already prescribing higher-than-average numbers of opioids. Purdue purchased data from companies such as IMS Health, which provided information regarding the prescribing patterns of physicians nationwide. Through this data, Purdue could identify those prescribers who were already prescribing high amounts of opioid-containing products and target those same doctors for Purdue opioids. Purdue created a database to identify physicians with large numbers of chronic-pain patients (which also showed which physicians were simply the most frequent prescribers of opioids). This database has given Purdue extensive knowledge of where and how its drugs are being used across the country, including in Utah, and has allowed Purdue to target doctors already susceptible to its message.[85]

II. Purdue is misrepresenting its actions with regard to the opioid epidemic.

106. Purdue has also misrepresented to the public that it is taking steps to curb the opioid epidemic, rather than creating it. As recently as November 2017, Purdue stated on its website that "...too often these medications [opioids] are diverted, misused, and abused.

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[84] Food and Drug Admin., Anesthetic and Life Support Drugs Advisory Comm., Tr. of Meeting 119 (Jan. 30, 2002), http://wayback.archiveit.org/7993/20170404083838/; https://www.fda.gov/ohrms/dockets/ac/02/transcripts/3820t1.pdf.

[85] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial triumph, public health tragedy*, 99 Am. J. of Public Health 221, 222 (Feb. 2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/pdf/221.pdf.

Teenagers, in particular, are vulnerable to prescription drug abuse, which has become a national epidemic."[86] In response to the misuse of opioids, Purdue said that "Corporations have a responsibility to address this issue, and Purdue has dedicated vast resources for helping to prevent drug abuse..."[87]

107. Purdue also stated in November 2017 that it is "committed to being part of the solution to prescription drug abuse" and that it "offers an array of programs focused on education, prevention, and deterrence and through partnerships with (1) healthcare professionals, (2) families and communities, and law enforcement and government" to combat the "widespread abuse of opioid prescription pain medications [that] can lead to tragic consequences, including addiction, overdose, and death."[88]

108. Also in November 2017, Purdue discussed the opioid epidemic and its response to it, stating that "The nation is experiencing a public health crisis involving licit and illicit opioids. Purdue endorses the following policies that support a comprehensive approach to reducing addiction, abuse, diversion, and overdose related to opioids."[89] The policies employed by Purdue include limiting the duration of a patient's first opioid prescription; use of prescription drug monitoring programs; requiring demonstrated competence for

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[86] Purdue Pharma, *Combating Opioid Abuse*, http://webcache.googleusercontent.com/search?q=cache:yQnPlZfguWAJ:www.purduepharma.com/healthcareprofessionals/responsible-use-of-opioids/combating-opioid-abuse/+&cd=1&hl=en&ct=clnk&gl=us.

[87] *Id.*

[88] *Id.*

[89] Purdue Pharma, *Public Policies to Address the Opioid Crisis*, http://www.purduepharma.com/about/purduepharma-public-policy/.

opioid prescribing; and expanding the use of naloxone, an opioid reversal agent, among other things.[90]

109. However, on information and belief, these representations are untrue. For example, notwithstanding its public statements of corporate responsibility, Purdue has failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse" and "strong record of coordination with law enforcement."[91]

110. Additionally, since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. According to Purdue, physicians could be added to this database based on observed indicators of illicit prescribing, such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing volume. Purdue has said publicly that "[o]ur procedures help ensure that whenever we observe potential abuse or diversion activity, we discontinue our company's interaction with the prescriber or pharmacist and initiate an investigation."[92]

111. Yet, according to a 2016 investigation by the *Los Angeles Times*, Purdue failed to cut off these providers' opioid supply at the pharmacy level and failed to report these providers to

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[90] *Id.*

[91] Purdue Pharma L.P., *Setting the Record Straight on OxyContin's FDA-Approved Label* (May 5, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approvedlabel/; Purdue Pharma L.P., *Setting the Record Straight on Our Anti-Diversion Programs* (July 11, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversionprograms/.

[92] *Id.*

state medical boards or law enforcement — meaning Purdue continued to generate sales revenue from their prescriptions.[93]

112. The *Times'* investigation also found that "for more than a decade, Purdue collected extensive evidence suggesting illegal trafficking of OxyContin" and yet consistently failed to report suspicious dispensing or to stop supplies to the pharmacy.[94] Despite its knowledge of illicit prescribing, Purdue did not report its suspicions, for example, until years after law enforcement shut down a Los Angeles clinic that Purdue's district manager described internally as "an organized drug ring" and that had prescribed more than 1.1 million OxyContin tablets.[95]

III. Purdue knowingly and intentionally misled Utah prescribers and consumers.

113. The problems engendered by the deceptive and unfair marketing of opioids were specifically known by Purdue. Purdue was aware that its statements were misleading not only because it knew these statements were contrary to established fact, but also because it was fined and otherwise sanctioned by various government entities for its misleading marketing, and yet continued to disseminate the same marketing messages.

114. In 2007, Purdue settled federal allegations that it had introduced misbranded drugs into interstate commerce. The settlement included over $700 million in payments to the United

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[93] *See* Harriet Ryan et al., *More Than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times, July 10, 2016, http://www.latimes.com/projects/la-me-oxycontin-part2/.

[94] *Id.*

[95] *Id.*

States and guilty pleas by three of Purdue's executive officers.[96] Purdue acknowledged that "some employees made, or told other employees to make, certain statements about OxyContin to some healthcare professionals that were inconsistent with the FDA-approved prescribing information for OxyContin and the express warning it contained about risks associated with the medicine."[97]

115. On August 20, 2015, New York State concluded a multiyear investigation of Purdue and settled claims against the company related to its marketing and sales practices. Specifically, the agreement required Purdue to ensure that its sales representatives flag doctors and other professionals who were improperly prescribing and/or diverting opioids, stop calling and/or marketing to doctors on the company's "no-call list," and provide information to health care providers about FDA-approved training programs regarding the appropriate prescription of opioids. The agreement also required Purdue to cease marketing representations on its website "www.inthefaceofpain.com" implying that the website was neutral or unbiased, and to disclose the financial relationships Purdue's purported neutral experts have with the company.[98]

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[96] *Id.*; Plea Agreement at 4, *United States of America v. The Purdue Frederick Co., Inc.*, Case No. 1:07-cr-00029-JPJ(W.D. Va. May 10, 2017), http://i.bnet.com/blogs/purdue-agreed-facts.pdf.

[97] Shannon Henson, *Purdue, Employees to Pay $700M in OxyContin Case*, LAW360, (May 10, 2007, 12:00 AM), https://www.law360.com/illinois/articles/24509/purdue-employees-to-pay-700m-in-oxycontin-case.

[98] Press Release, N.Y. State Office of the Attorney General, A.G. Schneiderman Announces Settlement With Purdue Pharma That Ensures Responsible And Transparent Marketing Of Prescription Opioid Drugs By The Manufacturer (August 20, 2015), https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensuresresponsible-and-transparent.

116. In August 2017, Purdue settled, for over $20 million, claims by numerous Canadian plaintiffs that the company failed to warn about the dangers of OxyContin, including its addictive properties.[99]

117. Respondents knew that their continuing efforts to employ deceptive and unfair marketing, despite Purdue being previously sanctioned by government agencies for such actions, would contribute to the opioid epidemic in Utah, and would create access to opioids by at-risk and unauthorized users, which, in turn, would perpetuate the cycle of abuse, addiction, demand, and illegal transactions.

118. [redacted]

119. Furthermore, Purdue knew that when more patients gained access to opioids based on deceptive and false marketing, tragic, preventable injuries would result, including addiction, abuse, overdoses, and death. It was reasonably foreseeable that many of these injuries would be suffered by Utah citizens, and that the costs of these injuries would be shouldered by the State and state agencies.

120. It was foreseeable that the increased number of prescriptions for opioids resulting from Purdue's deceptive and unfair marketing would cause harm to the citizens and government

[99] Will Davidson LLP, *Purdue Pharma Agrees to OxyContin Settlement, but Is it Fair?*, Lexology (Aug. 22, 2017), https://www.lexology.com/library/detail.aspx?g=d53ee1ee-44cb-4ef5-b916-e570a385b568.

of Utah. [redacted]

121. Purdue made substantial profits over the years based on the intentionally deceptive and unfair marketing of opioids in Utah.

122. Purdue's deceptive and unfair marketing of prescription opioids to Utah citizens showed a reckless disregard for the safety of Utah and its citizens. Its conduct poses a continuing threat to the health, safety, and welfare of Utah and its citizens.

123. Purdue's misleading marketing and failure to prevent opioid diversion in and around Utah has contributed to a range of social problems, including violence and delinquency, that were foreseeable to Respondents. These foreseeable adverse social outcomes include child neglect, family dysfunction, babies born addicted to opioids, criminal behavior, poverty, property damage, unemployment, and social despair. As a result, more and more of Utah's resources and those of its counties and municipalities are devoted to addiction-related problems. Meanwhile, the prescription opioid crisis diminishes Utah's available workforce, decreases productivity, increases poverty, and consequently requires greater State and local expenditures.

124. Prescription opioid abuse costs the State approximately $238 million in healthcare costs, not to mention additional social services and education expenses.[100] And, it adds an estimated $169 per capita in costs to Utah's healthcare system, loss in productivity, and criminal justice costs. Mortality costs brings the total to approximately $1,827 per Utahn.

IV. The Sackler Respondents are personally responsible.

125. Respondent Richard Sackler and Respondent Kathe Sackler each personally directed the unfair, deceptive and otherwise unlawful conduct alleged herein. Their actions were taken as members of the Purdue Board of Directors as well as individually as Purdue executive officers and owners of, as the company describes it, "the global Sackler pharmaceutical enterprise."

A. The Sackler Respondents' actions as members of the board

126. Purdue's Board of Directors is very hands-on, described in the company's own planning documents as "the 'de-facto' CEO." [redacted]

[100] Matric Global Advisors, *Health Care Costs from Opioid Abuse: A state-by-state analysis*, 5 (2015), http://drugfree.org/wp-content/uploads/2015/04/Matrix_OpioidAbuse_040415.pdf (prescription opioid abuse costs the citizens and State of Utah approximately $238 million in healthcare costs each year); Kohei Hasegawa et al., *Epidemiology of Emergency Department Visits for Opioid Overdose: A population-based study*, 89 Mayo Clinic Proceedings 462, 465, 467 (2014) (there are about two times as many opioid overdoses in Emergency Departments among publicly-insured individuals than among individuals with private insurance and publicly-insured individuals are approximately twice as likely to have a second visit to the Emergency Departments for opioid overdose as are privately-insured individuals); The Nat'l Ctr. on Addiction and Substance Abuse, *Shoveling Up II: The impact of substance abuse on federal, state, and local budgets*, 27 (May 2009), http://www.centeronaddiction.org/addictionresearch/reports/shoveling-ii-impact-substance-abuse-federal-state-and-local-budgets (State governments spend 27%of the amount they spend on healthcare to fund the social services related to substance abuse.); The Nat'l Ctr. On Addiction and Substance Abuse, *Shoveling Up II: The impact of substance abuse on federal, state, and local budgets*, 27 (May 2009), http://www.centeronaddiction.org/addiction-research/reports/shoveling-ii-impactsubstance-abuse-federal-state-and-local-budgets (State governments spend 77% of the amount they spend on healthcare on the K–12 education expenses associated with substance abuse.).

[redacted]

127. [redacted]

[redacted]

129. The Sackler Respondents were both longstanding members of Purdue's Board of Directors. As such, they were informed of and approved the decisions related to Purdue's marketing and compliance operations that were at the core of Purdue's business. However, as laid out below, Richard and Kathe Sackler exercised a level of involvement and control, particularly in the unlawful conduct described in this Citation, that surpassed even that of other Sackler Board member-owners. In addition, as also detailed below, each of the Sackler Respondents served for many years as executive officers of Purdue, taking many actions personally to carry out the unfair, deceptive and otherwise unlawful activity that led to Utah's opioid epidemic.

B. Richard Sackler

130. [redacted] "You won't believe how committed I am to make OxyContin a huge success. It is almost that I dedicated my life to it."

131. Accordingly, Respondent Richard Sackler personally oversaw, directed, made and approved many of the key decisions regarding Purdue's opioids and he is legally responsible for their outcomes in Utah. [redacted]

[redacted]

132. Respondent Richard Sackler spent 43 years at Purdue in his various capacities, including the head of marketing, President, Co-Chairman of the Board, and board member. Upon information and belief, as head of Purdue's marketing department and then President and Co-Chairman of Purdue's Board, with a demonstrated interest and involvement in Purdue's sales efforts and promotional messaging, Respondent Richard Sackler would have been aware of and approved all of Purdue's marketing themes and strategies.

133. Respondent Richard Sackler has been characterized in the press as having an appetite for micromanagement. [redacted] Throughout his tenure, Respondent Richard Sackler either had knowledge of Purdue's marketing misrepresentations, or was recklessly indifferent to their truth or falsity, [redacted]

[redacted]

101 [redacted]

[redacted]

134. This detailed involvement began even more than a year before Purdue launched OxyContin. [redacted] Upon information and belief, Defendant Richard Sackler and his team at Purdue decided not to disclose the study to the FDA.

135. [redacted] Richard Sackler, then head of Purdue's sales operations, launched the marketing of OxyContin with a speech [redacted] He spoke—perhaps prophetically—about the launch unleashing a "blizzard of prescriptions that will bury the competition."

136. [redacted]

137. Thereafter, Richard Sackler became involved—deeply—in every aspect of Purdue's marketing operations. [redacted]

[redacted]

138. For example, Richard Sackler, in particular, directed that Purdue intentionally promote OxyContin as a "weaker" opioid, without the stigma associated with other opioids, despite knowing the fact that OxyContin is twice as potent (and dangerous) as [redacted] morphine [redacted][102] In May 1997, an internal email from Michael Friedman, Purdue's Executive Vice President and Chief Operating Officer, revealed that Richard Sackler and Purdue were aware that doctors believed, incorrectly, that oxycodone was less powerful than morphine, [redacted] Mr. Friedman warned that "it would be extremely dangerous at this early stage in the life of the product [redacted] to make physicians think the drug is stronger or equal to morphine." In other words, it would hurt profits to tell the truth. Respondent Richard Sackler replied: "I agree with you. Is there general agreement, or are there some holdouts?" Respondents moved forward with their fraudulent acts and omissions designed to deceive.

139. Consistent with this initiative [redacted] The email states: "Since oxycodone is perceived as being a 'weaker' opioid than morphine, it has resulted in OxyContin being used much earlier for non-cancer pain." "[I]t is important that we allow this product to be

[redacted]

102 [redacted]

positioned where it currently is in the physician's mind." "It is important that we be careful not to change the perception of physicians toward oxycodone when developing promotional pieces, symposia, review articles, studies, etc." [redacted]

140. [redacted]

141. [redacted]

[redacted]

The Purdue official pleaded: "Anything you can do to reduce the direct contact of Richard into the organization is appreciated. [redacted]

144. Richard Sackler kept a particularly close eye on Purdue's sales numbers. In March 2008, for example, he directed staff to provide him with thousands of pieces of data about sales trends. Staff delivered the data early Sunday morning and Richard responded with detailed instructions for new data that he wanted that same day. An employee sent Richard the additional data only a few hours later. Richard responded by calling him at home, insisting that the sales forecast was too low, and threatening that he would have the Board reject it. On Monday [redacted] staff emailed among themselves to prepare for meeting with Richard, highlighting that Richard was looking for results that could only be achieved by hiring more sales representatives.

145. In August 2009, Richard Sackler convened a meeting of Board members and staff about "all the efforts Sales and Marketing is doing and planning to do to reverse the decline in OxyContin tablets market." He emphasized that $200 million in profit was at stake.

146. [redacted]

149. [redacted] Richard Sackler's solution was not to take responsibility and limit or correct Purdue's marketing, but to blame the victim. He wrote, confidentially, "we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are the reckless criminals."

150. In January of 2018, however, Respondent Richard Sackler received a patent for "a method of medication-assisted treatment for opioid addiction."[103] In Respondent Richard Sackler, it seems that a change in the bottom line may have inspired a change of heart.

[103] U.S. Patent No. 9,861,628

C. Kathe Sackler

151. Respondent Kathe Sackler is a current board member of Purdue, and has been a member of the board of directors of Purdue since the 1990s. She also spent a number of years as Purdue's Senior Vice President. Upon information and belief, she held the position of Senior Vice President from at least 2004-2014.

152. Respondent Kathe Sackler was also personally involved in Purdue's operations from the early days of planning the launch of OxyContin. [redacted]

[redacted]

For example, a November 2009 Budget Presentation notes that "Dr. Richard and Dr. Kathy [sic] asked for:

> [redacted]
>
> identify specific programs that Sales and Marketing will implement to profitably grow the OER market and OxyContin in light of competition.

provide analytics around why/how the proposed increase in share-of-voice translates into sales and profitability growth.

provide a copy of the OxyContin McKinsey report [104] on possible ways to increase OxyContin sales [redacted]."

157. In September 2014, Respondent Kathe Sackler was directly involved in a Purdue business development initiative dubbed "Project Tango," which explored a method by which Purdue could make profits not only from selling opioids, but also from treating resulting opioid addiction. [redacted] Purdue identified stigmas and misperceptions regarding opioid abuse—stigmas and misperceptions Purdue had deliberately cultivated—as an impediment to success. Even so, Purdue recognized the enormous potential: "Opioid addiction (other than heroin) has grown by ~20% CAGR [compound annual growth rate] from 2000 to 2010."

158. The following graphic from a Purdue presentation on Project Tango visually demonstrates Purdue's *internal* acknowledgment of the link between pain treatment and opioid addiction treatment. Thus, entry into the opioid addiction treatment market was merely "an opportunity to expand [Purdue's] offering as an end-to-end pain provider."

104 [redacted]

159. In 2001, Purdue was guided by Richard Sackler's strategy to "hammer on the abusers in every way possible" as "[t]hey are the culprits and the problem. They are reckless criminals." By 2014, Purdue had changed its strategy and its message, now stating: "[Addiction] can happen to anyone – from a 50 year old woman with chronic lower back pain to a 18 year old boy with a sports injury, from the very wealthy to the very poor."

160. [redacted] But Richard Sackler and Purdue did not give up on this new strategy. [redacted], Richard invented one, obtaining the patent for an addiction treatment drug that he then transferred to Purdue. In true form, the Sackler Respondents and Purdue are thus poised to further profit from the crisis they created.

RESPONDENTS' CONDUCT VIOLATED THE CONSUMER SALES PRACTICES ACT

161. At the Sackler Respondents' direction, Purdue has continued to promote, directly and indirectly, deceptive marketing messages that misrepresent, and fail to include material facts about, the dangers of opioid usage in Utah, despite knowing that these marketing messages are false, in order to increase their sales, revenue, and compensation.

COUNT I

162. The Division realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

163. The CSPA prohibits, in connection with a consumer transaction, deceptive consumer sales practices that mislead consumers about the nature of the product they are receiving. Utah Code § 13-11-1, *et seq*. This Count is brought in the public interest under the CSPA, Utah Code § 13-11-4(1).

164. As is described herein, Respondents mislead consumers about the nature of their products by disseminating marketing material and messages that overstated the benefits of opioids and understated their risks, and by omitting or concealing material facts.

COUNT II

165. The Division realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

166. In marketing and selling prescription opioids, Respondents have knowingly or intentionally and persistently committed deceptive acts or practices, in violation of the CSPA. Utah Code § 13-11-1, *et seq*.

167. Respondents violated the CSPA by knowingly or intentionally, and fraudulently indicating that opioids had sponsorship, approval, performance characteristics, uses, or benefits, when they did not, in violation of Utah Code § 13-11-4(2)(a).

168. Respondents violated the CSPA by knowingly or intentionally, and fraudulently omitting or concealing material facts and failing to correct prior misrepresentations and omissions about the risks and benefits of opioids. Respondents' omissions rendered even their seemingly truthful statements about opioids deceptive.

169. Respondents violated the CSPA by knowingly or intentionally, and fraudulently indicating that opioids were of a particular standard, quality, grade, style, or model, when they were not, in violation of Utah Code § 13-11-4(2)(b).

170. Respondents violated the CSPA by knowingly or intentionally, and fraudulently indicating that opioids had been supplied in accordance with Purdue's previous representations, when they had not, in violation of Utah Code § 13-11-4(2)(e).

COUNT III

171. The Division realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

172. Respondents have knowingly or intentionally, and fraudulently marketed drugs through misstatements and omissions of facts regarding the safety and efficacy of their drugs, and they have failed adequately to guard against misstatements and omissions concerning opioids made by their employees and agents. Respondents knew or had reason to know

that their misstatements, omissions, and failure to guard against misstatements and omissions made by their employees and agents would harm Utah's citizens.

173. By manufacturing and marketing opioids in the manner described above, or by directing others to do so, Respondents have also committed unconscionable acts or practices in violation of Utah Code § 13-11-5. Specifically, Respondents have violated their statutory duties to Utah and Utah citizens to report suspicious prescribers in Utah communities that were known to Respondents, have misused their position of trust in the community, and have preyed on Utah's most vulnerable residents for profit.

174. For purposes of penalty calculations, each instance where Respondents have misrepresented a material fact or suppressed, concealed, or omitted any material fact regarding the prescription opioids they manufactured or marketed constitutes a separate violation of the CSPA. The Division intends to calculate the administrative fines after the liability portion of the case has concluded.

THIS CITATION ISSUED this ____ day of January, 2019.

_____

UTAH DIVISION OF CONSUMER PROTECTION

CERTIFICATE OF SERVICE

I certify that I have this day served the foregoing document on the parties of record in this proceeding set forth below by mailing a copy thereof, properly addressed by certified mail, with postage prepaid, to:

With courtesy copies via email to:

Dated this ___ day of January, 2019.

_____

UTAH DIVISION OF CONSUMER PROTECTION

NOTICE
IMPORTANT - READ CAREFULLY

This citation may be contested by filing a request for review, in writing, within twenty (20) days of receipt of this citation. Following receipt of a request for review, an informal hearing will be scheduled before the State of Utah, Department of Commerce, Division of Consumer Protection pursuant to Utah Code § 63G-4-203, Procedures for Informal Adjudicative Proceedings. The purpose for the hearing is a review of the citation for factual and legal sufficiency and other questions to be determined by the presiding officer.

A citation that is not contested becomes the final default order of the Division. A defaulted party may make a motion to the presiding officer to set aside a default. Utah Code § 63G-4-209(3). The defaulted party may seek agency review pursuant to Utah Code § 63G-4-301, or reconsideration pursuant to Utah Code § 63G-4-302, only of the presiding officer's decision on the motion to set aside the default. *See* Utah Code § 63G-4-209(3)(c).

In addition to any fines that may be levied, a cease and desist order may be entered against you. An intentional violation of a final cease and desist order is a third degree felony. Utah Code § 13-2-6(2).

To request a review of the citation, mail your written request to:

Daniel R. S. O'Bannon – Director
Utah Division of Consumer Protection
PO Box 146704
Salt Lake City, UT 84114-6704

The presiding officer designated by the Director of the Division of Consumer Protection to conduct the hearing in your case is:

Bruce Dibb, Administrative Law Judge
Heber M. Wells Bldg., 2nd Floor
160 East 300 South
Salt Lake City, UT 84114
Telephone: (801) 531-6706

Please be advised that all inquiries, correspondence, or other contacts concerning this citation, with the exception of any written request for review as set out above, should be directed to the following, counsel for The Division of Consumer Protection:

Robert Wing or Kevin McLean
Assistant Attorneys General
Utah Attorney General's Office
160 East 300 South, 5th Floor
PO Box 140872
Salt Lake City, UT 84114-0872
Telephone: (801) 366-0310

FREQUENTLY ASKED QUESTIONS

1. **How can I talk to someone at the Division about this citation?** The name of the investigator assigned to your case appears at the end of your citation. If you call the Division, 801-530-6601 and press 0, the receptionist can help transfer you to the assigned investigator.
2. **Can I resolve the citation without a hearing?** Contact the investigator assigned to your case if you are interested in a settlement to see if a settlement is possible in your case.
3. **How do I respond to the citation?** You may challenge the citation by submitting a written Request for Review using the attached form or using your own form.
4. **How long do I have to respond to the citation?** You have 20 calendar days from issuance of the citation to submit a Request for Review.
5. **What happens after I submit a Request for Review?** The presiding officer will send you a Notice of Administrative Hearing specifying a time, date, and location of a hearing before the Division.
6. **Who will preside over the case?** The name of the presiding officer for the hearing will be on your Notice of Administrative Hearing. Please address the presiding officer by name (e.g., "Judge Smith"). You may contact the presiding officer with any technical or procedural questions, but the presiding officer may not discuss the merits of the case with you.
7. **What if I have a scheduling conflict with the scheduled hearing time?** Failure to attend a hearing may result in a default and entry of judgment against you. You may ask the presiding officer assigned to your case, in writing, to reschedule the hearing if you have a conflict or require more time to prepare. A request for additional time is within the discretion of the presiding officer and may not be granted, particularly if requested only shortly before the scheduled hearing.
8. **What should I expect at a hearing?** An administrative law judge will act as the presiding officer and direct the proceeding. The hearing room has two tables for the parties, with the presiding officer sitting at the front of the hearing room. Generally you (and your counsel, if applicable) will sit at one of the tables and Division staff will sit at the other table. Beginning with the Division, both sides will have an opportunity to present witnesses, evidence, and argument in support of why the citation should or should not stand.
9. **What kind of evidence can I present?** All parties may testify, present evidence, and comment on the issues. In presenting evidence, any party may examine witnesses and submit exhibits. At the request of either party, or at his or her own initiative, the presiding officer may also choose to examine a witness. Any party may ask to present a witness by telephone. The presiding officer may exclude any evidence he or she deems irrelevant, immaterial, or unduly repetitious or improper.
10. **How can I determine what evidence the Division has?** Discovery is prohibited in informal hearings, but parties may request information contained in the agency's files to the extent permitted by law. You may contact the assigned investigator to request access to this information.
11. **What is the burden of proof for the Division at a hearing?** Generally the Division is responsible to prove its case against you by substantial evidence.
12. **Must I have an attorney?** You may represent yourself or be represented through an attorney. You may also represent a business that you own or manage.

You should not rely on this letter alone for instructions regarding hearings. The hearing is governed by law (including the Administrative Procedures Act, *see* Utah Code § 63G-4 *et al.*, Utah Division of Consumer Protection, *see* Utah Code § 13-2 *et al.*, and Department of Commerce Administrative Procedures Act Rules, *see* Utah Admin. Code R151-4.) You may access these laws and rules at le.utah.gov and rules.utah.gov.

DIVISION OF CONSUMER PROTECTION
Heber M. Wells Building
160 East 300 South
PO Box 146704
Salt Lake City, UT 84114-6741
Telephone: (801) 530-6601
Fax: (801) 530-6001

REQUEST FOR REVIEW

DCP Legal File No.		Date of Citation:
Name:		Phone: ( )
Address:		
City:	State:	Zip:
Email:		

Requests for review must be received by the division within 20 calendar days of issuance of the citation. Utah Code § 13-2-6(3). If you fail to make a timely request, the citation shall become the final order of the division. If you represent multiple respondents, please submit a separate request for each respondent.

You may wish to consult an attorney before submitting this form and any attachments.

Select only one of the following:

☐	I admit to the statutory violation(s) described in the citation. The presiding officer will enter an order, assess a fine, and issue a cease and desist order.
☐	I admit to the statutory violation(s) described in the citation, but request a hearing to explain the circumstances of the violation(s) and request a reduced fine. *(If desired, attach a brief typewritten explanation of the circumstances of the violations. The presiding officer may ask you to submit an additional response.)*
☐	I contest the occurrence of the violation(s) described in the citation and request a hearing to contest the citation. *(If desired, attach a brief typewritten response to the allegations in the citation. The presiding officer may ask you to submit an additional response.)*

I certify that I have knowingly and voluntarily made the above election of rights. I understand that if I request a hearing the presiding officer will notify me in writing of the hearing date. If I fail to appear at the hearing, a default judgment may be entered against me. I acknowledge that I have either sought the advice of an attorney or have voluntarily chosen not to do so.

Signature	Date of Signature

NOTICE OF AGENCY ACTION

Robert G. Wing (4445)
Kevin M. McLean (16101)
Assistant Attorneys General
SEAN D. REYES (7969)
Utah Attorney General
Utah Attorney General's Office
160 East 300 South, 5th Floor
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401 9th St. NW, Suite 1001
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lsaltzburg@motleyrice.com

Attorneys for the Utah Division of Consumer Protection

**BEFORE THE DIVISION OF CONSUMER PROTECTION
OF THE DEPARTMENT OF COMMERCE
OF THE STATE OF UTAH**

IN THE MATTER OF: **PURDUE PHARMA L.P.**, a Delaware limited partnership; **PURDUE PHARMA INC.**, a New York Corporation; **THE PURDUE FREDERICK COMPANY**, a Delaware corporation; **RICHARD SACKLER, M.D.**, individually and as an owner, officer, director, member, principal, manager, and/or key employee of the above named entities; and **KATHE SACKLER, M.D.**, individually and as an owner, officer, director, member, principal, manager, and/or key employee of the above named entities; **Respondents.**	**NOTICE OF AGENCY ACTION** **DCP Legal File No. CP-2019-005** **DCP Case No. 107102**

DIVISION OF CONSUMER PROTECTION TO THE ABOVE-NAMED RESPONDENTS:

You are hereby notified that agency action ("Action") in the form of an adjudicative proceeding has been commenced against you by the Utah Division of Consumer Protection ("Division"). The name of this Action is as captioned above, and may be referred to as: In the

Matter of: Purdue Pharma L.P., et al., DCP Legal File No. CP-2019-005. The Division's legal authority and jurisdiction pursuant to which this Action is maintained includes Utah Code §§ 13-2-1(2)(c); 13-2-5(3); 13-2-6; and 13-11-17(4). The purpose of and questions to be decided by this adjudicative proceeding, and the information upon which this adjudicative proceeding is based, are set forth in the Division's Administrative Citation ("Citation"). A copy of the Citation is attached, and incorporated herein by reference.[1] This Action will be served, and the Citation was previously served, to Respondents as follows:

Citation service to:	
Purdue Pharma, L.P. One Stamford Forum 201 Tresser Boulevard Stamford, CT 06901	Richard Sackler, M.D. 9901 E. Powder Run Road Alta, UT 84092
Purdue Pharma Inc. One Stamford Forum 201 Tresser Boulevard Stamford, CT 06901	Richard Sackler, M.D. 25 Windrose Way Greenwich, CT 06830-7232
The Purdue Frederick Company One Stamford Forum 201 Tresser Boulevard Stamford, CT 06901	Kathe Sackler, M.D. 136 Wells Hill Road Easton, CT 06612-1556
Courtesy copies to:	Courtesy copies to:
Mark Cheffo Mark.Cheffo@dechert.com	Sara Roitman Sara.Roitman@dechert.com
Will Sachse Will.Sachse@dechert.com	Paul LaFata Paul.LaFata@dechert.com
	Elisabeth McOmber emcomber@swlaw.com

[1] As directed by the February 26, 2019 Order in this matter, an unredacted copy of the Citation will be provided to Acting Director Parker, Presiding Officer Dibb, and to counsel for Respondents. The unredacted Citation contains information subject to a protective order as detailed in the Division's Motion for Leave to File Redacted Notice of Agency Action ("Motion"), which is being filed contemporaneously with this Action. The Division requests that the Citation not be included in the public file until the Motion is decided.

Notice of Agency Action service to:	
Purdue Pharma, L.P. One Stamford Forum 201 Tresser Boulevard Stamford, CT 06901	Richard Sackler, M.D. 9901 E. Powder Run Road Alta, UT 84092
Purdue Pharma Inc. One Stamford Forum 201 Tresser Boulevard Stamford, CT 06901	Kathe Sackler, M.D. 136 Wells Hill Road Easton, CT 06612-1556
The Purdue Frederick Company One Stamford Forum 201 Tresser Boulevard Stamford, CT 06901	Cohne Kinghorn Attn: Patrick Johnson and Paul Moxley 111 East Broadway, 11th Floor Salt Lake City, UT 84111 pjohnson@ck.law pmoxley@ck.law
Snell & Wilmer L.L.P. Attn: Elisabeth McOmber 15 West South Temple, Suite 1200 Salt Lake City, UT 84101 emcomber@swlaw.com	
Courtesy copies to:	Courtesy copies to:
Mark Cheffo Mark.Cheffo@dechert.com	Sara Roitman Sara.Roitman@dechert.com
Will Sachse Will.Sachse@dechert.com	Paul LaFata Paul.LaFata@dechert.com

This adjudicative proceeding is initially designated as informal. Utah Code § 63G-4-202(1); Utah Admin. Code R152-6-1(A). It is thus subject to the provisions of Utah Code §§ 63G-4-201 through 203. In this proceeding you may, at your own expense, be represented by counsel, represent yourself individually, or, if not an individual, an entity may represent itself through an officer or employee. Utah Admin. Code R151-4-110. Any respondent may request a hearing from the presiding officer. If a hearing is requested or scheduled, notice of the hearing will be provided by the presiding officer. You may appear and be heard and present evidence on your behalf at any such hearings.

A prehearing conference has been scheduled in this matter, and will be held at 9:30 A.M. Mountain Daylight Time on Tuesday, April 23, 2019 in room 250 of the Heber M. Wells Building, 160 East 300 South, Salt Lake City, Utah 84114. Parties may participate in the prehearing conference by telephonic conference call, should they provide the presiding officer with their telephone number prior to the date of the prehearing conference. The purpose of the prehearing conference is to enter a scheduling order pursuant to Utah Admin. Code RR151-4-114, 503 and/or 510, as applicable, to set a date for pre-hearing motions, to set a hearing date to adjudicate the matter alleged in this Action, and to address such other matters as may be appropriate.

The presiding officer for this Action will be Bruce L. Dibb, Administrative Law Judge, Department of Commerce, who will preside over any matters designated by the Acting Director of the Division. Utah Admin. Code R152-6-2. If you or your counsel have questions regarding the procedure relative to the case, you may contact Judge Dibb in writing at 160 East 300 South, Second Floor, P.O. Box 146701, Salt Lake City, UT 84114-6701; by telephone at (801) 530-6706; or by electronic mail at bdibb@utah.gov.

You may file a written response to this Notice of Agency Action with the Division within thirty (30) days of the mailing date identified on the Certificate of Service accompanying this Notice of Agency Action. Utah Admin. Code R151-4-205(2)(a), (3)(a).

Your response, and any future pleadings or filings that should be part of the official files in this matter, should be sent to the following:

For the official file:	To the Acting Director:
Utah Division of Consumer Protection 160 East 300 South, 2nd Floor PO Box 146704 Salt Lake City, UT 84114-6704	Chris Parker Acting Director Utah Division of Consumer Protection chrisparker@utah.gov

	To the Administrative Law Judge: Utah Department of Commerce Bruce Dibb, Administrative Law Judge 160 East 300 South, 2nd Floor PO Box 146701 Salt Lake City, UT 84114-6701 bdibb@utah.gov
To counsel for the Division: Utah Attorney General's Office: Robert Wing Assistant Attorney General rwing@agutah.gov Kevin McLean Assistant Attorney General kmclean@agutah.gov	To counsel for the Division: Motley Rice: Linda Singer lsinger@motleyrice.com Elizabeth Smith esmith@motleyrice.com Lisa Saltzburg lsaltzburg@motleyrice.com

If you fail to participate in this adjudicative proceeding, or fail to file a written response within thirty (30) days of the mailing date identified on the Certificate of Service accompanying this Notice of Agency Action, the presiding officer may cancel the prehearing conference, and may enter a default order against you without any further notice. Utah Code § 63G-4-209; Utah Admin. Code Rl5l-4-510(1)(b)(i), (ii). After issuing the default order, the presiding officer may grant the relief sought against you in this Action and incorporated Citation, will conduct any further proceedings necessary to complete the adjudicative proceeding without your participation, and will determine all issues in the proceeding. Utah Code § 63G-4-209(4).

You may attempt to negotiate a settlement of the matter without filing a response or proceeding to hearing. To do so, please contact the Division's counsel, identified above.

ISSUED this 8th day of March, 2019.

Daniel Larsen
Utah Division of Consumer Protection
Presiding Officer for Issuance of this Notice of Agency Action

CERTIFICATE OF SERVICE

I certify that I have this day served the foregoing document on the parties of record in this proceeding set forth below:

By first class mail, postage prepaid:

Purdue Pharma, L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901

Purdue Pharma Inc.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901

The Purdue Frederick Company
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901

Snell & Wilmer L.L.P.
Attn: Elisabeth McOmber
15 West South Temple, Suite 1200
Salt Lake City, UT 84101

Richard Sackler, M.D.
9901 E. Powder Run Road
Alta, UT 84092

Kathe Sackler, M.D.
136 Wells Hill Road
Easton, CT 06612-1556

Cohne Kinghorn
Attn: Patrick Johnson and Paul Moxley
111 East Broadway, 11th Floor
Salt Lake City, UT 84111

By electronic mail:

Elisabeth McOmber
emcomber@swlaw.com

Mark Cheffo
Mark.Cheffo@dechert.com

Will Sachse
Will.Sachse@dechert.com

Paul Moxley
pmoxley@ck.law

Patrick Johnson
pjohnson@ck.law

Sara Roitman
Sara.Roitman@dechert.com

Paul LaFata
Paul.LaFata@dechert.com

DATED this 8th day of March, 2019.

/s/ Kevin McLean, Assistant Attorney General