

1 MARK BRNOVICH
2 Attorney General (Firm State Bar No. 014000)
3 Stephen J. Womack (State Bar No. 025097)
4 Jennifer Bonham (State Bar No. 032332)
5 Bryce Clark (State Bar No. 034080)
6 Office of the Attorney General
7 2005 N. Central Ave.
8 Phoenix, AZ 85004
9 Telephone: 602-542-7726
10 Email: stephen.womack@azag.gov
11 Attorneys for the State of Arizona
12 Electronic Filing Email: consumer@azag.gov

9 **SUPERIOR COURT OF ARIZONA**
10 **PIMA COUNTY**

11 STATE OF ARIZONA, *ex rel.*
12 MARK BRNOVICH, Attorney General,
13 Plaintiff,
14 vs.
15 PURDUE PHARMA L.P., PURDUE
16 PHARMA, INC., and THE PURDUE
17 FREDERICK COMPANY, INC. (d/b/a
18 THE PURDUE FREDERICK
19 COMPANY),
20 Defendants.

Case No. C20072471

**PLAINTIFF'S APPLICATION FOR
ORDER TO SHOW CAUSE**

RE:

**ORDER FOR CONSENT JUDGMENT
ENTERED MAY 14, 2007**

(Assigned to the Hon. Richard Gordon)

20 In 2007, this Court ordered Defendants to stop marketing their dangerous
21 oxycodone painkillers in deceptive ways. But, following entry of the judgment, Defendants
22 continued to engage in misleading and harmful practices, including promoting opioids as
23 safer and more effective than drugs like aspirin and ibuprofen. Pursuant to A.R.S. § 44-
24 1532, Plaintiff moves the Court to issue an order requiring Defendants to appear and show
25 cause as to why they should not be found in violation of the Court's *Order for Consent*
26 *Judgment* and be ordered to pay civil penalties of up to \$25,000 per violation.

27 This application is supported by the following memorandum.
28

1 **SUPPORTING MEMORANDUM**

2 Defendants Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick
3 Company, Inc., d/b/a The Purdue Frederick Company (collectively, “Purdue”)
4 manufactured, advertised and sold opioid painkillers, including Purdue’s oxycodone drug
5 OxyContin. Plaintiff, State of Arizona, *ex rel.* Attorney General Mark Brnovich (“State”),
6 alleges Purdue marketed oxycodone in Arizona by overstating benefits and downplaying
7 risks associated with taking the drug. In doing so, Purdue violated the *Order for Consent*
8 *Judgment* (“2007 Judgment”)¹ previously entered against Purdue in the above-captioned
9 matter, which expressly prohibited Purdue from deceptively advertising its oxycodone
10 drugs.

11 **I. Introduction**

12 This dispute is over dangerous oxycodone-based opioids manufactured by Purdue,
13 including the drug sold under the brand name “OxyContin.” Nationally, in 2016, an
14 estimated 17,087 deaths were attributable to prescription opioids, including, but not
15 limited to, oxycodone.² That year, in Arizona alone, an estimated 186 deaths were
16 attributable to prescription opioids.³ These deaths are a part of what has become a tragic
17 national opioid crisis.

18 Purdue marketed its potentially deadly drugs in ways that contributed to this
19 national crisis. Purdue admitted to doing so in the past. In 2007, Purdue consented to this
20 Court’s judgment, which curtailed Purdue’s wrongful sales tactics, imposed safeguards in
21 an effort to prevent such wrongdoing in the future, and required Purdue to pay \$19.5
22 million to states participating in the settlement underlying the judgment. At that time, in

23 ¹ The 2007 Judgment is referenced in this application, but has not been refiled with the
24 Court pursuant to Ariz. R. Civ. P. Rule 5.1(c)(2)(D); however, the State has delivered a
25 courtesy copy of the judgment to the court and Defendants.

26 ² Puja Seth, *et al.*, *Overdose Deaths Involving Opioids, Cocaine, and Psychostimulants—*
United States, 2015—2016, Ctrs. for Disease Control & Prevention, Table 1 (March 30,
27 2018), available at <https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6712a1-H.pdf>, a
28 copy of which is attached as Exhibit A.

³ *Id.*

1 federal court, Purdue and three of its top executives pled guilty to a felony charge of
2 illegally misbranding OxyContin in an effort to mislead and defraud physicians and
3 consumers, and they agreed to pay an additional \$634.5 million in criminal and civil
4 penalties, fines and forfeitures.⁴ Undaunted, Purdue continued to aggressively market
5 prescription opioids, including OxyContin, in the years following 2007.

6 As a result of its aggressive marketing, Purdue earned more than \$35 billion since
7 the release of OxyContin in 1995.⁵ According to the 2010 Census, about 2% of the
8 country's population resides in Arizona.⁶ Based on Arizona's estimated share of the U.S.
9 population, Purdue generated approximately \$700 million of its \$35 billion in revenue
10 from prescriptions filled in Arizona.

11 Purdue's lucrative-but-deceptive post-2007 marketing put Arizonans at grave risk,
12 with ongoing repercussions. The Arizona Department of Health Services estimated that
13 between June 15, 2017, and August 30, 2018, the state suffered 10,974 suspected
14 overdoses attributable to all opioids, licit and illicit, 15% of which were fatal.⁷

15 Because of the seriousness of the opioid crisis and Purdue's disregard for this
16 Court's order, the State seeks relief from the Court.

19
20 ⁴ *Statement of United States Attorney John Brownlee on the Guilty Plea of the Purdue*
21 *Frederick Company and Its Executives for Illegally Misbranding OxyContin*, U.S. Dept. of
22 *Justice*, 2 (May 10, 2007), available at [https://www.ctnewsjunkie.com/upload/](https://www.ctnewsjunkie.com/upload/2016/02/usdoj-purdue-guilty-plea-5-10-2007.pdf)
23 [2016/02/usdoj-purdue-guilty-plea-5-10-2007.pdf](https://www.ctnewsjunkie.com/upload/2016/02/usdoj-purdue-guilty-plea-5-10-2007.pdf), attached as Exhibit B.

24 ⁵ Alex Morrell, *The OxyContin Clan: The \$14 Billion Newcomer to Forbes 2015 List of*
25 *Richest U.S. Families*, Forbes (July 1, 2015), [https://www.forbes.com/sites/alexmorrell/](https://www.forbes.com/sites/alexmorrell/2015/07/01/the-oxycontin-clan-the-14-billion-newcomer-to-forbes-2015-list-of-richest-u-s-families/#6d3667fc75e0)
26 [2015/07/01/the-oxycontin-clan-the-14-billion-newcomer-to-forbes-2015-list-of-richest-u-](https://www.forbes.com/sites/alexmorrell/2015/07/01/the-oxycontin-clan-the-14-billion-newcomer-to-forbes-2015-list-of-richest-u-s-families/#6d3667fc75e0)
27 [s-families/#6d3667fc75e0](https://www.forbes.com/sites/alexmorrell/2015/07/01/the-oxycontin-clan-the-14-billion-newcomer-to-forbes-2015-list-of-richest-u-s-families/#6d3667fc75e0), attached as Exhibit C.

28 ⁶ *Quick Facts: Arizona; UNITED STATES*, U.S. Census Bureau,
<https://www.census.gov/quickfacts/fact/table/az,US/PST045217> (accessed Sept. 5, 2018).

⁷ *Opioid Report: Opioid Overdoses & Deaths*, Ariz. Dep't of Health Servs.,
[https://www.azdhs.gov/documents/prevention/womens-childrens-health/injury-](https://www.azdhs.gov/documents/prevention/womens-childrens-health/injury-prevention/opioid-prevention/opioid-report.pdf)
[prevention/opioid-prevention/opioid-report.pdf](https://www.azdhs.gov/documents/prevention/womens-childrens-health/injury-prevention/opioid-prevention/opioid-report.pdf) (accessed Sept. 5, 2018), attached as
Exhibit D.

II. Factual Background

A. This Court Ordered Purdue to Eliminate Its Deceptive Marketing of Oxycodone Drugs in 2007

In 2007, Purdue agreed to stop marketing its oxycodone drugs in Arizona. As a result of that agreement, on May 14, 2007, the Court entered its 2007 Judgment in the above-styled action. This judgment, among other things, prohibited Purdue from promoting and marketing OxyContin in misleading ways. The judgment defined “OxyContin” as “any controlled-release drug distributed by Purdue which contains oxycodone as an active pharmaceutical ingredient,” hereinafter referred to as “oxycodone.” 2007 Judgment, § I(1)(G). More specifically, the 2007 Judgment orders, in part, as follows:

a. “Purdue shall not make any written or oral claim that is false, misleading or deceptive.” 2007 Judgment, ¶ 2.

b. “Purdue shall provide ‘fair balance’ statements, as defined in 21 C.F.R. § 202.1,⁸ . . . regarding contraindications and adverse events, including but not limited to statements regarding [oxycodone]’s potential for abuse, addiction, or physical dependence as set forth in the Package Insert.” 2007 Judgment, ¶ 4.

c. “Purdue shall not make misrepresentations with respect to [oxycodone]’s potential for abuse, addiction, or physical dependence as set forth in the Package Insert.” 2007 Judgment, ¶ 5.

d. “Purdue shall not misrepresent the existence, non-existence, or findings of any medical or scientific evidence, including anecdotal evidence, relating to Off-Label Uses” of oxycodone and “shall not provide any information

⁸ 21 C.F.R. § 202.1 requires marketing to be fairly balanced between information favorable to the drug, on one hand, and information unfavorable to the drug, on the other hand. § 202.1(e)(5)(ii).

1 that is misleading or lacking in fair balance, as defined by 21 C.F.R. [§] 202.1,⁹ . . .
2 or as appearing in FDA Guidances for Industry . . . in any discussion of the Off-
3 Label Uses” of oxycodone. 2007 Judgment, ¶ 11.

4 e. “All material used in promoting [oxycodone], regardless of format
5 (audio, internet, video, print) and whether directed primarily to patients or to
6 Health Care Professionals, shall, not inconsistent with the Package Insert, contain
7 only information that is truthful, balanced, accurately communicated, and not
8 minimize the risk of abuse, addiction or physical dependence associated with the
9 use of [oxycodone].” 2007 Judgment, ¶ 20.

10 As detailed below, Purdue repeatedly violated the 2007 Judgment.

11 **B. Purdue Manufactured and Marketed Oxycodone in Arizona**

12 At all times relevant herein, Purdue manufactured at least one controlled-release
13 opioid that contained oxycodone as an active pharmaceutical ingredient. “Prescription
14 opioids are powerful pain-reducing medications”¹⁰ Opioids include illegal drugs, like
15 heroin and black-market fentanyl, and legal drugs, like prescription oxycodone.¹¹ The
16 U.S. Centers for Disease Control and Prevention (“CDC”) cautions that “because [opioid
17 pain medications] produce euphoria in addition to pain relief, they can be misused.”¹²

18
19 ⁹ 21 C.F.R. § 202.1(e)(6)-(7) addresses 33 different types of advertisements that are
20 misleading or lacking in fair balance, including advertisements that contain unsubstantiated
21 claims that a drug is safer or more effective than other drugs, § 202.1(e)(6)(ii);
22 advertisements that promote a drug on the bases that have been rendered invalid,
23 § 202.1(e)(6)(iii); and advertisements that present a drug as safer to use than can be
24 demonstrated, § 202.1(e)(6)(iv). The regulation also addresses advertisements that use
25 headings, pictures or graphic matter that are misleading. 21 C.F.R. § 202.1(e)(6)(xviii). It
26 further addresses advertisements that create a false impression through over-emphasizing
27 favorable information or de-emphasizing unfavorable information. 21 C.F.R.
28 § 202.1(e)(7)(iv), (vii)-(ix), and (xi)-(xii).

¹⁰ *Opioid Medications*, U.S. Ctrs. for Disease Control & Prevention, (n.d.), <https://www.cdc.gov/drugoverdose/opioids/terms.html> (last visited July 26, 2018).

¹¹ *Commonly Used Terms*, U.S. Ctrs. for Disease Control & Prevention, (n.d.), <https://www.cdc.gov/drugoverdose/opioids/terms.html> (last visited July 26, 2018).

¹² *Id.*

1 And, even when used as prescribed, opioids may have potentially dangerous side effects.¹³
2 Despite knowing the dangers inherent with prescription opioids, even after consenting to
3 the 2007 Judgment and pleading guilty to the federal felony charge, Purdue aggressively
4 marketed its oxycodone drugs, in particular, and prescription opioids, in general.

5 Purdue marketed its oxycodone through both branded media specifically
6 identifying OxyContin and through unbranded media that generally promoted prescription
7 opioid painkillers, which, by definition, includes OxyContin. It did so by overstating
8 benefits and downplaying risks associated with using oxycodone. Purdue promoted
9 OxyContin in branded materials that included the product's name and attributes. And
10 Purdue promoted opioids through unbranded materials that did not directly identify a
11 particular product by name (e.g., OxyContin), but advertised a class of products (i.e.,
12 opioid painkillers) that includes oxycodone. Accordingly, this branded and unbranded
13 marketing falls squarely within the 2007 Judgment.

14 Purdue conducted its branded and unbranded marketing in Arizona through sales
15 representatives, printed and digital materials, websites, presentations, webinars, and third-
16 party publications.

17 Purdue's representatives made over [REDACTED] sales calls to healthcare professionals
18 in Arizona between May 15, 2007—the day after the 2007 Judgment was entered—and
19 December 22, 2017.¹⁴

20 Purdue marketed oxycodone directly to patients through written materials it
21 produced, including a publication entitled *Resource Guide for People with Pain*¹⁵ and a
22 brochure entitled *Providing Relief, Preventing Abuse*.¹⁶ In addition to other materials,

23 ¹³ See *Prescription Opioids*, U.S. Ctrs. for Disease Control & Prevention, (n.d.), [https://](https://www.cdc.gov/drugoverdose/opioids/prescribed.html)
24 www.cdc.gov/drugoverdose/opioids/prescribed.html (last visited July 26, 2018).

25 ¹⁴ Paragraph 9(a) of the *Declaration of Francisco Arvizu in Support of State's Application*
26 *for Order to Show Cause* ("Arvizu Dec."), attached as Exhibit E.

26 ¹⁵ *Resource Guide for People with Pain*, Purdue Pharma L.P. (2009); and Arvizu Dec.,
¶ 9(d)(i) and Exhibit E-4.

27 ¹⁶ *Providing Relief, Preventing Abuse*, Purdue Pharma L.P. (2007); see Arvizu Dec.,
28 ¶ 9(d)(ii) and Exhibit E-5.

1 Purdue distributed over [REDACTED] copies of this brochure in Arizona between 2008 and
2 2017.¹⁷

3 Purdue promoted opioid use in general, including oxycodone-based opioids,
4 through its website www.inthefaceofpain.com until it deactivated the website about
5 October 1, 2015.¹⁸ On information and belief, Purdue misled the public for years through
6 the website by failing to disclose that from 2008 to 2013 it provided financial
7 compensation to the doctors and other healthcare professionals whose testimonials
8 appeared on the site.¹⁹

9 Purdue also promoted use of unbranded opioids like oxycodone through its
10 “Partners Against Pain” campaign. In 1993, Purdue established Partners Against Pain to
11 provide “pain management education and advocacy.”²⁰ The campaign’s website,
12 www.partnersagainstpain.com, served as a primary conduit through which Purdue
13 promoted use of opioid painkillers. Purdue deactivated the website in 2016.

14 Purdue’s websites were accessed by Arizona residents [REDACTED] of times before
15 being deactivated by Purdue.²¹

16 On Purdue’s website www.partnersagainstpain.com, Purdue maintained links to
17 various promotional materials, many of which were published by Purdue directly,
18 sponsored by Purdue but published by third parties, or published by third parties that were,
19 themselves, funded by Purdue.²² In creating these links, Purdue surely knew of and
20 acquiesced to the contents of these materials.

21 _____
¹⁷ Arvizu Dec., ¶ 9(e) and Exhibit E-8.

22 ¹⁸ See screen capture from August 29, 2018, at <http://www.inthefaceofpain.com>, a copy of
23 which is attached as Exhibit F.

24 ¹⁹ See Pat Anson, *Purdue Pharma’s “Misleading” Websites*, Pain News Network (Aug.
25 21, 2015), available at [https://www.painnewsnetwork.org/stories/2015/8/21/purdue-](https://www.painnewsnetwork.org/stories/2015/8/21/purdue-pharmas-misleading-websites)
26 [pharmas-misleading-websites](https://www.painnewsnetwork.org/stories/2015/8/21/purdue-pharmas-misleading-websites), a copy of relevant pages of which is attached as Exhibit G.

27 ²⁰ *Caregiver Cornerstones: A Resource Guide for Family Caregivers Caring for People*
28 *with Pain*, Purdue Pharma L.P., back page (2013); see Arvizu Dec., ¶ 9(d)(iii) and Exhibit
E-6.

²¹ Arvizu Dec., ¶ 9(b) and Exhibit E-2.

²² Arvizu Dec., ¶ 9(c); see Exhibit E-3.

1 For example, Purdue directly funded the American Pain Foundation (“APF”), as
2 well as sponsored APF publications like *A Policymaker’s Guide to Understanding Pain &*
3 *Its Management*,²³ *Treatment Options: A Guide for People Living with Pain*,²⁴ and *Pain*
4 *Resource Guide: Getting the Help You Need*.²⁵ And Purdue’s website
5 www.partnersagainstpain.com maintained links to both APF’s website and APF
6 publications.²⁶ As is detailed below, APF was a key proponent of opioid use.

7 Between 2012 and 2017, Purdue paid in excess of \$4 million to advocacy groups to
8 promote opioid use.²⁷ During this time period, Purdue also compensated individuals,
9 including executives, staff members, board members and advisory board members
10 affiliated with these groups.²⁸ The U.S. Senate Homeland Security & Governmental
11 Affairs Committee, as a result of its investigation into the financial ties between opioid
12 manufacturers and third-party advocacy groups, found that “organizations receiving
13 substantial funding from manufacturers have, in fact, amplified and reinforced messages
14 favoring increased opioid use.”²⁹ The Committee concluded, “By aligning medical culture
15 with industry goals in this way, many of the [advocacy groups] may have played a
16

17
18 ²³ *A Policymaker’s Guide to Understanding Pain & Its Management*, Am. Pain Found.,
19 (2011), available at [http://s3.documentcloud.org/documents/277603/apf-policymakers-](http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf)
20 [guide.pdf](http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf), a copy of relevant pages of which is attached as Exhibit H.

21 ²⁴ *Treatment Options: A Guide for People Living with Pain*, Am. Pain Found., (2006,
22 updated 2007), available at [https://web.archive.org/web/20111115011348/http://](https://web.archive.org/web/20111115011348/http://www.painfoundation.org/learn/publications/files/TreatmentOptions2006.pdf)
23 [www.painfoundation.org/learn/publications/files/TreatmentOptions2006.pdf](https://web.archive.org/web/20111115011348/http://www.painfoundation.org/learn/publications/files/TreatmentOptions2006.pdf), a copy of
24 relevant pages of which is attached as Exhibit I.

25 ²⁵ *Pain Resource Guide: Getting the Help You Need*, Am. Pain Found., 13 (Sept. 2007),
26 available at [https://www.michigan.gov/documents/mdch/PainResourceGuide2007](https://www.michigan.gov/documents/mdch/PainResourceGuide2007_237868_7.pdf)
27 [_237868_7.pdf](https://www.michigan.gov/documents/mdch/PainResourceGuide2007_237868_7.pdf), a copy of relevant pages of which is attached as Exhibit J.

28 ²⁶ Arvizu Dec., at ¶ 9(c); see Exhibit E-3.

29 ²⁷ *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and*
30 *Third Party Advocacy Groups*, U.S. S. Homeland Sec. & Governmental Affairs Comm.,
31 Ranking Member’s Office, 4, Fig. 1 (2018), available at: [https://www.hsdl.org/?view](https://www.hsdl.org/?view&did=808171)
32 [&did=808171](https://www.hsdl.org/?view&did=808171), a copy of relevant pages of which is attached as Exhibit K.

33 ²⁸ *Id.* at 10-11.

34 ²⁹ *Id.* at 17.

1 significant role in creating the necessary conditions for the U.S. opioids epidemic.”³⁰

2 Purdue used unbranded websites, advocacy groups, societies and industry
3 representatives it funded to create the impression of legitimacy regarding its opioid
4 marketing campaign.

5 6 **III. Argument**

7 **A. Despite the 2007 Judgment, Purdue Continued to Engage in Deceptive and** 8 **Unbalanced Marketing of Its Oxycodone Drugs**

9 Following the entry of the 2007 Judgment, in the course of promoting its dangerous
10 painkillers, Purdue engaged in deceptive and unbalanced marketing in violation of the
11 2007 Judgment, including:

- 12 • Falsely representing oxycodone’s efficacy;
- 13 • Deceptively representing oxycodone as safer than can be demonstrated by
14 substantial clinical evidence;
- 15 • Failing to balance promotion of oxycodone’s favorable characteristics with
16 education regarding the drug’s serious side effects; and
- 17 • Deceptively minimizing oxycodone’s potential for abuse, addiction or
18 dependence.

19 **1. Purdue Falsely Represented Its Oxycodone Drug’s Efficacy**

20 **a. Purdue Stated Its Oxycodone Drug Was Effective for 12 Hours** 21 **When Purdue Knew the Drug Did Not Provide 12-Hour Pain** 22 **Relief**

23 Purdue sought to deceive the public as to the relief provided by its oxycodone drug.
24 At all relevant times, Purdue marketed the drug as offering “every-12-hour dosing.”³¹ As
25 early as 2007, however, Purdue knew its oxycodone drug did not provide 12-hour pain
26

27 ³⁰ *Id.*

28 ³¹ Arvizu Dec., ¶ 9(g) and Exhibit E-13.

1 relief. Purdue received numerous complaints contending that the drug did not provide
2 continuous pain relief for a full 12 hours and it knew that this led the patients to seek more
3 medicine. For example, [REDACTED]

4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED], not the 12-hour dosing Purdue promoted.³⁴

8 Despite evidence to the contrary and without scientific or clinical support, Purdue
9 continued to falsely market its oxycodone drug as providing uniformly distributed
10 medication throughout a 12-hour dose through the tagline “Every-12-hour OxyContin
11 Tablets.”³⁵ This promotion was deceptive and unbalanced.

12 **b. Purdue Marketed Its Oxycodone Drug as Effective for Chronic**
13 **Pain Without Scientific Evidence to Support the Claim**

14 Purdue deceptively promoted oxycodone as effective for treating chronic pain by
15 failing to balance its advocacy for this use with an admission that its position was not
16 supported by scientific evidence. Purdue conducted this deceptive and unbalanced
17 marketing through materials it produced and through materials produced by third parties
18 that it sponsored. In its brochure *Providing Relief, Preventing Abuse*, for example, Purdue
19 adopted the claim that opioids “are the most effective way to treat . . . pain, and often the
20 only treatment option that provides significant relief.”³⁶ Third parties funded by Purdue
21 also overstated the effectiveness of opioids in treating chronic pain. This is evident in the
22 Purdue-sponsored American Pain Foundation’s publication *A Policymaker’s Guide to*
23 *Understanding Pain & Its Management*. This publication overstated the benefits of
24 opioids for the treatment of chronic pain, claiming, “Multiple clinical studies have shown

25 ³² *Id.* at ¶ 9(f) and Exhibit E-9.

26 ³³ *Id.* at Exhibit E-10.

27 ³⁴ *See id.* at ¶ 9(f) and Exhibit E-11.

28 ³⁵ *Id.* at ¶ 9(g) and Exhibit E-13.

³⁶ *See Providing Relief, Preventing Abuse, supra* note 12, and Exhibit E-5 at 4.

1 that long-acting opioids, in particular, are effective in improving: daily function;
2 psychological health; and overall health-related quality of life for people with chronic
3 pain.”³⁷

4 Contrary to Purdue’s representations, scientific studies call into question the claim
5 that opioids are effective for treating chronic pain. Scientific reviews have concluded that
6 “no evidence exists to support long-term use . . . of opioids to treat chronic pain.”³⁸ The
7 CDC stressed, “While benefits for pain relief, function, and quality of life with long-term
8 opioid use for chronic pain are uncertain, risks associated with long-term opioid use are
9 clearer and significant.”³⁹ The CDC continued, “Based on the clinical evidence review,
10 long-term opioid use for chronic pain is associated with serious risks including increased
11 risk for opioid use disorder, overdose, myocardial infarction, and motor vehicle
12 injury”⁴⁰

13 Purdue’s marketing oxycodone as effective for treating chronic pain was deceptive
14 because it was done without acknowledging the claim was unsupported by scientific
15 evidence and without acknowledging long-term use was risky.

21 ³⁷ *A Policymaker’s Guide to Understanding Pain & Its Management*, *supra* note 23, and
22 Exhibit H at 29.

23 ³⁸ Donald Teater, *Evidence for the Efficacy of Pain Medications*, Nat’l Safety Council, 6
24 (Oct. 2014), available at [https://www.nsc.org/Portals/0/Documents/RxDrugOverdose
Documents/Evidence-Efficacy-Pain-Medications.pdf](https://www.nsc.org/Portals/0/Documents/RxDrugOverdose/Documents/Evidence-Efficacy-Pain-Medications.pdf), a copy of relevant pages of which is
attached as Exhibit L.

25 ³⁹ Deborah Dowell, *et al.*, *CDC Guideline for Prescribing Opioids for Chronic Pain —*
26 *United States, 2016*, MMWR Recomm. Rep. 2016; 65 (No. RR-#1), 18 (March 18, 2016),
27 available at <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf> [hereinafter
“CDC Guideline”], a copy of relevant pages of which is attached as Exhibit M.

28 ⁴⁰ *Id.*

1 **2. Purdue Deceptively Represented Oxycodone as Safer Than Has Been**
2 **Demonstrated by Substantial Evidence or Clinical Experience**

3 Purdue engaged in deceptive and unbalanced marketing when it attempted to create
4 the false impression that its extended-release oxycodone drug was safer to use than it
5 actually was by promoting the drug as remaining effective for 12 hours, by
6 overemphasizing opioids’ lack of a dose ceiling while minimizing the risks associated
7 with higher doses, and by painting alternative pain medications, like nonsteroidal anti-
8 inflammatory drugs (“NSAIDs”), such as aspirin, ibuprofen, and naproxen, as more
9 dangerous than opioids.⁴¹

10 **a. Purdue Created a False Impression that Oxycodone Is Safer**
11 **Than It Is by Marketing the Drug as Less Likely to Be Abused**
12 **Because It Is Effective for 12 Hours**

13 As noted above, Purdue marketed its oxycodone drug as offering “every-12-hour
14 dosing.”⁴² From the outset, Purdue argued the drug was safer than immediate-release
15 opioids because the drug’s “delayed absorption . . . is believed to reduce the abuse liability
16 of the drug.”⁴³ The extended-release nature of the drug, Purdue claimed, resulted in less of
17 the spiking euphoria that might lead users to abuse the medication.⁴⁴ As detailed above,
18 Purdue knew that its oxycodone drug did not provide continuous pain relief for a full 12
19 hours and it knew that this led patients to seek more medicine. For example, [REDACTED]

20 [REDACTED]
21 [REDACTED].⁴⁵ Despite evidence to the contrary and without scientific or clinical

22 _____
23 ⁴¹ *Nonsteroidal Anti-inflammatory Drugs (NSAIDs)*, U.S. Food & Drug Admin., (n.d.)
24 [https://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsand](https://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm103420.htm)
25 [providers/ucm103420.htm](https://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm103420.htm), (last visited August 1, 2018).

26 ⁴² Arvizu Dec., ¶ 9(g) and Exhibit E-13.

27 ⁴³ *See Agreed Statement of Facts*, ¶ 40, filed in 1:07-cr-00029-jpj-1; *U.S. v. The Purdue*
28 *Frederick Company, Inc., et al.*; USDC-W.Va., a copy of which is attached hereto as
Exhibit N.

⁴⁴ *Id.* at ¶ 20(a)-(e).

⁴⁵ Arvizu Dec. at ¶ 9(f) and Exhibit E-12.

1 support, Purdue continued to falsely market its oxycodone drug as providing uniformly
2 distributed oxycodone throughout a 12-hour dose to implicitly maintain the misperception
3 that the drug was safer to use than immediate-release opioids.

4 **b. Purdue Created a False Impression that Oxycodone Is Safer**
5 **Than It Is by Emphasizing Opioids’ Lack of Dose Ceiling**

6 Purdue created a false impression that chronic pain could be safely treated with
7 opioids by representing that doctors and patients could simply increase opioid doses
8 without added risk. For example, a Purdue-sponsored publication, *Treatment Options: A*
9 *Guide for People Living with Pain*, claimed that opioids have “no ceiling dose.”⁴⁶ And
10 another Purdue-sponsored publication, *A Policymaker’s Guide to Understanding Pain &*
11 *Its Management*, claimed that dosage escalations are “sometimes necessary,” even
12 unlimited ones, and it did not disclose the inherent risks of high opioid doses.⁴⁷ But the
13 CDC stated, “Higher dosages of opioids are associated with higher risk of overdose and
14 death—even relatively low dosages . . . increase risk.”⁴⁸ It warned that doses of 50 MME
15 per day or more are at least twice as likely to lead to overdose as are doses of 20 MME per
16 day or less.⁴⁹ Moreover, “[h]igher dosages haven’t been shown to reduce pain over the
17 long term.”⁵⁰ By claiming that oxycodone had no ceiling without explaining the risks of
18 high doses, Purdue carefully crafted an impression of safety that failed to provide
19 balanced and non-misleading information regarding its drug.

20
21
22 _____
23 ⁴⁶ See *Treatment Options: A Guide for People Living with Pain*, *supra* note 24, and
Exhibit I at 8-12.

24 ⁴⁷ *A Policymaker’s Guide to Understanding Pain & Its Management*, *supra* note 23, and
Exhibit H at 32.

25 ⁴⁸ *Calculating Total Daily Dose of Opioids for Safer Dosage*, Ctrs. for Disease Control &
26 Prevention, (n.d.), [https:// www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-](https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf)
a.pdf (last visited August 2, 2018), a copy of which is attached as Exhibit O.

27 ⁴⁹ *Id.*

28 ⁵⁰ *Id.*

1 c. **Purdue Created a False Impression that Oxycodone Is Safer**
2 **Than NSAIDs by Emphasizing Information Favorable to Opioids**
3 **and Unfavorable to NSAIDs While De-Emphasizing Information**
4 **Unfavorable to Opioids and Favorable to NSAIDs**

4 Purdue created the false impression that its opioids were superior to NSAIDs, like
5 ibuprofen, by claiming opioids were more effective than NSAIDs at treating pain, even
6 though Purdue lacked scientific or clinical support for this claim. NSAIDs have a dose
7 ceiling while opioids do not, Purdue argued, so if a patient on the maximum dosage of an
8 NSAID remained in pain, the NSAID had failed that patient, but if a patient on an opioid
9 remained in pain, the patient could have taken a higher dose of the opioid to achieve relief.
10 At the time of these misrepresentations, Purdue was aware this claim was dubious and that
11 no head-to-head clinical studies substantiated it.

12 In 2010, Purdue distributed a letter to health care providers [REDACTED]
13 [REDACTED]
14 [REDACTED] . . .⁵¹ The letter claimed the
15 superiority of opioids.⁵²

16 The Purdue-sponsored publication *Pain: A Guide for Physician Assistants and*
17 *Patients* favorably compared opioids to NSAIDs for pain treatment in older adults.⁵³
18 Specifically, while the publication cautioned that “[c]hronic NSAID use should be
19 avoided unless other alternatives are not effective,”⁵⁴ it failed to provide a similar warning
20 for opioid use. Further, that section of the publication discussing the side effects of opioids
21 made no mention of the risk of addiction.⁵⁵

22 Another Purdue-sponsored publication, *Treatment Options: A Guide for People*
23

24 ⁵¹ Ex. E-14, p. 9.

25 ⁵² See generally Ex. E-14.

26 ⁵³ *Pain: A Guide for Physician Assistants and Patients*, Physician Assistant Found., 12-17
(n.d.), available at <https://pa-foundation.org/wp-content/uploads/Pain-Guide-for-PAs-and-Patients.pdf>, a copy of relevant pages of which is attached as Exhibit P.

27 ⁵⁴ See *id.* at 12.

28 ⁵⁵ See *id.* at 13.

1 *with Pain*, also deceptively compared opioids to NSAIDs. The publication asserted, “It’s
2 been known for a long time that NSAIDs can cause life-threatening side effects in some
3 persons. There are 10,000 to 20,000 deaths each year because of the side effects of this
4 class of medicines. In spite of that, these drugs are widely used.”⁵⁶ In discussing opioids,
5 though, the publication failed to mention corresponding statistics for opioid deaths, failed
6 to mention that opioids also have life-threatening side effects, and favorably compared
7 opioids to NSAIDs as an option for pain treatment.⁵⁷

8 These misrepresentations were made despite clear scientific evidence that higher
9 opioid doses increased the risk of addiction, dependence, and overdose. According to the
10 National Safety Council’s 2014 examination of the efficacy of types of pain medications,
11 even in cases of acute pain, there is no scientific evidence supporting a preference for
12 opioids over NSAIDs, and, in fact, “the evidence seems to indicate that NSAIDs are more
13 effective for severe pain.”⁵⁸ Moreover, the CDC contended that over 17,000 people died
14 of prescription opioid deaths in 2016 alone.⁵⁹ This figure is not in *Treatment Options: A*
15 *Guide for People with Pain*. Its omission constituted a failure to provide balanced
16 information and contributed to an impression that opioids, like oxycodone, are safer than
17 NSAIDs.

18 By emphasizing the risks associated with NSAIDs, while downplaying the risks
19 and emphasizing the benefits of opioids, Purdue failed to provide balanced and non-
20 misleading information regarding opioid use.

25 ⁵⁶ *Treatment Options: A Guide for People Living with Pain*, *supra* note 24, and Exhibit I
26 at 10.

27 ⁵⁷ *Id.* at 10-11.

28 ⁵⁸ Teater, *supra* note 38, and Exhibit L at 6.

⁵⁹ Seth, *supra* note 2, and Exhibit A.

1 **d. Purdue Created a False Impression That Its Oxycodone Drug Is**
2 **Safer Than It Was by Emphasizing Its Abuse-Deterrent**
3 **Characteristics, While Minimizing or Failing to Address Its**
4 **Susceptibility to Abuse**

5 Purdue deceptively suggested that its oxycodone drug deterred abuse because the
6 extended-release drug did not cause a “buzz” or euphoria, caused less euphoria than
7 immediate-release opioids, and had less addiction potential than immediate-release
8 opioids. Therefore, Purdue claimed that its drug could be used to “weed out” addicts or
9 drug seekers only interested in obtaining a “high.”⁶⁰ Purdue repeated its claims in its
10 publication *Resource Guide for People in Pain*, in which the company argued that users
11 are less likely to abuse its oxycodone drug because these drugs do not provide a “high.”⁶¹

12 But there is no scientific evidence in support of Purdue’s claim that its so-called
13 abuse-deterrent formula (“ADF”) reduced the risk of abuse compared to other opioid
14 medications. In fact, even after Purdue reformulated its oxycodone drug to supposedly be
15 more “abuse-deterrent,” Purdue admitted that “there is no evidence that the reformulation
16 of OxyContin is less subject to misuse, abuse, diversion, overdose or addiction.”⁶²
17 According to CDC guidelines, no reliable studies have established that extended-release or
18 long-acting ADFs, like OxyContin, effectively deter or mitigate the risks associated with
19 opioid abuse.⁶³ Similarly, the CDC stated ADFs “do not prevent opiate abuse through oral
20 intake, the most common route of opioid abuse,” “can still be abused by nonoral routes,”
21 and “do not prevent overdose through oral intake.”⁶⁴

22 Purdue’s representations regarding abuse deterrence were designed to mislead

23 ⁶⁰ See *Agreed Statement of Facts*, *supra* note 43, and Exhibit N at ¶ 40.

24 ⁶¹ See *Resource Guide for People with Pain*, *supra* note 11, and Exhibit E-4 at 8.

25 ⁶² *Statement of Purdue Pharma L.P. Regarding FDA’s Approval of Reformulated*
26 *OxyContin® (oxycodone HCl controlled-release) Tablets*, Purdue Pharma (April 15,
27 2010), <https://www.purduepharma.com/news-media/2010/04/statement-of-purdue-pharma-l-p-regarding-fdas-approval-of-reformulated-oxycontin-oxycodone-hcl-controlled-release-tablets/>, a copy of which is attached as Exhibit Q.

28 ⁶³ CDC Guideline, *supra* note 39, and Exhibit M at 21–22.

⁶⁴ *Id.*

1 healthcare professionals into prescribing, and the public into purchasing, more oxycodone
2 than they would have otherwise. Such representations were deceptive and unbalanced.

3 **3. Purdue Failed to Balance Promotion of Oxycodone’s Favorable**
4 **Characteristics With Education Regarding the Drug’s Serious Side**
5 **Effects**

6 Purdue engaged in deceptive and unbalanced marketing when, knowing prescribers
7 tended to think oxycodone was less addictive because it was less potent than morphine,
8 chose not to correct the misperception. Purdue, through its sales staff, its own
9 publications, and third-party publications that it sponsored, instead sought to allay fears by
10 discounting the more serious risks of opioid use or by wholly failing to acknowledge the
11 existence of these risks.

12 Purdue’s own publication *Resource Guide for People in Pain* states, “Many people
13 living with pain and even some healthcare providers believe that opioid medications are
14 addictive. The truth is that when properly prescribed by a healthcare professional and
15 taken as directed, these medications give relief—not a high.”⁶⁵

16 Purdue taught its sales staff how to reassure healthcare professionals, patients and
17 family members that addiction was rare.⁶⁶ [REDACTED]

18 [REDACTED]

19 [REDACTED].⁶⁷

20 Purdue also sought to use third-party publications to quiet concerns regarding use
21 of oxycodone. The Purdue-maintained website www.partnersagainstpain.com, which was
22 accessible by the public until about 2016, contained links to publications providing
23 information about how patients could communicate with healthcare providers, including

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26 _____
27 ⁶⁵ *Resource Guide for People with Pain*, *supra* note 11, and Exhibit E-4 at 8.

28 ⁶⁶ Arvizu Dec., ¶ (9)(i) and Exhibit E-15.

⁶⁷ *Id.*

1 approaches to discussing pain and asking for pain relief.⁶⁸ These linked publications,
2 including Purdue-funded third-party marketing materials, minimized the risk of addiction
3 to opioids by implying that fear of addiction is based on “myths and misunderstandings”
4 because the risk of addiction was “low in the general population.”⁶⁹

5 The Purdue-funded American Pain Foundation’s guide entitled *Getting the Help*
6 *You Need* assured consumers: “Unless you have a past or current history of substance
7 abuse, the chance of addiction is very low when these medications are prescribed by a
8 doctor and taken as directed.”⁷⁰

9 In the Purdue-sponsored *Pain: A Guide for Physician Assistants and Patients*, risks
10 inherent with opioids, like addiction and overdose, were not listed under the heading
11 “Opioid Side Effects,” but less serious side effects, such as mild nausea or stomach upset,
12 sleepiness or drowsiness, and even constipation, were emphasized.⁷¹

13 The Purdue-funded American Pain Foundation often deceptively downplayed the
14 risks of opioids. For example, *Treatment Options, A Guide for People with Pain* claimed:

15 Despite the great benefits of opioids, they are often under-used. For a
16 number of reasons, providers may be afraid to give them and the public may
17 be afraid to take them. Some feel opioids should not be used to treat
18 persistent pain except in persons who are dying. Others are concerned that
19 the average person will become addicted to these drugs. These concerns lead
20 to confusion and hesitation on the part of some providers to prescribe these
for pain control.⁷²

21 ⁶⁸ See *Patient Comfort Assessment Guide*, Partners Against Pain, (n.d.), available at
22 <https://web.archive.org/web/20130605121611/http://www.partnersagainstpain.com/printouts/Patient-Comfort-Assessment-Guide.pdf>, and at Arvizu Dec., ¶ 9(d)(iv) and Exhibit E-
23 7. And see *Questions to Ask Your Doctor*, Partners Against Pain, (n.d.),
24 <https://web.archive.org/web/20110621100122/http://partnersagainstpain.com/pain-management-resources/questions.aspx>, a copy of which is attached as Exhibit R.

25 ⁶⁹ *A Policymaker’s Guide to Understanding Pain & Its Management*, *supra* note 23, and
Exhibit H at 40.

26 ⁷⁰ *Pain Resource Guide: Getting the Help You Need*, *supra* note 25, and Exhibit J at 13.

27 ⁷¹ *Pain: A Guide for Physician Assistants and Patients*, *supra* note 53, and Exhibit P at 13.

28 ⁷² *Treatment Options: A Guide for People Living with Pain*, *supra* note 24, and Exhibit I
at 11-12.

1 This guide failed to disclose that opioids posed a risk of addiction to those who were
2 prescribed the medication and it implied that any risk attending the drugs applied only to
3 those who obtained them illegally.⁷³

4 The Purdue-sponsored publication *A Policy Maker's Guide to Understanding Pain*
5 *& Its Management* argued that pain is undertreated due to “misconceptions about opioid
6 addiction.”⁷⁴

7 *Treatment Options: A Guide for People with Pain* and *A Policy Maker's Guide to*
8 *Understanding Pain & Its Management* are still available to Arizonans online, albeit
9 through third-party websites with no known connection to Purdue or the American Pain
10 Foundation.

11 Notwithstanding the claims in these publications, opioids posed substantial risks of
12 addiction, even to those who take the drugs as prescribed. OxyContin's federally-
13 mandated label stated that there are “risks of addiction, abuse and misuse” that accompany
14 opioid use, “even at recommended doses,” and there are “greater risks of overdose and
15 death with extended-release formulations.”⁷⁵

16 By discounting the more serious risks of opioid use or by wholly failing to
17 acknowledge these risks, Purdue failed to provide balanced information and deceptively
18 promoted its products as safer than they were.

24 ⁷³ See *id.* at 14-15.

25 ⁷⁴ *A Policymaker's Guide to Understanding Pain & Its Management*, *supra* note 23, and
26 Exhibit H at 40.

27 ⁷⁵ OxyContin label, U.S. Food & Drug Admin., 1 (Dec. 16, 2016), available at [https://](https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022272s034lbl.pdf)
28 www.accessdata.fda.gov/drugsatfda_docs/label/2016/022272s034lbl.pdf, a copy of
relevant pages of which is attached as Exhibit S.

1 **4. Purdue Deceptively Minimized Oxycodone’s Potential for Abuse,**
2 **Addiction or Dependence**

3 **a. Purdue Misled the Public as to What Constitutes Signs of Opioid**
4 **Addiction**

5 Purdue misleadingly downplayed the risks of opioid addiction by arguing that what
6 may have appeared to be signs of addiction did not actually indicate addiction, and could
7 actually indicate a need for more opioids.

8 Purdue’s front groups, such as the American Pain Foundation, often failed to
9 disclose that physical dependence on opioids could signal addiction. Instead, they
10 typically claimed: “*Physical dependence is normal; any patient who is taking an opioid on*
11 *a regular basis for a few days should be assumed to be physically dependent. This does*
12 **NOT** mean you are addicted. In fact, many non-addictive drugs can produce physical
13 dependence.”⁷⁶

14 In the Purdue-sponsored publication *A Policymaker’s Guide to Understanding Pain*
15 *& Its Management*, the American Pain Foundation failed to disclose that dose escalations
16 and tolerance could indicate addiction. For example, the guide stated that “[d]ose
17 escalations of opioid therapies are sometimes necessary and reflect a biological adaptation
18 to the medication. Although the exact mechanisms are unclear, current research indicates
19 that tolerance to opioid therapy develops from changes in opioid receptors on the surface
20 of cells. Thus, the need for higher doses of medication is not necessarily indicative of
21 addiction.”⁷⁷

22 In the Purdue-sponsored publication *Treatment Options: A Guide for People Living*
23 *with Pain*, the American Pain Foundation also failed to disclose that dose escalations
24 could indicate addiction. That publication stated that “many persons with persistent pain

25
26 ⁷⁶ *Treatment Options: A Guide for People Living with Pain*, *supra* note 24, and Exhibit I
at 14 (emphasis in original).

27 ⁷⁷ *A Policymaker’s Guide to Understanding Pain & Its Management*, *supra* note 23, and
28 Exhibit H at 32.

1 don't develop tolerance and stay on the same dose of opioid for a long time. Many times
2 when a person needs a larger dose of a drug, it's because their pain is worse or the
3 problem causing their pain has changed.”⁷⁸ It further stated, “[C]urrent evidence indicates
4 that addiction prevalence in pain patients may be no different from prevalence of
5 addiction in the general U.S. population.”⁷⁹ These statements deceptively suggested risk
6 of addiction was low when opioids were taken as prescribed by physicians.

7 The article *Opioid Prescribing: Clinical Tools and Risk Management Strategies*,
8 which was partially funded by Purdue, argued that physical dependence and tolerance did
9 not indicate addiction. It admitted that “physical dependence and tolerance were equated
10 with addiction, and withdrawal was considered a critical indicator of addiction.”⁸⁰ But it
11 sought to diminish the significance of the relationship between physical tolerance and
12 withdrawal, on one hand, and addiction, on the other. In an effort to disassociate physical
13 tolerance from addiction, it argued that correlating the concepts “does not explain high
14 rates of relapse long after withdrawal, or the observation that addiction is rare in patients
15 who become physiologically dependent on opioids while using them for pain control.”⁸¹

16 Purdue also sought to distinguish opioid dependence and tolerance and addiction
17 by conveniently attributing addiction solely to external factors, not the medication:
18 “Addiction is a disease. It is not caused by drugs; it is triggered in a susceptible individual
19 by the exposure to drugs, most commonly through abuse. The kind of drugs, the person’s
20 environment, their psychological makeup, and other social factors can contribute to the
21 risk of addiction.”⁸²

22
23 ⁷⁸ *Treatment Options: A Guide for People Living with Pain*, *supra* note 24, and Exhibit I
at 14.

24 ⁷⁹ *A Policymaker’s Guide to Understanding Pain & Its Management*, *supra* note 23, and
Exhibit H at 28.

25 ⁸⁰ *Opioid Prescribing: Clinical Tools and Risk Management Strategies*, 9 (2009),
26 available at http://www.cecily.com/aapm/2009/opioids/opioids_print.pdf, a copy of
relevant pages of which is attached as Exhibit T.

27 ⁸¹ *Id.*

28 ⁸² *Providing Relief, Preventing Abuse*, *supra* note 12, and Exhibit E-5 at 12.

1 Additionally, Purdue sought to alleviate concerns about opioid addiction and
2 misled the public as to what constitutes addiction through unsubstantiated representations
3 about the concept of “pseudoaddiction.” Purdue, for example, stated in its brochure
4 *Providing Relief, Preventing Abuse* that medical professionals often misinterpret signs of
5 pseudoaddiction for signs of actual addiction.⁸³

6 Addiction, explains the Substance Abuse and Mental Health Services
7 Administration (“SAMHSA”), “is characterized by inability to consistently abstain,
8 impairment in behavioral control, craving, diminished recognition of significant problems
9 with one’s behaviors and interpersonal relationships, and a dysfunctional emotional
10 response.”⁸⁴ SAMHSA further explains that opioid addiction, or “Opioid Use Disorder,”
11 is “characterized by loss of control of opioid use, risky opioid use, impaired social
12 functioning, tolerance, and withdrawal.”⁸⁵

13 The concept of “pseudoaddiction” attempts to explain patient behaviors that may
14 appear to indicate addiction as behaviors that merely result from untreated pain. In such
15 situations, Purdue argued, patients with unrelieved pain may become focused on obtaining
16 medications or may otherwise seem to inappropriately seek drugs. This behavior, Purdue
17 asserted, may be misidentified as addiction because it is characterized by: craving opioids;
18 watching the clock in anticipation of the next dose; and doctor shopping and behaving
19 deceptively to obtain relief.⁸⁶ Purdue claimed that unlike truly addictive behavior, the
20 pseudoaddictive conduct ceases when pain is effectively treated by additional
21 medication.⁸⁷

22
23 ⁸³ *Id.* at 13.

24 ⁸⁴ *TIP 63: Medications for Opioid Use Disorder*, SAMHSA, 5-57 (Feb. 15, 2018),
25 available at <https://store.samhsa.gov/shin/content//SMA18-5063FULLDOC/SMA18-5063FULLDOC.pdf>, a copy of which is attached as Exhibit U.

26 ⁸⁵ *Id.* at 5-58.

27 ⁸⁶ *Providing Relief, Preventing Abuse*, *supra* note 12, and Exhibit E-5 at 13; *see Opioid*
Prescribing: Clinical Tools and Risk Management Strategies, *supra* note 76, Exhibit Q at

28 ⁸⁷ *Id.*

1 A 2015 study of scholarly articles in the National Library of Medicine’s
2 bibliographic database/article index, however, failed to identify a single article that sought
3 to empirically validate the concept of pseudoaddiction.⁸⁸ The study concluded that the
4 concept had not been verified.⁸⁹ Additionally, the study called into question
5 pseudoaddiction’s diagnostic value, stating:

6 The distinction then is understood as resting on the idea that
7 pseudoaddiction patients cease aberrant drug-related behaviors and opioid
8 misuse after their pain has been effectively treated. However, even this
9 description of pseudoaddiction does not ultimately address how it can be
10 reliably teased apart from addiction since “true addicts” will refrain from
11 drug-seeking at least temporarily after receiving opioids⁹⁰

12 Despite pseudoaddiction’s lack of empirical validation in scientific literature and its
13 questionable clinical value, Purdue used the concept of pseudoaddiction to promote higher
14 doses of opioids to treat patients with drug-seeking behaviors. This promotion was
15 deceptive and lacked balance.

16 **b. Purdue Deceptively Minimized the Difficulties of Preventing
17 Addiction**

18 Purdue downplayed the difficulties of preventing addiction. Purdue’s deceptive
19 messaging misrepresented the true risk of addiction posed by long-term opioid use by
20 falsely creating the impression that “problem” patients who were likely to become
21 addicted could be accurately identified and screened out. [REDACTED]

22 [REDACTED]
23 [REDACTED].⁹¹ On information and belief, in 2011, Purdue sponsored a webinar, “Managing

24 _____
25 ⁸⁸ Marion S. Greene and R. Andrew Chambers, *Pseudoaddiction: Fact or Fiction?*,
26 *Current Addict. Rep.*, 312 (2015), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4628053>, a copy of relevant pages of which is attached as Exhibit V.

27 ⁸⁹ *Id.* at 313.

28 ⁹⁰ *Id.* (internal citation omitted).

⁹¹ Arvizu Dec., ¶ (9)(i) and Exhibit E-15.

1 Patient’s Opioid Use: Balancing the Need and Risk,” in which it claimed that screening
2 tools, urine tests, and patient agreements prevented “overuse of prescriptions” and
3 “overdose deaths.”⁹² Many of these tools were touted on Purdue’s now-defunct website
4 www.partnersagainstpain.com as late as 2016.⁹³

5 Purdue oversold the effectiveness of patient screening. The CDC found in 2016
6 that studies on the accuracy of screening tools and other mechanisms for identifying and
7 predicting risk of addiction were “extremely inconsistent” and noted that “currently
8 available tools do not allow clinicians to reliably identify patients who are at low risk for
9 substance abuse disorder.”⁹⁴

10 **B. The State Notified Purdue of Its Alleged Violations**

11 After an extensive investigation, which included the issuance of several civil
12 investigative demands under A.R.S. § 44-1524, on June 29, 2018, pursuant to section VIII
13 of the 2007 Judgment, the State sent Purdue written notification of the State’s contention
14 that Purdue had violated the 2007 Judgment. The State’s notification detailed the sections
15 of the judgment that Purdue violated and the third-party front groups and promotional
16 materials through which these violations occurred.⁹⁵ Purdue received this notice on July 2,
17 2018, and, after requesting and receiving an extension of its deadline to respond,
18 responded on August 24, 2018.⁹⁶

19 In Purdue’s response, among other conclusory statements, it denied that it violated
20 the 2007 Judgment. Purdue did admit it paid the third parties at issue above. And Purdue
21 extolled remedial actions it has taken to address the opioid crisis. But Purdue failed to

22
23 ⁹² See *CE Education, Managing Patient’s Opioid Use: Balancing the Need and the Risk*,
Emerging Solutions in Pain, MediCom Worldwide, Inc., [http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&
24 view=frontmatter&Itemid=303&course=209](http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209) (last visited July 26, 2018), a screen capture
25 of which is attached as Exhibit W.

26 ⁹³ Arvizu Dec., ¶ (9)(i) and Exhibit E-15.

27 ⁹⁴ CDC Guideline, *supra* note 39, and Exhibit M at 10–11, 31.

28 ⁹⁵ See Arvizu Dec., ¶ 10 and Exhibit E-16.

⁹⁶ *Id.*

1 account for violations occurring before it took remedial action and it failed to support its
2 arguments by providing the State documentary evidence or by referencing documents it
3 had produced to the State previously.⁹⁷

4 **IV. Violations**

5 Section X of the 2007 Judgment granted the State the right to claim that Purdue
6 violated the judgment in a separate civil action to enforce the judgment or to seek any
7 other relief afforded by law.

8 Purdue engaged in deceptive and unbalanced marketing, including: misleadingly
9 representing oxycodone's efficacy; deceptively representing oxycodone as safer than can
10 be demonstrated by substantial clinical evidence; failing to balance promotion of
11 oxycodone's favorable characteristics with education regarding the drug's serious side
12 effects; and minimizing oxycodone's potential for abuse, addiction or dependence.
13 Whether through branded or unbranded materials, Purdue did so to sell its oxycodone
14 drugs. Therefore, this marketing falls within the scope of the 2007 Judgment's
15 prohibitions and requirements regarding the promotion and marketing of oxycodone.

16 As is evident in the misrepresentations and material omissions described in above,
17 Purdue violated section II of the 2007 Judgment, particularly: paragraph 2 and 11's
18 prohibitions against false, misleading or deceptive marketing and paragraph 20's
19 corresponding requirement to communicate truthfully and accurately; paragraph 4, 11 and
20 20's requirements to provide balanced statements in marketing materials; and paragraph 5
21 and 20's prohibitions against deceptive representations minimizing oxycodone's potential
22 for abuse, addiction or physical dependence.

23 Under A.R.S. § 44-1532, if a person violates an order or injunction issued pursuant
24 to the Consumer Fraud Act, that person shall pay civil penalties of not more than \$25,000
25 per violation. The State intends to seek the maximum allowable penalties in this case,
26 given that Purdue misled consumers about the risks of potentially deadly drugs, and did so

27 ⁹⁷ See *id.* at ¶ 11 and Exhibit E-17.
28

1 in defiance of this Court's order.

2 The State also intends to seek any other remedy available by law or equity,
3 including restitution and disgorgement under A.R.S. § 44-1528 and costs and attorneys'
4 fees under A.R.S. § 44-1534.

5 Purdue should be required to appear and show cause as to why it should not be
6 found to have violated the 2007 Judgment.

7 **V. Conclusion**

8 The State's evidence shows that Defendants violated this Court's 2007 Judgment.
9 Therefore, the State respectfully requests that the court enter the form of *Order to Show*
10 *Cause* submitted with this application.

11 Dated September 10, 2018.

12 MARK BRNOVICH
13 ATTORNEY GENERAL

14 By: /s/ Stephen J. Womack
15 Stephen J. Womack
16 Jennifer Bonham
17 Bryce Clark
Assistant Attorneys General

18 *Attorneys for Plaintiff State of Arizona*

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1 Original of the foregoing e-filed on September 10, 2018, with:

2 Pima County Clerk of Court
3 Arizona Superior Court in Pima County
4 110 W. Congress St.
5 Tucson, AZ 85701-1317

6 Unredacted copy of the foregoing mailed on September 10, 2018, to:

7 Honorable Richard Gordon
8 Arizona Superior Court in Pima County
9 110 W. Congress St.
10 Tucson, AZ 85701-1317

11 Unredacted copy of the foregoing emailed or mailed September 10, 2018, to:

12 Timothy J. Shea
13 Morgan, Lewis & Bockius LLP
14 Morgan Lewis Consulting LLC
15 One Federal St.
16 Boston, MA 02110
17 Tele: 617-951-8806
18 Email: timothy.shea@morganlewis.com

19 Timothy M. Frey
20 Skadden, Arps, Slate, Meagher & Flom LLP
21 155 N. Wacker Dr.
22 Chicago, IL 60606-1720
23 Tele: 312-407-0654
24 Email: timothy.frey@skadden.com

25 Robert S. Hoff
26 Wiggin and Dana
27 281 Tresser Blvd.
28 Stamford, CT 06901
Tele: 203.363.7626
Email: rhoff@wiggin.com

Patrick Fitzgerald
Skadden, Arps, Slate, Meagher & Flom LLP
155 N. Wacker Dr.
Chicago, IL 60606-1720
Tele: 312-407-0508
Email: patrick.fitzgerald@skadden.com

Attorneys for Defendants

By: /s/ Jennifer Gunther