# IN THE CIRCUIT COURT FOR KNOX COUNTY SIXTH JUDICIAL DISTRICT AT KNOXVILLE

STATE OF TENNESSEE, ex rel. HERBERT H. SLATERY III,	LAOX COUNTY OF THE
ATTORNEY GENERAL and REPORTER,	) ) JURY DEMAND
Plaintiff,	)
<b>v.</b>	) Case No. 1-173-18
PURDUE PHARMA L.P., a foreign limited partnership,	) ) Judge Kristi Davis )
Defendant.	, )

# STATE OF TENNESSEE'S RESPONSE IN OPPOSITION TO DEFENDANT'S MOTION FOR PROTECTIVE ORDER

### **SUMMARY**

The State of Tennessee opposes Defendant Purdue Pharma L.P.'s Motion for a Protective Order and asserts that the Complaint should be made available to the public without restriction. Defendant seeks full or partial redactions to 418 paragraphs of the filed Complaint that it submits contain confidential, proprietary, and trade secret information about its opioid sales and promotional activities. If granted, a protective order would hide specific examples of Defendant's unlawful conduct, its scale and statewide impact, Defendant's knowledge of its unlawful acts, and Defendant's financial gain from the prescriptions written by specific prescribers whose practices showed indications of abuse or diversion of OxyContin from the public. The Motion should be denied. The opioid crisis is one of the most devastating public health crises in the State's history.

<sup>&</sup>lt;sup>1</sup> A chart that summarizes the information at issue and grounds for disclosure is attached as Ex. 1 to this Response.

Tennesseans are entitled to see the evidence supporting the allegations in the Complaint that detail Defendant's substantial role in causing the opioid crisis including:

- how, to whom, where, and the frequency with which Defendant misrepresented the safety, efficacy, comparative benefits, and other aspects of its opioid products;
- what Defendant knew about red flags for abuse or diversion of OxyContin at the practices of prescribers its sales representatives called upon;
- whether Defendant continued to promote opioids to these prescribers after knowledge of warning signs for abuse or diversion of OxyContin;
- how much Defendant profited from the prescriptions of prescribers whose practices showed signs of abuse or diversion of OxyContin;
- how Defendant's savings cards functioned as vehicles for OxyContin abuse or diversion that the Company knew or should have known about;
- the type of prescribers and health care providers Defendant targeted; and
- the number of high dose OxyContin pills sold in Tennessee over time.

In its Motion, Defendant simply has not met the substantial burden necessary to abridge the public's right of access to the Complaint. Specifically, Defendant has not established the confidentiality of any of the information it seeks to redact and has not shown a clearly defined injury that would result from disclosure.

The vast majority of information Defendant seeks to redact relates to the promotion of opioids to prescribers, which Defendant says it has stopped and will no longer do,<sup>2</sup> that Defendant's branded competitors state they no longer do,<sup>3</sup> and that future generic competitors would be highly unlikely to do because they engage in little or no promotion.<sup>4</sup> Further, the vast majority of information Defendant seeks to redact:

<sup>&</sup>lt;sup>2</sup> See Def. Mem. in Supp., at 9; Ex. 2 to State's Resp., Purdue Pharma L.P. Issues Statement on Opioid Promotion (Feb. 9, 2018).

<sup>&</sup>lt;sup>3</sup> Ex. 3 to the State's Resp., Beat You to It, Purdue. Other Opioid Makers Already Ditched Promotions, FIERCEPHARMA, available at https://www.fiercepharma.com/marketing/beat-you-to-it-purdue-other-opioid-makers-already-ditched-promotions (Feb. 14, 2018) (article quoting Endo, Teva, Allergan, and Johnson & Johnson's Janssen spokespersons each stating that promotion of opioids has stopped).

<sup>&</sup>lt;sup>4</sup> Ex. 4 to State's Resp., ABA ANTITRUST PHARMACEUTICAL INDUSTRY HANDBOOK, at 402.

- is evidence of Defendant's misrepresentations, omissions, and other unlawful conduct;
- consists of call notes that memorialize discussions to third-party prescribers that, if done lawfully, should be based on claims contained on its publicly-available label;
- is substantially similar to information already in the public domain through other lawsuits and news stories:
- is substantially similar to sales and promotional data available from third parties;
- would have limited use for branded competitors in the current opioid marketplace because of the dates of the information; and
- only identifies prescribers Defendant called upon by name who have had criminal convictions related to controlled substances, disciplinary actions related to controlled substances, or are deceased.

Defendant's conclusory allegations as to harm do not satisfy its burden and they must yield to the greater public interest in disclosure of the Company's role in substantially causing the opioid crisis in the State.

### **BACKGROUND**

Under the Tennessee Consumer Protection Act (TCPA), the State is authorized to both issue requests for information to gather materials that may be relevant to an investigation *and* to present these materials to a court when the State deems it necessary for enforcement. Tenn. Code Ann. § 47-18-106. Under this authority, the State issued a series of requests for information to Defendant beginning in September 2014.

The parties negotiated two confidentiality agreements, one dated January 2015, Exhibit A to Defendant's Memorandum in Support, which is not the controlling agreement, and the second, dated February 2017, which expressly supersedes and revokes all previous agreements.<sup>5</sup> Significantly, neither agreement contains an acknowledgment by the State that the documents

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<sup>&</sup>lt;sup>5</sup> Ex. 5 to the State's Resp., at ¶ 12.

turned over to the Attorney General were within the definition of confidential and neither agreement precluded use of documents Defendant marked as confidential in litigation.

As part of its investigation, the State reviewed documents and information that Defendant produced in response to the State's requests for information and subsequently placed detailed examples of this evidence in an annotated 272-page Complaint. The State's Complaint contains specific examples of Defendant's unlawful conduct, its scale and impact on the State, the Company's knowledge of its activities, and financial gain. The State used this evidence to plead its Complaint with specificity and to provide transparency as to the basis for specific allegations.

Prior to filing suit, the State separately provided Defendant with the groundwork for its Complaint in both a ten days' notice of its intent to sue under the TCPA and a thirty business days' advanced notice under the 2007 Consent Judgment. In accordance with both confidentiality agreements that *Defendant negotiated and agreed to*, the State filed its Complaint under a temporary seal that expired ten days after service.

### LEGAL STANDARD

The public has a right of access to court records, which may only be abridged upon a showing of good cause. *Ballard v. Herzke*, 924 S.W.2d 652, 658 (Tenn. 1996) (citations omitted); Tenn. R. Civ. P. 26.03. To establish good cause, a "moving party *must* show that disclosure will result in a clearly defined injury to the party seeking closure." *Ballard*, 924 S.W.2d at 658 (emphasis added). Mere conclusory allegations as to harm are legally insufficient to prevent disclosure and the burden of justifying the confidentiality of each document sought to be covered by a protective order is on the party seeking the order. *Id*; *Loveall v. Am. Honda Motor Co., Inc.*, 694 S.W.2d 937, 939 (Tenn. 1985). A showing of good cause is required for trade secrets and other

confidential commercial information because they "enjoy no privilege from disclosure[.]" *Loveall*, 694 S.W.2d at 939; Tenn. R. Civ. P. 26.03.

Factors weighing *in favor* of good cause include: (1) the litigation involves private litigants; (2) the litigation concerns matters of private concern or of little legitimate public interest; and (3) disclosure would result in serious embarrassment or other specific harm. *Ballard*, 924 S.W.2d at 658-59 (citations omitted). No particular weight is assigned to any factor, and the balancing test allows trial courts to evaluate the competing considerations in light of the facts of each individual case. *In re NHC – Nashville Fire Litig.*, 293 S.W.3d 547, 563 (Tenn. Ct. App. 2008).

In considering a motion for a protective order, the court "must consider whether the information sought to be shielded from public view is important to public health and safety." In re NHC—Nashville Fire Litig., 293 S.W.3d at 567 (emphasis added) (citations omitted). Further, any restriction on public access to judicial records must be narrowly tailored to accommodate the competing interests without unduly impeding the free flow of information. Knoxville News-Sentinel v. Huskey, 982 S.W.2d 359, 362 (Tenn. Crim. App. 1998). Within these principles, "[t]he ultimate decision as to whether or not a protective order should issue is entrusted to the sound discretion of the trial court." Ballard, 924 S.W.2d at 659 (citations omitted).

### **ARGUMENT**

The public's right of access to the State's Complaint should not be abridged because Defendant has not made a showing of good cause. The State is a public litigant, the litigation concerns matters of public interest, and Defendant has not shown that disclosure will result in a clearly defined injury. Moreover, the information that Defendant seeks to shield from public view is important to public health and safety, which weighs in favor of disclosure.

# I. The public has a right of access to the State's Complaint.

The public has a common law right of access to filed judicial records and documents. *See Nixon v. Warner Commc'ns*, 435 U.S. 589, 597, n. 7, n. 8 (1978); *see also In re NHC—Nashville Fire Litig.*, 293 S.W.3d at 560. The Tennessee Supreme Court described the general right to access judicial records and documents as "beyond dispute" and as serving to:

(1) promote community respect for the rule of law, (2) provide a check on the activities of judges and litigants, and (3) foster more accurate fact finding. [T]he right of access to judicial proceedings and records was originally justified by common law traditions predating the enactment of the federal Constitution. The common law right of access establishes that court files and documents should be open, unless the court finds that the records are being used for improper purposes. [M]oreover, the First Amendment to the Constitution presumes that there is a right of access to proceedings and documents which have "historically been open to the public" and which disclosure would serve a significant role in the functioning of the process.

Ballard, 924 S.W.2d at 661 (internal citations omitted).

The public has both a common law and a First Amendment right of access to the State's Complaint under these principles. First, the State has filed its Complaint and cited the documents and information at issue for a proper purpose, namely to substantiate and detail the serious allegations contained in its enforcement action in a transparent manner. Second, civil enforcement complaints filed by the State in its sovereign capacity have historically been open to the public. Third, disclosure would serve a significant role in the functioning of the process especially because Defendant's misrepresentations about the safety and efficacy of its opioid products and how it responded to red flags for the abuse and diversion of OxyContin are matters of significant consequence for public health and safety. Broad access to the State's Complaint will ensure that the means used to achieve justice for those responsible for the opioid crisis have support derived from public acceptance of both the legal process and its results.

# II. Defendant has not established good cause for a protective order.

A party seeking to limit the public's right of access to judicial records must establish good cause for doing so. "In determining whether good cause has been established for a protective order, it is important that trial courts balance one party's need for information against the injury that would allegedly result if disclosure were compelled." *Ballard*, 924 S.W.2d at 658. Here, the *Ballard* factors weigh in favor of disclosure and Defendant has not met its burden to show good cause.

# A. The litigation is brought by the sovereign and is of substantial public interest.

The public interest in disclosure of the State's Complaint is substantial. The State's action is brought in its sovereign capacity by its Attorney General, as part of its civil enforcement action to combat and help remedy the opioid epidemic—one of the largest public health crises the State has faced in its history—against the country's largest branded opioid manufacturer. It is difficult to imagine litigation that is of more public concern.

Defendant concedes that the State's litigation as a whole "involves issues of public concern," but asserts that *the information* it seeks to redact is of little public concern. Def.'s Mem. in Supp., at 9. But, Defendant misapplies *Ballard*'s *public interest* factors to establish good cause for a protective order, which are whether the litigants are public or private and whether "the litigation concerns matters of private concern or of little legitimate public interest." 924 S.W.2d at 658-59 (citations omitted) (emphasis added). Here, two of the three *Ballard* factors that weigh against a protective order, namely that the litigation involves a public litigant and involves issues of public concern, are undisputed.

Even if one were to apply *Ballard* as Defendant submits, the argument does not provide good cause. At the outset, *all* of the pieces of information Defendant seeks to redact constitutes

examples of evidence in the case that will be submitted to the Court through a summary judgment motion or at trial. The information can be categorized into direct evidence of Defendant's unlawful conduct, its scale and impact on the State, Defendant's knowledge of its actions, and Defendant's financial gain from prescribers whose practices showed warning signs for abuse or diversion of OxyContin. Common sense suggests the public has a substantial interest in the specific pieces of information that Defendant seeks to redact, which concern all or part of 418 separate paragraphs of the State's Complaint. *See* Def. Mot., Ex. A, Darragh Aff., at ¶10.

Based on Tennessee Supreme Court precedent, the information should be disclosed. In Loveall v. American Honda Motor Company, the Court modified a protective order that prohibited dissemination of confidential development reports for Honda motorcycles in a personal injury case. 694 S.W.2d at 940. Even though the case involved private parties and an undisputed trade secret, the Tennessee Supreme Court expressly placed "no restriction on the dissemination of the information actually introduced at trial or obtained other than through discovery" and limited the protective order Honda sought "to only competitively sensitive information not introduced into evidence." Id.

While the information in the State's Complaint is not yet introduced into evidence, there is good reason to believe it will be. The State cites to and quotes from Defendant's own documents and Defendant, through its Motion, does not contest the accuracy of the information it seeks to redact. Rather, Defendant seeks to redact this information *because of* its accuracy. While admissibility determinations are premature, the strong likelihood of the information being used as evidence to support summary judgment motions or at trial weighs in favor of disclosure.

Regardless, a determination of the merits of the allegations is not a prerequisite for the public's right of access because the Tennessee Supreme Court has described the right of access to

judicial documents interchangeably with the right of access to judicial proceedings that occur prior to a final adjudication. *See Ballard*, 924 S.W.2d at 661 (internal citations omitted). The public has a right of access even to the State's *allegations*, which vindicate the concerns of victims and the community in knowing that offenders are being brought to account for their actions. *Id*.

The public has an interest in knowing each of the ten categories of information contained in the State's allegations that Defendant seeks to withhold. These categories include:

- (1) the text of call notes that document conversations sales representatives had with prescribers (300 paragraphs);<sup>6</sup>
- (2) the text of reports from Defendant's abuse and diversion detection (ADD) program that concern prescribers (43 paragraphs);<sup>7</sup>
- (3) the frequency of Defendant's visits to individual Tennessee prescribers who were flagged or should have been flagged by Defendant's abuse and diversion detection program (20 paragraphs);<sup>8</sup>
- (4) the percentage of Defendant's sales that stem from new patients as compared to existing patients (2 paragraphs);<sup>9</sup>
- (5) the number of prescriptions and tablets prescribed by individual Tennessee prescribers on an annual basis and revenue Defendant acquired from these Tennessee sales (22 paragraphs);<sup>10</sup>
- (6) the number, percentage, and dollar figures from Defendant's savings card redemptions from individual Tennessee prescribers (4 paragraphs);<sup>11</sup>
- (7) research about how the savings card program impacts sales (5 paragraphs);<sup>12</sup>
- (8) the number of sales representatives Defendant employed in Tennessee and the total number of sales visits they made statewide on an annual basis (6 paragraphs);<sup>13</sup>
- (9) internal research on what factors impact prescription rates (1 paragraph);14 and
- (10) details of Defendant's marketing and training materials (26 paragraphs). 15

<sup>&</sup>lt;sup>6</sup> Def. Mot. Ex. A, Darragh Aff., at ¶10a.

<sup>&</sup>lt;sup>7</sup> Def. Mot. Ex. A, Darragh Aff., at ¶10a.

<sup>&</sup>lt;sup>8</sup> Def. Mot. Ex. A, Darragh Aff., at ¶10b.

<sup>&</sup>lt;sup>9</sup> Def. Mot. Ex. A, Darragh Aff., at ¶10c.

<sup>&</sup>lt;sup>10</sup> Def. Mot. Ex. A, Darragh Aff., at ¶10d.

<sup>&</sup>lt;sup>11</sup> Def. Mot. Ex. A, Darragh Aff., at ¶10e.

<sup>&</sup>lt;sup>12</sup> Def. Mot. Ex. A, Darragh Aff., at ¶10f.

<sup>&</sup>lt;sup>13</sup> Def. Mot. Ex. A, Darragh Aff., at ¶10g.

<sup>&</sup>lt;sup>14</sup> Def. Mot. Ex. A, Darragh Aff., at ¶10h.

<sup>15</sup> Def. Mot. Ex. A, Darragh Aff., at ¶10i.

A summary of the information at issue and the reasons for disclosure are attached as Ex. 1 to the State's Response.

1. The information Defendant seeks to redact is direct evidence of its unlawful conduct (Categories 1, 2, and 3).

The State asserts that Defendant misrepresented the safety, efficacy, and comparative benefits of its opioid products, among other things. The public has an interest in seeing specific examples of Defendant's unlawful conduct. First, the text of call notes (category 1), which are contained in 300 of the 418 paragraphs that Defendant seeks to redact, are evidence of specific misrepresentations and omissions Defendant made to third-party prescribers in Tennessee. The call notes identify the date, type of provider, location in Tennessee, and contain an excerpt of the discussion Defendant's sales representative had with the third-party prescriber.

The State alleges that Defendant failed to comply with the 2007 Consent Judgment it entered into with the State of Tennessee that required it to take appropriate steps including the cessation of promotion to prescribers whose practices showed red flags for abuse or diversion. The text of the ADD notes (category 2) and the frequency of Defendant's visits to these prescribers (category 3), both of which Defendant seeks to redact, demonstrate red flags for abuse and diversion of OxyContin at the practices of specific prescribers, when the Company knew it, and whether the Company continued to make sales calls to these prescribers or follow its own policies.

The public has an interest in these examples of Defendant's unlawful conduct, which collectively comprise about 86% of the paragraphs Defendants seek to redact.

2. The information Defendant seeks to redact shows the statewide impact and scale of Defendant's unlawful conduct and aggressive marketing. (Categories 5, 8, and 10)

The State asserts that Defendant engaged in highly aggressive, statewide marketing of its opioid products, particularly for high dose OxyContin, and that this and other conduct substantially

contributed to the opioid crisis in Tennessee. Defendant seeks to withhold information that shows the statewide impact and scale of its conduct in two main ways.

First, Defendant seeks to withhold compelling information about the statewide impact and scale of its conduct, especially facts about quantities of high dose OxyContin, including:

- the total number of OxyContin tablets prescribed in Tennessee from 2008 to 2017<sup>16</sup> (category 8);
- the percentage of these tablets that were 40 mg or higher<sup>17</sup> (category 8);
- the percentage of 40 mg or higher tablets from January 2007 to August 2017 that were prescribed by different types of prescribers in Tennessee<sup>18</sup> (category 10);
- the total morphine milligram equivalents (common units to establish the potency of different opioids) of OxyContin sold in Tennessee from 2008 to 2017<sup>19</sup> (category 5); and
- the number of OxyContin tablets per person in Morristown, Memphis, Nashville, and Knoxville from 2008 to 2017 (category 5).

Second, Defendant seeks to restrict information about the scale of its marketing presence in Tennessee, including:

- the number and percentage of Defendant's sales calls in Tennessee that were devoted to specific types of health care prescribers over the last 10 years<sup>20</sup> (category 8);
- the total number of Defendant's sales representatives, district managers, and regional managers who worked in Tennessee from 2006 to 2017<sup>21</sup> (category 8);
- the approximate total number of sales calls Defendant made in Tennessee from May 7, 2007 to December 2017<sup>22</sup> (category 8); and
- the number of sales calls Defendant made in Tennessee from 2007 to 2016<sup>23</sup> (category 8).

<sup>&</sup>lt;sup>16</sup> Def. Mot., Ex. A, Darragh Aff. ¶10g (citing Compl. ¶20).

<sup>&</sup>lt;sup>17</sup> Def. Mot., Ex. A, Darragh Aff. ¶10g (citing Compl. ¶20).

<sup>18</sup> Def. Mot., Ex. A, Darragh Aff. ¶10i (citing Compl. ¶896).

<sup>&</sup>lt;sup>19</sup> Def. Mot., Ex. A, Darragh Aff. ¶10d (citing Compl. ¶872).

<sup>&</sup>lt;sup>20</sup> Def. Mot., Ex. A, Darragh Aff. ¶10g (citing Compl. ¶29).

<sup>&</sup>lt;sup>21</sup> Def. Mot., Ex. A, Darragh Aff. ¶10g (citing Compl. ¶13). <sup>22</sup> Def. Mot., Ex. A, Darragh Aff. ¶10g (citing Compl. ¶51).

<sup>&</sup>lt;sup>23</sup> Def. Mot., Ex. A, Darragh Aff. ¶10g (citing Compl. ¶51).

These are all highly relevant facts to the State's enforcement action, which concerns the impact of Defendant's marketing and other conduct throughout the State, that should be disclosed to the public.

# 3. The information Defendant seeks to redact shows Defendant's knowledge of its conduct. (All categories)

Defendant seeks to withhold information that establishes the Company's knowledge of its conduct and its intent and success in achieving specific marketing outcomes that the State asserts substantially contributed to the opioid epidemic. In addition to the categories discussed above, Defendant seeks to do this in multiple other ways as well.

First, Defendant seeks to redact highly-relevant information concerning prescribers whose practices Defendant knew to have indications of abuse of diversion of OxyContin, including:

- the total number of tablets of high dose OxyContin they prescribed in a set time period<sup>24</sup> (category 5),
- the total number of OxyContin tablets they prescribed in a set time period<sup>25</sup> (category 5),
- the total number of OxyContin prescriptions they prescribed in a set time period<sup>26</sup> (category 5),
- the percentage of patients of these prescribers who Defendant knew to pay in cash<sup>27</sup> (a red flag for abuse or diversion) (category 5),
- revenue Defendant knew it received for OxyContin prescriptions from prescribers whose practices showed red flags for abuse and diversion<sup>28</sup> (category 5), and
- information it possessed on the impact of its abuse and diversion detection programs on its business<sup>29</sup> (category 10).

<sup>&</sup>lt;sup>24</sup> Def. Mot., Ex. A, Darragh Aff. ¶10d (citing Compl. ¶¶474, 533, 560, 575, 587, 608, 638, 685, 735, 744, 760, 769, 798, 823, 860).

<sup>&</sup>lt;sup>25</sup> Def. Mot., Ex. A, Darragh Aff. ¶10d (citing Compl. ¶¶474, 560, 575, 608-09, 638, 685, 735, 744, 760, 769, 798, 823, 860).

<sup>&</sup>lt;sup>26</sup> Def. Mot., Ex. A, Darragh Aff. ¶10d (citing Compl. ¶¶475, 576, 587, 608-09, 638, 744, 760, 798).

<sup>&</sup>lt;sup>27</sup> Def. Mot., Ex. A, Darragh Aff. ¶10d (citing Compl. ¶¶545, 587, 608, 798).

<sup>&</sup>lt;sup>28</sup> Def. Mot., Ex. A, Darragh Aff. ¶10d (citing Compl. ¶¶533, 590).

<sup>&</sup>lt;sup>29</sup> Def. Mot., Ex. A, Darragh Aff. ¶10i (citing Compl. ¶462).

Second, Defendant seeks to withhold details about its OxyContin savings cards (categories 6 and 7), which the Company knew or should have known were being used to subsidize diversion. Defendant's savings cards acted like a coupon to offset the cost of OxyContin prescription purchases, could be used by cash-paying patients (a red flag for diversion) until 2015, and were used to track patient-specific data about the prescription including dose, quantity, and refills. The savings card information that Defendant seeks to redact show savings card redemption rates for patients of prescribers whose practices showed signs of abuse or diversion<sup>30</sup> and data Defendant collected from savings card redemptions showing prescriptions for large quantities of high dose OxyContin that were highly unlikely to be consumed by a single patient and that had high street values.<sup>31</sup>

Third, Defendant seeks to redact the exact percentages of its business that it knew came from *continued users* from August 2009 to March 2011, during another six-month period in 2011, and an eight-month period in 2015 (category 4).<sup>32</sup> These figures are highly relevant to the State's allegations that Defendant made misrepresentations and omissions as to the safety and addictiveness of its opioid products through an aggressive marketing campaign and sales model that emphasized and relied on patients who continued to use Defendant's opioid products. Defendant also seeks to redact the percentage of those patients who switched from immediate release opioids, which are less potent, to oxycodone extended release, which is more potent, in 2008 (category 4).<sup>33</sup> Figures showing the success of Defendant's efforts to move patients from less potent to its more potent opioids are highly relevant to the State's allegations that Defendant

<sup>&</sup>lt;sup>30</sup> Def. Mot., Ex. A, Darragh Aff. ¶10g (citing Compl. ¶¶534, 536, 643, 719).

<sup>&</sup>lt;sup>31</sup> Def. Mot., Ex. A, Darragh Aff. ¶10e (citing Compl. ¶536).

<sup>&</sup>lt;sup>32</sup> Def. Mot., Ex. A, Darragh Aff. ¶10c (citing Compl. ¶133).

<sup>&</sup>lt;sup>33</sup> Def. Mot., Ex. A, Darragh Aff. ¶10c (citing Compl. ¶249).

misrepresented the addictive potential of its high does opioids and its substantiation for long term use. Both the percentages and the underlying documents cited show that Defendant knew about the extent of its OxyContin business that came from immediate release opioids and from continued users. This information is of immense public concern.

Fourth, Defendant seeks to redact information about specific examples of its marketing initiatives and training for its sales representatives including:

- information showing the types of prescribers Defendant targeted for sales calls<sup>34</sup> (category 8);
- information concerning Defendant's coordination with distributors to ensure that pharmacies carried more OxyContin<sup>35</sup> (category 9);
- information about how Defendant's unbranded marketing was used to promote Defendant's branded products<sup>36</sup> (category 10);
- information about the relationship between compensation of sales representatives and certain prescribers (category 10);
- details as to how Defendant trained sales representatives to make prescribers more likely to prescribe Defendant's products<sup>37</sup> (category 10);
- details as to how Defendant trained sales representatives to promote high doses of OxyContin<sup>38</sup> and OxyContin generally<sup>39</sup> (category 10);
- details about how the company trained sales representatives to generate additional prescriptions of OxyContin<sup>40</sup> (category 10); and
- details about how to make comparisons between OxyContin and competing opioid products including Opana and opioids with acetaminophen<sup>41</sup> (category 10).

All of this information, which establishes Defendant's knowledge of actions the State alleges substantially contributed to the opioid epidemic, is of public concern.

<sup>&</sup>lt;sup>34</sup> Def. Mot., Ex. A, Darragh Aff. ¶10g (citing Compl. ¶30-31); ¶10i (citing Compl. ¶29-32).

<sup>&</sup>lt;sup>35</sup> Def. Mot., Ex. A, Darragh Aff. ¶10h (citing Compl. ¶887).

<sup>&</sup>lt;sup>36</sup> Def. Mot., Ex. A, Darragh Aff. ¶10i (citing Compl. ¶45).

<sup>&</sup>lt;sup>37</sup> Def. Mot., Ex. A, Darragh Aff. ¶10i (citing Compl. ¶97).

<sup>&</sup>lt;sup>38</sup> Def. Mot., Ex. A, Darragh Aff. ¶10i (citing Compl. ¶¶155-56).

<sup>&</sup>lt;sup>39</sup> Def. Mot., Ex. A, Darragh Aff. ¶10i (citing Compl. ¶188).

<sup>&</sup>lt;sup>40</sup> Def. Mot., Ex. A, Darragh Aff. ¶10i (citing Compl. ¶879).

<sup>&</sup>lt;sup>41</sup> Def. Mot., Ex. A, Darragh Aff. ¶10i (citing Compl. ¶¶202, 283-85, 299, 360).

4. The information Defendant seeks to redact shows Defendant's financial gain from the prescriptions of prescribers whose practices showed red flags for abuse or diversion of OxyContin. (Category 5)

Defendant seeks to redact its financial gain from the prescriptions of Tennessee prescribers whose practices showed indications of abuse or diversion of OxyContin. The State asserts that Defendant ignored red flags for abuse and diversion because these prescribers were valuable to Defendant. The revenue that Defendant obtained from these prescribers shows motive and its failure to comply with the 2007 Consent Judgment, which is of public concern.

B. Defendant has not shown disclosure would result in serious embarrassment or other specific harm.

To establish good cause for a protective order, Defendant *must* show that disclosure will result in a clearly defined injury, namely serious embarrassment or other specific harm. *Ballard*, 924 S.W.2d at 658-59; *In re NHC-Nashville Fire Litig.*, 293 S.W.3d at 561. Defendant asserts that disclosure will "reveal Purdue's proprietary business and marketing research, as well as Purdue-specific sales and marketing data" and that the details could give a competitor "insight into Purdue's structure, internal workings, and its marketing and development strategies." Def. Mot. Ex. A, Darragh Aff. at ¶8. These generalized assertions are insufficient and do not provide the Court with the "clearly defined injury" that would result if the Complaint is made public. "Broad allegations of harm, unsubstantiated by specific examples of articulated reasoning, do not amount to a showing of good cause" under Rule 26.03. *In re NHC-Nashville Fire Litig.*, 293 S.W.3d at 563 (internal citations and quotations omitted).

Defendant cannot show a clearly defined injury from disclosure for the reasons listed below:

<sup>&</sup>lt;sup>42</sup> Def.'s Mem. in Supp., at 5-6.

# 1. Much of the information Defendant seeks to redact is not a trade secret.

While a finding that select information is a trade secret alone is not determinative for a protective order and still requires a showing of good cause, 43 much of the information that Defendant seeks to redact is not a trade secret in the first place. For example, Defendant's sales call notes are supposed to memorialize discussions that Defendant's sales representative had with a third-party prescriber, which by their nature are not confidential. Further, unlike other industries, the primary basis for marketing claims Defendant can lawfully make is already known to Defendant's competitors through Defendant's product labels which are available to the public.44 Here, the State asserts that Defendant's marketing claims were unlawful. Defendant cannot assert specific harm for disclosure of marketing claims that it cannot lawfully make in the first place. "[D]eceptive, illegal or fraudulent activity simply cannot qualify for protection as a trade secret." *Goodman v. Genworth Fin. Wealth Mgmt.*, 881 F. Supp. 2d 347, 355 (E.D.N.Y. 2012).

Aside from call notes, much of the other information Defendant seeks to redact is evidence of unlawful conduct—not a trade secret. For example, Defendant seeks to redact:

- 43 paragraphs of abuse and diversion detection program notes that the State asserts contain evidence showing Defendant's violation of the 2007 Consent Judgment and the TCPA;<sup>45</sup>
- 20 paragraphs showing the frequency of visits to specific prescribers despite warning signs for abuse or diversion at their practices that are also evidence of Defendant's violation of the 2007 Consent Judgment and the TCPA;<sup>46</sup>
- 4 paragraphs concerning savings card data that Defendant collected that it knew or should have known were used to fund the diversion of OxyContin;<sup>47</sup> and

<sup>43</sup> Loveall, 694 S.W.2d at 939.

<sup>&</sup>lt;sup>44</sup> See, e.g., https://www.accessdata.fda.gov/drugsatfda docs/label/2015/022272s027lbl.pdf.

<sup>&</sup>lt;sup>45</sup> Def. Mot. Ex. A, Darragh Aff., at ¶10a.

<sup>&</sup>lt;sup>46</sup> Def. Mot. Ex. A, Darragh Aff., at ¶10b.

<sup>&</sup>lt;sup>47</sup> Def. Mot. Ex. A, Darragh Aff., at ¶10e.

 other evidence that shows the impact and scale of Defendant's unlawful conduct on the State, Defendant's knowledge of its unlawful acts, and indications of Defendant's financial gain from these activities from public view.

# 2. The vast majority of information Defendant seeks to redact relates to marketing that Defendant and its major branded competitors say they no longer perform.

Defendant cannot show specific harm from disclosure because the vast majority of information Defendant seeks to redact relates to marketing that Defendant and its competitors say they no longer perform. Defendant announced on February 9, 2018 that its "sales representatives will no longer promote opioids to prescribers." Its competitors, namely Endo, Janssen, Allergan, and Teva, have also stated publicly that they no longer promote opioids to prescribers. Yet, the vast majority of information Defendant seeks to redact, including call notes from prescriber promotion, notes from its abuse and diversion detection program, marketing documents that recommend targeting specific types of prescribers, facts about which prescribers Defendant made sales calls to, and other information relate to the promotion of opioids to prescribers.

The Affidavit of Keith Darragh, which is attached as Exhibit A to Defendant's Motion, does not reference Defendant's cessation of promotion of opioids to prescribers at all, much less show how Defendant can now be harmed by the release of this information. Defendant briefly references the cessation of promotional activities concerning opioids to prescribers in its Memorandum, but baldly asserts that this information has commercial value because the company continues to sell non-opioid and opioid products. Def.'s Mem. in Supp., at 9.

<sup>&</sup>lt;sup>48</sup> Ex. 2 to State's Resp., Purdue Pharma L.P. Issues Statement on Opioid Promotion (Feb. 9, 2018).

<sup>&</sup>lt;sup>49</sup> Ex. 3 to the State's Resp., *Beat You To It, Purdue. Other Opioid Makers Already Ditched Promotions*, FIERCEPHARMA, available at https://www.fiercepharma.com/marketing/beat-you-to-it-purdue-other-opioid-makers-already-ditched-promotions (Feb. 14, 2018) (article quoting Endo, Teva, Allergan, and Johnson & Johnson's Janssen spokespersons each stating that promotion of opioids has stopped).

Defendant's argument is without merit because it does not show that disclosure will result in a clearly defined injury concerning the sales it claims will be affected. Defendant does not explain how disclosure of the information it seeks to redact would adversely impact non-opioid sales. Nowhere does Defendant show that the marketing and competitive landscape for Defendant's non-opioid products, such as laxatives, is the same or substantially similar to those for its opioid products.

Finally, Defendant does not explain how disclosure of information that relates to the promotion to prescribers would adversely impact Defendant's general sales of opioids in the current opioid market in which its branded competitors have stated they no longer promote opioids to prescribers.

# 3. The information Defendant seeks to redact has limited relevance for branded competitors in the current opioid marketplace.

Even if one of Defendant's competitors were to start promoting opioids to prescribers again, Defendant fails to show how disclosure of call notes, abuse and diversion report notes, and other information as far back as 2007 would harm it today given the significant changes to the branded and generic opioid market. While the exact dates and time span of the information Defendant seeks to redact is highly relevant for remediation and liability purposes, especially considering the lingering impact of addiction, it has marginal use to competitors in the current opioid marketplace.

As illustrative examples, Defendant seeks to withhold from the public:

• the percentage of individuals who switched from an immediate release opioid to extended release oxycodone in 2008;

- the specific percentage of its business that came from continued users from August 2009 to March 2011, a six month period later in 2011, and an eight month period in 2015,<sup>50</sup> and
- revenue information for a six month period in 2009 for a provider without a current license.<sup>51</sup>

Defendant has not shown a specific harm from disclosure of this information to branded competitors.

# 4. Generic competitors would have little to no use for the marketing information Defendant seeks to redact.

Defendant says that the information it seeks to restrict is valuable to competitors, but never explains how. In the lifecycle of a branded drug, the most significant competition comes from generic competitors. A generic drug has the same active ingredient as a brand-name product and is equivalent in the route of administration, dosage, and strength. See 21 U.S.C. § 355(j)(2)(A). Generic drugs enter the market after review by the FDA and after a set time that the brand-name version has market exclusivity. See generally, Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98-417, 98 Stat 1585 (codified as amended in scattered sections of 21 U.S.C.) (Hatch-Waxman Amendments). Generic drugs create competition for a branded drug. They increase supply and drive down the market price.

While Defendant enjoys protection from generic competitors for the moment for OxyContin<sup>52</sup> and other opioid products, even if a generic competitor were to quickly come onto the market, it would have little use for Defendant's marketing information. This is because "[v]irtually all drug advertising and promotion is focused on brand name products; generic

<sup>&</sup>lt;sup>50</sup> Def. Mot. Ex. A, Darragh Aff., at ¶10c (citing Compl. ¶133).

<sup>&</sup>lt;sup>51</sup> Def. Mot. Ex. A, Darragh Aff., at ¶10d (citing Compl. ¶590).

<sup>&</sup>lt;sup>52</sup> See Coll. Ex. 6 to State Resp., ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EVALUATIONS, U.S. FOOD AND DRUG ADMINISTRATION (showing various patents on its seven dosing strengths for OxyContin that expire between 2022 and 2030 and exclusivity data for new patient populations that expires August 13, 2018).

companies compete primarily on price, and do little or no promotion. . ." Ex. 4 to State's Resp., ABA ANTITRUST PHARMACEUTICAL INDUSTRY HANDBOOK, at 402. Thus, Defendant cannot show specific harm from the disclosure of this information to generic competitors.

# 5. Defendant will not be harmed by disclosure of "customer lists" based on names of prescribers identified in the Complaint.

Defendant's argument that it is harmed by disclosure of its "customer lists" collected during sales visits is likewise without merit based on the naming convention contained in the State's Complaint. Def.'s Mem. in Supp., at 11 (citing Hamilton-Ryker Grp., LLC v. Keymon, 2010 WL 323057, at \*13 (Tenn. Ct. App. Jan. 28, 2010)). Aside from the fact that Hamilton-Ryker Group is not applicable because it involved misappropriation of commercial information by a former employee—not disclosure of legally-obtained information in a court proceeding, Defendant's assertion fails because the only health care prescribers that are identified by name in the State's Complaint are those who have been criminally convicted of a crime related to controlled substances, had disciplinary action taken against them related to controlled substances, or are deceased. Defendant cannot plausibly assert a legitimate basis for harm from disclosure of this "customer list."

### 6. Substantially similar information is already available to the public.

Substantially similar information to that which Defendant seeks to redact is already widely available to the public. The State of Washington filed an unredacted complaint against Defendant on January 5, 2018. Likewise, the Commonwealth of Massachusetts filed an unredacted complaint on June 12, 2018. These complaints detail: (1) text from call notes,<sup>53</sup> (2) notes concerning the

<sup>53</sup> MA Compl., available at https://www.mass.gov/files/documents/2018/06/12/Purdue%20Complaint%20FILED.pdf, at ¶¶37-38 ("[A] sales

abuse and diversion of OxyContin,<sup>54</sup> (3) the frequency of Defendant's visits to individual health care prescribers,<sup>55</sup> (4) the percentage of Defendant's sales that stem from new patients compared to existing patients,<sup>56</sup> (5) the number of prescriptions and tablets prescribed by individual prescribers on an annual basis and revenue Defendant acquired from these sales,<sup>57</sup> (6) provider-specific sales data on savings card promotions,<sup>58</sup> (7) the number of statewide sales visits by Defendant's sales representatives,<sup>59</sup> (8) details of Defendant's training and marketing

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\$1,565,670.51 worth of OxyContin prescriptions."), 4.303, 4.306-07.

representative reported that one doctor: 'let me know that she will Rx OxyContin when the pts has chronic pain and are trustworthy.' The representative added that he would 'Follow up with Dr and ask what pts does she consider 'trust worthy' A Purdue district manager responded: 'Great follow up question on what patients does he consider trustworthy.'), ¶43, ¶107, ¶114, ¶124-125; WA Compl., available at s3bucket.s3.amazonaws.com/uploadedfiles/Another/News/Press\_Releases/Compl\_Highlighted.pdf, at ¶¶4.55, 4.122,

<sup>4.151, 4.169-70, 4.182, 4.209, 4.216, 4.252, 4.268-70, 4.273, 4.275, 4.277-78,</sup> n. 177, 4.286, 4.294-97, 4.299-300.

MA Compl., at ¶115 ("In 2015, even after Purdue's sales representative reported 'a huge concern with the issue of narcotics in the cape,' Purdue continued to target Benoit, calling on him 27 times through 2015 and into 2016 and making particular note of efforts to promote Hysingla and OxyContin. In February 2016, Purdue's sales representative logged a "Report of Concern" when a newspaper reported on Benoit's excessive opioid prescribing

representative logged a "Report of Concern" when a newspaper reported on Benoit's excessive opioid prescribing and police found a patient with 420 pills. Purdue kept promoting opioids to the doctor anyway."), ¶119, ¶130, ¶134; WA Compl., at ¶¶4.235-40, 4.248, 4.250-53, 4.257-60.

<sup>55</sup> MA Compl., at ¶102 ("Purdue knew Jacobs's practice inside and out. Purdue sales representatives visited him more than a hundred times."), ¶109, ¶112, ¶115, ¶118; WA Compl., at ¶¶4.272, 4.306-307.

<sup>&</sup>lt;sup>56</sup> WA Compl., at ¶4.54 ("According to internal documents, 87% of Purdue's OxyContin business is driven by continuing prescriptions. Similarly, 82% of Purdue's Butrans business was driven by continuing prescriptions.").

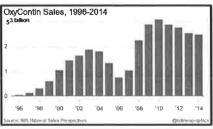
<sup>57</sup> MA Compl., at ¶¶16, 58, 74; WA Compl., at ¶¶4.261, 4.271, 4.274, 4.285, 4.298 ("[F]or example, an internal Purdue study of Ms. Bell's prescriptions on December 8, 2008 showed that over the preceding six months she had written

<sup>&</sup>lt;sup>58</sup> MA Compl., at ¶81 ("According to Purdue's internal analysis, the savings cards had "the highest ROI" in the entire 'OxyContin Marketing Mix.' The Return on Investment for Purdue was 4.28, so that every \$1,000,000 Purdue gave away in 'savings' came back to Purdue as \$4,280,000 in revenue, because patients stayed on dangerous opioids longer.')

<sup>&</sup>lt;sup>59</sup> MA Compl., at ¶26 ("[S]ince May 15, 2007, Purdue salespeople met with Massachusetts prescribers and pharmacists more than 150,000 times. A list of each sales meeting is attached as Exhibit 1."); WA Compl., at ¶4.264.

information, 60 including Defendant's statewide opioid sales dating back to May 15, 2007, 61 and (9) OxyContin pricing data.<sup>62</sup>

Multiple news reports have also already disclosed substantially similar pieces of information to what Defendant seeks to redact. Two CBS News reports on June 20 and June 21, 2018, which featured an interview with a former Purdue sales representative, disclosed details about its marketing efforts, including that the Company's bonus system incentivized the sales representative to convince doctors to prescribe higher doses of OxyContin, that the Company was trying to expand its reach beyond just pain doctors, and that the Company trained her to advance the concept of pseudoaddiction in sales discussions with doctors and that the cure for pseudoaddiction was more opioids.<sup>63</sup> Similarly, a 2016 report by THE LOS ANGELES TIMES disclosed Defendant's OxyContin sales from 1996 to 2014, which is shown below.<sup>64</sup>



<sup>&</sup>lt;sup>60</sup> MA Compl, at ¶40, 49 ("Purdue trained its sales representatives to promote its drugs specifically for opioid-naïve patients. In training calls, Purdue managers instructed: 'Your opportunity here is with the naïve community, let's use the naïve trial to make your case ..."), 60-62, 78, 81; WA Compl., at ¶¶4.111-13, 4.119-21, 4.123-27, 4.141, 4.143, 4.148, 4.160(e), 4.163, 4.194-95, 4.204-05, 4.208(g), 4.213(e)-16, 4.267, 4.276-78, n. 177, 4.296, 4.304-05.

<sup>&</sup>lt;sup>61</sup> MA Compl., at ¶16 ("Since May 15, 2007, . . . Purdue has sold more than 70 million doses of opioids in Massachusetts").

<sup>&</sup>lt;sup>62</sup> MA Compl., at ¶58 ("Purdue earns more money every time a patient moves to a higher dose. For example, Purdue's 2015 prices increased dramatically as patients move to higher doses: OxyContin Prices bottle of 100 tablets (10 mg) \$269.17... bottle of 100 tablets (80 mg) \$1,500.18"), ¶74.

<sup>63</sup> Ex. 7 to State Resp., Purdue Pharma Used Deceptive Sales Tactic for OxyContin After Settlement, Ex-Sales Rep Says, CBS NEWS, June 21, 2018, available at https://www.cbsnews.com/news/oxycontin-purdue-pharma-formersales-representative-deceptive-sales-psuedoaddiction/; Purdue Pharma Continued Deceptive Sales Practices for OxyContin after 2007, Whistleblower Says, CBS NEWS, JUNE 20, 2018, available at

https://www.cbsnews.com/news/oxycontin-purdue-whistleblower-says-drug-maker-continued-deceptive-salespractices/.

<sup>&</sup>lt;sup>64</sup> Coll. Ex. 8 to State Resp., 'You Want a Description of Hell?' OxyContin's 12-Hour Problem, LOS ANGELES TIMES, MAY 5, 2016, available at: http://www.latimes.com/projects/oxycontin-part1/; More than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew, LOS ANGELES TIMES, July 10, 2016, available at http://www.latimes.com/projects/la-me-oxycontin-part2/.

Defendant cannot show harm from disclosure of information in the State's Complaint, when substantially similar information has already been made available to the public.

7. Defendant's competitors already have access to much of Defendant's sales information through data sets that can be purchased from third parties.

Defendant argues that the information contained in the State's Complaint is valuable to Defendant's competitors "in large part because this information is *not generally known* and cannot be purchased, copied, or easily acquired." Def. Mem. in Supp., at 8-9 (emphasis in original). However, Defendant's competitors can already purchase third-party data sets that include detailed reports about the sales, pricing, and promotional information for Defendant's drugs. In fact, news reports about Defendant state that its sales representatives used these third-party data sets themselves "to identify doctors writing a small number of OxyContin prescriptions who might be persuaded to write more." 65

Most pharmaceutical manufacturers subscribe to pricing and sales data sets compiled by third-party research firms, such as IMS Health (now IQVIA) and Symphony Health Solutions. Ex. 4 to State's Resp., ABA PHARMACEUTICAL HANDBOOK, at 402. These data sets include almost all manufacturers and products over a long period of time, allowing estimates of total market size as well as comparisons among manufacturers and products over time. *Id.* These sources typically include extensive historical information on prescription sales (in units, prescriptions, and dollars) and average prices. *Id.* 

IMS Health offers data sets that measure national prescription activity and demand for prescription drugs through survey data on prescription orders and dispensing information. It also

<sup>&</sup>lt;sup>65</sup> Coll. Ex. 9 to State Resp., 'You Want a Description of Hell?' OxyContin's 12-Hour Problem, LOS ANGELES TIMES, MAY 5, 2016, available at: http://www.latimes.com/projects/oxycontin-part1/; More than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew, LOS ANGELES TIMES, July 10, 2016, available at http://www.latimes.com/projects/la-me-oxycontin-part2/.

tracks pharmaceutical purchases made by wholesalers, drug chain distributors, non-federal hospitals, and mail service pharmacies (from distribution centers and directly from manufacturers).

Overall, this sales and pricing data, while having some limitations, already provides competitors with a detailed picture of Defendant's pharmaceutical sales and pricing.

Defendant's competitors can also purchase marketing and promotional information from third-party market research groups such as IMS Health and Encuity Research, which provide monthly data on office and hospital detailing, provision of free samples, journal advertising, and direct-to-consumer advertising. ABA PHARMACEUTICAL HANDBOOK, at 404. Aside from this, Defendant's competitors also have access to detailed data sets concerning provider, patient, and payor characteristics, a drug's formulary position, medical charts, and physician surveys. ABA PHARMACEUTICAL HANDBOOK, at 405-07.

Defendant cannot credibly assert a specific harm from disclosure when substantially similar information is already available for purchase from third-parties.

### CONCLUSION

Defendant's Motion for a Protective Order seeks to conceal its bad conduct from the public. It should be denied, and the State's Complaint should be disclosed in full.

Respectfully submitted,

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# **CERTIFICATE OF SERVICE**

On this the 2nd day of July, 2018, I, BRANT HARRELL, certify that the above-referenced document was served via e-mail and either hand-delivery (\*) or U.S. Mail, First Class (\*\*) as follows:

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FILED 8

# EXHIBIT 1 TO STATE'S RESPONSE AM 10:

# **SUMMARY CHART**

# 418 Separate Paragraphs from State's Complaint that the Defendant Seeks to Redact Summary of Information

Reasons to Make Public	Similar Information Already  Disclosed  July Folio 5 1810:	MA Compl., at 107, 114, and 124-25.  WA Compl., at 4154-55.  MA Compl., at 4169-4.151, 4.169-50, 4.216, 4.252, 4.268-70, 4.275.  To, 4.273, 4.277-78. Found within product lebel. 70, 4.273, 4.277-78. Foomote 177, 4.286, 4.294-97, and 4.299-3.00.	
easons t	Similar to Private Data Set osedoruf 101 əldelievA		
R	Muisance Evidence	×	
200	sonsbivA inemgbut	×	
	TCPA Evidence	×	
	Direct Evidence of Promotion to Prescribers	×	
	Paragraphs the Defendant Seeks to Redact	300 paragraphs including: 162–74, 88–92, 103–112, 116–21, 125, 158–167, 169, 176–79, 181–87, 194–200, 203–212, 216–27, 231–35, 238–47, 250, 252–63, 268, 271–80, 292–97, 301–06, 308–12, 314–22, 325, 328–38, 342–42 [sic], 346, 350–52, 354–56, 358–59, 368–71, 383–86, 390–98, 406–15, 433–43, 466, 471, 480–83, 485, 487–91, 493, 496–97, 504, 508–09, 511, 513, 515–19, 528, 543, 549, 555, 566, 569, 578, 582, 592, 596, 605–06, 627, 646, 654, 656, 670–71, 680–81, 691–94, 696, 698–99, 702–09, 711, 725–28, 737, 739–40, 752–53, 772, 774, 778–83, 800–03, 816–17, 845, 854, 866, and 891.	
	Description	Text of sales call notes with prescribers	
	Catogory	T (Darragh Aff. ¶ 10a)	

	Category	Text of Defende & Discontinuous (Darragh Aff.	Frequen to in prescr showed (Darragh Aff. ¶ Oxy
Description		Text of reports to Defendant's Abuse & Diversion Detection Program concerning prescribers	Frequency of visits to individual prescribers who showed red flags for abuse or diversion of OxyContin.
	Paragraphs the Defendant Seeks to Redact	43 paragraphs including:  ¶ 458, 472, 495, 500–01, 512, 520, 524–26, 530, 542, 548, 550, 552–54, 579, 581, 584, 647–48, 650–51, 669, 671, 673–75, 723, 731–32, 754, 775, 794, 812, 826, 828, 844, 847, 855, 857, and 861.	20 paragraphs including: 454, 476–77, 510, 527, 541, 578, 610, 621, 630, 637, 655, 661–62, 689, 717, 756, 761, 771, and 777.
	Direct Evidence of Promotion to Prescribers	×	×
	TCPA Evidence	×	
	Judgment Evidence	×	×
Reasons	Similar to Private Data Set Available for Purchase	×	×
Reasons to Make Public	Similar Information Already declosed	MA Compl., at 115, 119, 130, and 134.  WA Compl., at ¶ 4.235–40, 4.248, 4.250–53, and 4.257–60	MA Compl., at ¶102, 109, 112, 115, and 118.  WA Compl., at ¶14.272, 4.306307
A STATE OF THE PARTY OF THE PAR	Other	Only prescribers identified by name in ADD notes are those who have criminal convictions or pleas related to controlled substances, disciplinary action related to controlled substances, disciplinary action deceased.	Same as Above (Category 2 – Other Column)

A STATE OF	Офек	Time period covered by ¶133 (which concerns % of continued users) is 2009 to 2011, six months in 2011, and an eight-month period in 2015.  Time period covered by ¶ 249 (which concerns % of switches from immediate release opioids to oxycodone extended release) is 2008.
Reasons to Make Public	Similar Information Alveady Disclosed	WA Compl., at ¶ 4.54.
easons t	Similar to Private Data Set Available for Purchase	×
Re	Nuisance Evidence	×
	Judgment Evidence	
	TCPA Evidence	×
	Direct Evidence of Promotion to Prescribers	
	Paragraphs the Defendant Seeks to Redact	2 paragraphs including: ¶ 133 and 249.
	Description	Percentage of Defendant's sales that stem from new patients as compared to existing patients and percentage of prescription switches from immediate release opioids to extended release oxycodone
	Category	4 (Darragh Aff.¶ 10c)

	Other	All paragraphs except for ¶872 and ¶893 concern prescribers whose practices showed red flags for abuse or diversion.  ¶872 concerns the statewide morphine milligram equivalent statewide total for Oxycontin from 2008 to 2017. ¶893 concerns the number of OxyContin tablets per person from 2008 to 2017 in Knoxville, Memphis, Nashville, and Morristown.	
Reasons to Make Public	Similar Information Already Disclosed	MA Comply., at ¶¶ 16, 58, and 74.  WA Compl., at ¶¶ 4.261, 4.271, 4.274, 4.285, 4.298, 4.306–07.	
easons t	Similar to Private Data Set Available for Purchase	×	
R	Nuisance Evidence	×	
	Judgment Evidence	×	
	TCPA Evidence	×	
	Direct Evidence of Promotion to Prescribers	×	
	Paragraphs the Defendant Seeks to Redact	22 paragraphs including:  ¶ 474–75, 533, 545, 560, 575–76, 587, 590, 608–09, 638, 685, 735, 744, 760, 769, 798, 823, 860, 872, and 893	
	Description	Number of prescriptions and tablets prescribed by individual Tennessee prescribers on an annual basis and revenue Defendant acquired from these sales	
	Category	S (Darragh Aff. ¶ 10d)	

	Other	Savings cards could be used by cashpaying customers until 2015. The paragraphs listed show savings card redemption statistics for patients of prescribers whose practices showed red flags for abuse or diversion.	
Reasons to Make Public	Similar Information Already Disclosed	MA Compl., at ¶ 103.	
easons	Similar to Private Data Set Available for Purchase		
R	Nuisance Evidence	×	
	Judgment Evidence	×	
	TCPA Evidence	×	
	Direct Evidence of Promotion to Prescribers	×	
	Paragraphs the Defendant Seeks to Redact	4 paragraphs including: ¶ 534, 536, 643, and 719	
	Description	Number, percentage, and dollar figures from Defendant's savings card redemptions from prescriptions of prescribers whose practices showed red flags for abuse or diversion of OxyContin	
	Category	Oarragh Aff. (Darragh 10e)	

	Other		
Reasons to Make Public	Similar Information Already Desclosed	MA Compl., at ¶81	MA Compl., at ¶26 WA Compl., at ¶4.264
easons 1	Similar to Private Data Set Available for Purchase		
R	Nuisance Evidence	×	×
	Judgment Evidence	×	
	TCPA Evidence	×	×
	Direct Evidence of Prescribers	×	×
	Paragraphs the Defendant Seeks to Redact	5 paragraphs including:  ¶ 881–84 and 892  ¶¶ 881–84 concern the use of savings cards in Def.'s sales calls with by prescribers.  ¶892 concerns redemption of savings cards at pharmacy linked to clinic referenced in abuse and diversion detection section.	6 paragraphs including: ¶ 13, 20, 29–31, and 51 All paragraphs relate to scale of Def.'s promotion to prescribers.
	Description	Research about how the savings card program impacted sales	Number of sales representatives Defendant employed in Tennessee, number of sales visits for specific type of prescriber, and the total number of sales visits made
	Category	7 (Darragh Aff.¶ 10f)	S (Darragh Aff. ¶ 10g)

	Other		
Reasons to Make Public	Similar Information Already besolvsid		WA Compl., at ¶ 4.111–14
easons	Similar to Private Data Set Available for Purchase		
R	Nuisance Evidence		×
	Indgment Evidence		
	TCPA Evidence		
	Direct Evidence of Promotion to Prescribers		×
Paragraphs the Defendant Seeks to Redact			1 paragraph including:  ¶ 887 in its entirety.  ¶ 887 concerns information on the Def.'s coordinated efforts to increase availability of OxyContin.
Description		statewide on an annual basis	Research on what factors impact prescription rates
Category			Oarragh Aff. ¶ 10h)

	Одиск		
Reasons to Make Public	Similar Information Already declosed	MA Compl., at ¶ 40, 49, 60–62, 78, and 81.  WA Compl., at ¶ 4.119–21, 4.123–27, 4.141, 4.143, 4.160(e), 4.163, 4.194–95, 4.208(g), 4.267, 4.276–78, footnote 177, 4.296, and 4.304–05.	
easons	Similar to Private Data Set Available for Purchase		
R	Nuisance Evidence	×	
	Judgment Evidence	×	
	TCPA Evidence	×	
	Direct Evidence of Promotion to Prescribers	×	
	Paragraphs the Defendant Seeks to Redact	21 paragraphs including:  29–32, 45, 97, 155–56, 188, 202, 283–85, 299, 360, 462, 468–69, 879, 887, and 896.  Information Def. seeks to redact includes: marketing information for unbranded materials (¶45); training for prescriber promotion (¶¶97, 155-56, 188, 202, 283-85, 299, 360, 879); statements about the impact of Purdue's ADD program on sales (¶462); and facts concerning sales representative compensation (¶¶468-69).	
	Description	Details of Defendant's marketing and training materials relating to prescriber promotion	
	Category	10 (Darragh Aff. ¶ 10i)	

# EXHIBIT 2 TO STATE'S RESPONSE N GOAL TO STATE S RESPONSE N GOAL TO STATE S

# **PURDUE PRESS RELEASE**

### News & Media

# Purdue Pharma L.P. Issues Statement on Opioid Promotion

STAMFORD, Conn. - February 9, 2018 - Purdue Pharma L.P. issued the following statement today:





We have restructured and significantly reduced our commercial operation and our sales representatives will no longer promote opioids to prescribers.

Going forward, questions and requests for information about our opioid products will be handled through direct communication with the highly experienced healthcare professionals that comprise our Medical Affairs department.

Purdue Pharma Medical Affairs can be contacted at (888) 726-7535 (option #1), PurdueMedInfo@pharma.com, or www.AskPurdueMedical.com.

### ABOUT PURDUE PHARMA L.P.

Purdue Pharma L.P. is a privately held pharmaceutical company headquartered in Stamford, Conn. Purdue Pharma is part of a network of independent associated companies dedicated to providing patients and providers with innovative medicines. The company's leadership and employees are committed to serving healthcare professionals, patients and caregivers by providing quality products and educational resources that make a positive impact on healthcare and on lives. For more information, please visit www.purduepharma.com.

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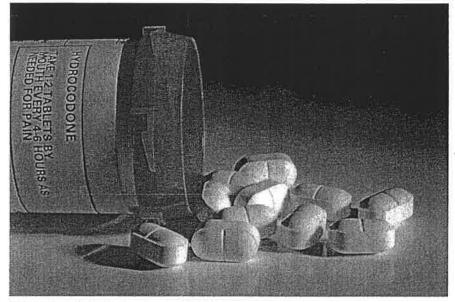
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Marketing

# Beat you to it, Purdue. Other opioid makers already ditched promotions

by Beth Snyder Bulik I Feb 14, 2018 9:35am



While Purdue said it will quit marketing opioids including OxyContin this week, many other opioid makers have already quit. (Getty/smartstock)

While the news that Purdue Pharma plans to stop marketing opioids made a media splash this week, other opioid makers probably wondered why it was a big deal—because they had already quit.

Endo, Teva, Allergan and Johnson & Johnson's Janssen unit all stopped marketing opioids before Purdue's announcement, with some backing off several years ago. And some have not only given up marketing, but also development and production of the powerful painkillers whose abuse has become a nationwide epidemic.

A Janssen spokesperson said the company stopped promoting and developing opioid products in 2015, and noted in its email statement to FiercePharma that, since 2008, the volume of Janssen opioids is less than 1% of the total opioid prescriptions written annually.



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**About the Author** 

Beth Snyder Bulik



TREE DAILT NEWSLETTER

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Endo stopped promoting Opana ER in 2016 and eliminated the drug's salesforce shortly after that, said an Endo spokesperson via email. In 2017, it pulled the drug from the market at the FDA's request "despite having a statutory right to challenge that request, (and) implemented additional anti-diversion measures and terminated its new opioid product development programs," she said.

Allergan doesn't "actively market or promote any opioid products today," said a spokesperson via email. Allergan's branded opioid drugs, which came to Allergan through acquisitions, haven't been marketed in years—for Norco not since 2003 and for Kadian and Fiorinal not since 2012.

Allergan also pointed out its drugs' small market share, noting they accounted for less than .04 % of all opioid products prescribed in 2017. Allergan sold its Activis and Watson businesses, which contained all its generic opioid products, to Teva in 2016.

Teva, for its part, stopped promoting Fentora earlier this year, said a spokesperson in email, noting that the company's other branded opioid Actiq has not been promoted in more than a decade.

Insys Therapeutics, which has been named in lawsuits along with other opioid makers in this story, declined to comment to FiercePharma about opioid marketing. A spokesman said in an email, "We have no comment on this subject presently and typically don't comment on the decisions of other companies."

#### RELATED: Ex-Insys executive wants term 'opioid crisis' censored from his trial

Of course, quitting marketing or even stopping the sale of opioid products won't make the pharma companies' legal woes go away. Dozens of states and even more cities and counties are suing drugmakers on allegations of improper marketing stretching back years. Sen. Claire McCaskill, D-Mo., this week published details of \$10 million in pharma payments to groups that pushed opioid use in a report of her probe looking at five companies: Purdue, Janssen, Depomed, Insys and Mylan.

Some of the pharma companies that responded to FiercePharma's query about opioid marketing also added statements about their company's commitment to help address the opioid crisis, even as they support safe and responsible use of pain medicines for patients.

Teva, for instance, wrote, "Teva recognizes the critical public health issues affecting communities across the U.S. and our goal is to prevent prescription drug abuse without sacrificing patients' needed access to pain medicine."

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# EXHIBIT 4 2018 JUL -2 MM 10: 17 2018 JUL -2 AM TO STATE'S RESPONSE



# **ABA ANTITRUST** PHARMACEUTICAL INDUSTRY HANDBOOK (EXCERPT)

2018 JUL -2 AM 10: 17

# Pharmaceutical Industry Antitrust Handbook

**Second Edition** 



Promoting Competition



The remainder of this section describes several data sources that address the categories listed above, grouped into the following five categories: (1) Product Characteristics, (2) Price and Sales Information, (3) Marketing and Promotion Information, (4) Provider, Patient, and Payor Characteristics, and (5) Clinical Trial Data.

#### 1. Data on Product Characteristics

A natural starting point for an economic analysis of the pharmaceutical industry is descriptive data on the pharmaceuticals of interest. This may include approval dates, manufacturers, dosage forms, indications, and recognized therapeutic substitutes.

#### a. Food and Drug Administration

The FDA provides several helpful data sources. *Drugs@FDA* is a website that provides product approval histories, labels (e.g., including approved indications and dosages), and therapeutically equivalent drugs for drugs approved after 1997. The *Orange Book* provides information on the timing of regulatory approvals of generic competitors, patents asserted by drug manufacturers, and marketing exclusivity periods (including pediatric exclusivity extensions). The *Orange Book* also identifies products that pharmacists are permitted to substitute for one another at any given moment. The FDA also provides the *National Drug Code Directory*, the *FDA Adverse Event Reporting System* database, and access to warning letters issued since 1996.

#### b. Third-Party Data

A widely used source of pharmaceutical product information is the *Physicians' Desk Reference (PDR)*, a comprehensive listing of products by manufacturer, product category, and brand/generic name. The annually-updated *PDR* includes drug usage information, warnings dosages, figures and photographs, drug-drug interactions, contraindicated medical conditions, and other FDA-required information. These data can be combined with manufacturer specific clinical trials data available from company Websites documenting the inherent characteristics of a particular product in terms of its safety, efficacy, and side-effects profiles.

Another source of pharmaceutical product information is the Medi-Span Electronic Drug File (MED-File), provided by Medi-Span, a part of Wolters Kluwer Health. MED-File provides information on dose form, route of administration, strength, a proprietary generic product identifier,

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product information is the Medi-, provided by Medi-Span, a part of ovides information on dose form, prietary generic product identifier, and various standard price measures (e.g., Average Wholesale Price (AWP) and Wholesale Acquisition Price (WAC)).

Drug compendia provide information that many payors rely upon in making reimbursement decisions, including therapeutic guidelines and off-label uses for drugs. These include the Truven Health Micromedex® System, Clinical Pharmacology, and American Hospital Formulary Services (AHFS), as well as disease specific compendia such as the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium. Clinical applications cited in these compendia are considered to be medically acceptable by Medicare and Medicaid, which reimburse accordingly. By broadening the list of acceptable uses for a drug beyond FDA-approved indications, these compendia can provide additional insight into product competition over time.

#### 2. Data on Prices and Sales

Most economic antitrust analyses of the pharmaceutical industry will require information on quantities bought and sold and the prices paid. There are many potential sources for this information, each with its own advantages and drawbacks. Each data source typically captures information for only one of the relationships shown in Figure 1, making it important to carefully consider the limitations of the data provided. For example, a database of sales from wholesalers to retail pharmacies will capture the prices and quantities exchanged between these parties, but it is likely to miss payments from pharmacy benefit managers (PBMs) to pharmacies that may be tied to those sales. The data may therefore miss an important determinant of the net prices obtained by the manufacturer and paid by the retail pharmacies.

#### a. Pharmaceutical Company Financial Reports

Internal pharmaceutical company financials often are the first source to which economists turn for price and quantity sales data. They are usually accessible historically at the product level, and may even be available at the invoice level. Company financials typically capture sales by the manufacturer to wholesalers for subsequent shipment to an indirect purchaser, with explicit attention to the chargeback arrangements that exist between the manufacturer and that end-user. The chargeback mechanism accommodates indirect purchasers who have negotiated lower prices with the manufacturer than the wholesaler initially received, and this arrangement can be important to recognize in computing prices.

Although retail pharmacies, hospitals, clinics, and nursing homes may rely on wholesaler intermediaries at times, their purchases may alternatively be sourced directly from the manufacturer. Company financials also capture direct purchases of this sort, and include attention to any transaction-specific discounts as well as rebate arrangements that may be afforded the purchaser. Such data thus can be helpful in understanding price differences and competitive dynamics across different channels and over time. Company-specific financials are rarely available to the economist in comparable depth for competitor products. However, company sales and pricing data can provide useful benchmarks against which to compare other data sources that attempt to capture a broader view of competition within a therapeutic class. However, when making these comparisons one must remember that drug inventories may be held at different levels of the industry, which may cause unit sales at one level to be somewhat different than unit sales at another level.

#### b. Market Research Data

Price and sales data from market research firms, such as IMS Health and Symphony Health Solutions, are also widely used by economists (and industry participants) because they provide an aggregate industry picture. These data often include almost all manufacturers and products over a long period of time, allowing estimates of total market size as well as comparisons among manufacturers and products over time. These data also have comprehensive channel coverage, including retail, wholesale, and direct-from-manufacturer sales. These sources typically include extensive historical information on prescription sales (in units, prescriptions, and dollars) and average prices (i.e., typically, with attention to transaction-specific chargebacks and discounts, but not off-invoice rebates or prompt payment discounts).

For the United States, IMS Health provides two complementary sources of sales data: IMS National Sales Perspectives (NSP) and IMS National Prescription Audit (NPA). IMS NSP provides sales data that track pharmaceutical purchases made by wholesalers, drug chain distributors, non-federal hospitals, and mail service pharmacies (from distribution centers and directly from manufacturers). This includes both pharmacy-dispensed as well as physician-administered drugs. IMS NPA

<sup>4.</sup> These data are also available for sales in foreign countries. However, the surveys of foreign markets may be less comprehensive (e.g., they may only include sales in the private sector and fail to include sales made to government entities).

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is a source of national prescription activity and measures demand for prescription drugs through data on prescription orders and the ultimate dispensing of products to consumers. These data are based on a sample of drug stores, mail service pharmacy outlets, and long-term care facilities. They are projected to reflect national prescriptions. IMS sales are available by presentational form (e.g., bottles of 100 tablets, unit-dose syringes) and distribution channel (e.g., hospital, chain store, independent store). Unit volume, number of prescriptions, and dollar value data are reported for each brand and generic manufacturer, which permits calculation of average revenue per unit sold or per prescription (i.e., price). Similar to IMS, Symphony Health Solutions offers sales data covering retail, non-retail, and mail order channels.

One potential limitation of these data sources, however, is that their estimates of product-specific magnitudes with respect to each of these variables can be systematically too high or too low compared with company financials (since they are based on survey data). In addition, the smaller players are not always adequately represented. As a result, it can be helpful to compare totals and trends over time with company data to see the direction and extent of bias, if any, and to make appropriate adjustments. Indeed, it is not uncommon for pharmaceutical companies to develop their own estimates based on a variety of data sources.

Because most pharmaceutical manufacturers subscribe to IMS or Symphony Health data, these data often are obtained from the client. Custom data requests also can be negotiated directly with these companies.

For OTC drug sales and prices, economists often turn to Nielsen and IRI which provide weekly retail scanner data of OTC medications from selected distribution channels (e.g., drugstore chains, supermarkets, mass merchandisers) in particular geographic areas (e.g., region or total United States), and such data can be provided at the store level for certain customers. Both Nielsen and IRI data include retail quantities and revenues as well as measures of in-store advertising effectiveness (e.g., percentage of sales made under certain promotional conditions). Both companies provide essentially the same type of data, with slight differences in their sampling methodologies. These data are not completely comprehensive, however, as some companies do not submit sales data.

#### Data on Government Purchases

Another important source of pharmaceutical sales data is the government. With the growing importance of state and federal pharmaceutical reimbursement programs (e.g., Medicaid, Medicare, and Veterans Affairs), government data are of increasing relevance in understanding the economic forces at work in the pharmaceutical industry. For example, quarterly Medicaid reimbursements (in dollars and prescriptions) for outpatient drugs are available on a state-by-state and product-specific basis from the State Drug Utilization Data (SDUD) files. Such data can be helpful in providing insight into competitive dynamics underlying the portion of sales that involve a government payor because states vary in terms of reimbursement policies and amounts. State-specific information can also be very useful when analyzing variation in prices paid for pharmaceutical products where Medicaid reimbursement comprises a large portion of a product's total sales. A key limitation of the data is that the prices reported in the SDUD files represent reimbursement amounts rather than prices paid by direct purchasers such as pharmacies, and do not reflect rebates paid to the state.

#### 3. Marketing and Promotion Information

Given the sizable amount of marketing and promotion in this industry, attention to marketing and promotion data is often important for assessing competitive dynamics.

#### a. Pharmaceutical Company Marketing and Promotion Data

Internal pharmaceutical company data are an important source of information on marketing and promotion. Companies track their own spending and activities related to physician detailing, print and television advertising campaigns, distribution of free samples, patient coupon use, and promotional events, such as sponsored presentations. In addition to measuring spending, firms sometimes commission surveys to learn about the effectiveness of their promotional efforts. Company marketing documents can also provide insight into the firm's perception of the competitive environment.

#### b. Third-Party Marketing and Promotion Data

Third-party market research firms like IMS Health and Encuity Research also track a variety of important marketing variables. IMS Integrated Promotional Services (IPS) and Encuity Research AnswerSuite™ both provide monthly data on office and hospital detailing provision of free samples, journal advertising, and direct-to-consumer (DTC) advertising. DTC advertising is typically broken down by outlet:

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television, magazine, newspaper, radio, and outdoor (e.g., billboards). Where both company data and third-party data are available, they are sometimes found to differ substantially. Third-party data is nonetheless valuable, as it can allow for comparison of marketing efforts across different products in a therapeutic area.

#### 4. Data on Provider, Patient, and Payor Characteristics

Provider, patient, and payor information from a variety of sources, including insurance claims, formularies, medical charts, and surveys, can shed additional light on economic activity in the pharmaceutical sector. Advantages of these data can include increased granularity and information at the insurance plan level. Drawbacks may include data on fewer individuals and potentially shorter timespans than market-level sales data.

#### a. Claims Data

Administrative claims data are records used for billing purposes and are available from a variety of sources, including public and private payors (e.g., Medicaid, Medicare, and large self-insured companies). Nearly every time a healthcare service is used or a prescription is filled, a claim is created, which forms the basis for administrative claims databases. The numerous private databases that are available generally contain complete medical and pharmaceutical claims for beneficiaries below age sixty-five. Administrative claims data provide information on characteristics of patients, physicians, and payors at a granular level. These data are useful because they reflect a large number of patient-specific encounters; however, the data typically omit details about the severity of a patient's condition and reasons for drug prescriptions. Where detailed clinical information is needed, electronic medical records (EMR) data may be used. Several EMR databases are available, including Centricity, iKnowMed, and KP Health Connect from Kaiser Permanente. Some of these databases combine EMR data with health insurance billing information.

Publicly available state Medicaid claims data capture medical and pharmaceutical claims for Medicaid patients on a state-by-state basis over time. These claims include Medicaid reimbursements for all people eligible for Medicaid, including Medicare/Medicaid crossovers. However, Medicaid data are not publicly available in all states. Medicare claims data are typically available as standard analytic files for a 5 percent sample of Medicare beneficiaries, including all prescription drug claims

that are reimbursed under Part A (for drugs prescribed during an inpatient stay, e.g., in a hospital or skilled nursing facility), Part B (e.g., for injectable drugs administered in a physician's office, such as those used for oncology, rheumatoid arthritis, and renal disease). Outpatient drug claims reimbursed under Medicare Part D (e.g., those prescribed during a visit to the doctor) are available on a more limited basis.

#### b. Formulary Data

A drug's formulary position can impact cost sharing between patients and payors. Knowing a drug's position on formularies is therefore useful for evaluating the impact of price changes and generic availability. Formulary data are compiled by third parties, such as Managed Markets Insight & Technology, LLC (MMIT), formerly MediMedia Information Technologies. MMIT provides historical formulary information for a wide range of prescription pharmaceuticals. Its database contains drug formulary information for over 95 percent of the insured U.S. population, including plan name, plan type (e.g., HMO, PPO, POS, Medicaid HMO), formulary status (e.g., Tier 2, Tier 3, prior authorization), and any advisory notes and/or restrictions. It also includes the number of members covered by each plan at a particular point in time. The data do not, however, include information on copayment amounts.

#### c. Medical Chart Data

Data can also be collected directly from patients' medical charts. Companies like Ipsos Healthcare offer custom and syndicated research using medical chart data. Custom chart review has the advantage that it can be tailored to answer specific questions of interest. For example, chart review can be used to measure adoption rates for new products, market shares within narrowly defined treatment areas, and therapeutic success of treatments.

#### d. Survey Data

Another potentially helpful source of pharmaceutical data is large-scale, population-based surveys. The Medical Expenditure Panel Survey (MEPS), the National Health Interview Survey (NHIS), the National Health and Nutrition Examination Survey (NHANES), and the National Hospital Care Survey (NHCS) are all examples of nationally representative federal surveys that include questions on prescription drug consumption. The advantage of these sources is that they provide a wealth

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Valuable information also can be gleaned from physician surveys that assess their perceptions of the advantages and disadvantages of prescription drug alternatives within a therapeutic class—as well as drug-specific factors physicians consider when choosing one treatment alternative over another in a specific patient encounter. Many such studies are privately commissioned on a one-time basis, while others are regularly compiled with respect to particular medical conditions or therapeutic classes of treatment.

For example, the IMS National Disease and Therapeutic Index (NDTI) database contains information on prescriptions and patient diagnoses based on a survey conducted by IMS of over four thousand physicians. This database tracks the indications for which products are prescribed, the specialties of physicians prescribing those products, and the number of prescriptions by patient characteristics such as age group. The survey only includes office-based physicians and therefore omits prescribing physicians in other locations such as hospitals or nursing homes.

The main advantage of physician surveys is that the data can be used to develop intertemporal quality comparisons across products within the same therapeutic category, allowing researchers to analyze the key quality differences among competing products. One example of a limitation is that the survey questions may not be standardized over time, so that answers to certain questions for certain drugs may not be available in every relevant period. These data can be highly informative in developing an understanding of the context of physician prescribing and can be used in conjunction with other types of economic data to shed light on the dynamics of the marketplace.

#### 5. Clinical Trial Data

Clinical trial data are the primary source for information on the efficacy and side effect profile of pharmaceuticals. Due to the high standards for data collection and recording, these data are generally considered highly reliable. While most relevant for product liability and patent litigation, clinical trial data are another source that economists might consider using in an antitrust litigation.

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# EXHIBIT 5 2018 JUL -2 AM 10: 17 TO STATE'S RESPONSE

# 2017 CONFIDENTIALITY AGREEMENT

IN RE PURDUE PHARMA L.P.

2018 JUL -2 AM (0: 17

#### CONFIDENTIALITY AGREEMENT

#### Recitals

- A. From 2014 to 2017, the Offices of the Attorney General for the District of Columbia, Delaware, Illinois, Iowa, Maine, Maryland, Nevada, New Hampshire, Pennsylvania, South Carolina, Tennessee, Texas, Vermont, and Washington (the "Subpoenaing States") served civil investigative demands, requests for information, and subpoenas in accordance with the law of each Subpoenaing State (the "Subpoenas") on Purdue Pharma L.P. ("Purdue") in connection with the Subpoenaing States' investigation of whether Purdue's marketing, promotion, and advertising of opioids violated state consumer protection laws ("the Investigation"). The Investigation has now expanded and is being conducted jointly with other State Attorneys General ("the Multistate Investigation").
- B. The purpose of this Confidentiality Agreement is to respond to the confidentiality concerns raised on behalf of Purdue concerning the handling of documents and information provided by Purdue to the Subpoenaing States. In order to facilitate the sharing of documents and information received by the Subpoenaing States among themselves and with the other Attorneys General, and to ensure that any highly confidential, proprietary or trade secret documents and information provided by Purdue to the Subpoenaing States remains protected under applicable law, the Subpoenaing States and Purdue enter into this Confidentiality Agreement.
- C. This Confidentiality Agreement applies to all documents and information Purdue produces to the Subpoening States, directly or indirectly through representatives of the Multistate Investigation, in response to any of the Subpoenas issued by the Subpoenaing States.

#### Confidential Information

In order to resolve Purdue's confidentiality concerns regarding both the Subpoenas issued between 2014 and 2017 as well as any subsequent Subpoenas issued by the Subpoenaing States, Purdue and the Subpoenaing States agree as follows:

1. Purdue may mark as "Confidential" any documents or information that Purdue provides to the Subpoenaing States that it reasonably believes contain highly confidential, proprietary or trade secret information (collectively "Sensitive Information"). Purdue shall mark documents or information as "Confidential" only if, in good faith, it believes the documents or information contain Sensitive Information and that the documents or information have in fact been so treated by Purdue. If Purdue inadvertently fails to mark produced documents or information as "Confidential" when they are produced, it may later make such a designation by

providing written notification to all parties to whom it produced the documents or information. Those marked documents or information will thereafter be treated as confidential pursuant to the terms of this Confidentiality Agreement.

- 2. Except as otherwise provided in this Confidentiality Agreement, if one or more of the Subpoening States object to Purdue's designation of certain documents or information as "Confidential," the Subpoening State(s) shall notify Purdue of that determination. The Subpoening State(s) shall continue to afford the documents or information in question confidential treatment for 15 days following notification of the objection, unless a shorter time is required by law.
- 3. The Subpoening States agree that any documents or information that Purdue provides to the Subpoening States in response to the Subpoening States in response to the Subpoening States as "Confidential" shall be treated as confidential to the extent permitted by law, and disclosed only as allowed by law and subject to the limitations contained in this Confidentiality Agreement, except that the Subpoening States may disclose documents and information marked as "Confidential" for any law enforcement purpose.
- 4. To the extent applicable state law affords protections against disclosure of documents that are not designated as Confidential, nothing in this agreement shall be construed to waive those provisions or Purdue's rights under those provisions.
- marked as "Confidential," or disclosing the content of documents or information marked as "Confidential," in any complaint or charging document unless that Subpoening State either (i) resolves any dispute with Purdue regarding the designation of such documents or information as "Confidential;" (ii) files or makes application to file the document or information marked as "Confidential" with a court or administrative tribunal conditionally under seal; or (iii) provides 15 days' written notice to Purdue of its intent to so attach or disclose. Following the filing of its charging document or complaint, the confidentiality or non-confidentiality of documents or information attached to, or disclosed in, the complaint or charging document will be determined by the terms of a protective order entered in the case either by stipulation or court order, or by the absence of such order. Subject to applicable local rule, if no protective order is entered within 10 days after Purdue is served with the complaint or charging document, the documents or information attached to, or disclosed in, the complaint and filed under seal may be treated by the Subpoening States as non-confidential.
- 6. In the event that any of the Subpoenaing States receive a third-party request pursuant to (i) that respective Subpoenaing State's public information act, data practices act, public record act, freedom of information act or similar state law, (ii) subpoena, or (iii) court order, for any documents or information provided by Purdue that have been marked as "Confidential" and that the Subpoenaing State believes were improperly marked as "Confidential," or otherwise believes it is required by applicable law, subpoena, or court order to produce the document or information, the Subpoenaing State agrees to provide Purdue with at least 14 days' advance notice before producing documents or information in response to such a request, or any lesser period as necessary to comply with any law, subpoena, or court order.

Such notice period shall begin to run upon transmission of the notice, which shall be made either by first class mail to Maria Barton, Vice President and General Counsel of Purdue, and Patrick Fitzgerald, counsel to Purdue; or by email to maria barton@pharma.com and patrick.fitzgerald@skadden.com, or to such other postal and email addresses as Purdue or its attorneys may designate by written notice to the Subpoenaing States.

- 7. In the event that any Subpoenaing State's withholding of documents from disclosure based on confidentiality grounds (e.g., withheld as containing Sensitive Information) is challenged in any court, agency or administrative body, Purdue agrees to seek to intervene in a timely fashion to defend the claim of confidentiality.
- 8. The limitations on disclosure of "Confidential" documents or information imposed by this Confidentiality Agreement shall not apply to documents or information marked "Confidential" that: (i) have been published; (ii) Purdue discloses to another or to others without restriction; or (iii) a Subpoening State lawfully obtains or receives from a source other than Purdue, provided that the Subpoening State has no knowledge that the source obtained the documents or information improperly or is prohibited from disclosing them.
- 9. Nothing contained herein shall limit the obligations of the Subpoening States that may be imposed by the provisions of their respective public information acts, data practices acts, public record acts, freedom of information acts, or similar state laws.
- 10. Nothing contained herein shall alter or limit any right the Subpoening State(s) would otherwise have under applicable law to disclose documents or information marked as "Confidential" provided to the Subpoening State(s) under the terms of this Confidentiality Agreement to any other Attorney General or local, municipal, county, state, or federal agency empowered to investigate or prosecute any laws, regulations, or rules, provided that, prior to making the disclosure, the Subpoening State(s) shall obtain either:
- a) that Attorney General's or agency's agreement in writing to abide by the terms of this Confidentiality Agreement; or
- b) a copy of an executed confidentiality agreement between that Attorney General or agency and Purdue containing similar provisions for the protection of confidential information for purposes of an investigation concerning substantially the same subject matter as the Multistate Investigation.
- 11. If Purdue inadvertently produces documents or information subject to a claim of attorney-client privilege or work-product protection, such production shall not, pursuant to applicable state law, operate as a waiver of privilege or protection if the disclosure was inadvertent, Purdue took reasonable steps to prevent disclosure, and Purdue promptly took reasonable steps to rectify the error. If Purdue notifies the Subpoenaing State(s) in writing that it inadvertently disclosed privileged information promptly after discovering that error, the Subpoenaing State(s) will promptly return or destroy the documents or information. If, however, the Subpoenaing State(s) disagrees with Purdue's claim of attorney-client privilege or work-product protection, the Subpoenaing State(s) and Purdue shall confer in good faith to resolve the disagreement. The Subpoenaing State(s) shall continue to treat the produced documents or

information as privileged or protected until the end of 15 days' notice by the Subpoening State(s) of its disagreement.

12. This Confidentiality Agreement supersedes and revokes all prior confidentiality agreements entered into between the Subpoenaing States and Purdue in connection with this Multistate Investigation.

Agreed to and accepted this 10 th day of February 2017,

PURDUE PHARMA L.P.

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# COLLECTIVE EXHIBIT 6 1. COLLEC

# FDA ORANGE BOOK (EXCERPT)

# Orange Book: Approved Drug **Products with Therapeutic Equivalence Evaluations**

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#### Additional Information about Patents

- Patent information is published on or after the submission date as defined in 21 CFR 314.53 (d)(5).
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- · As of December 5, 2016, an NDA holder submitting information on a patent that claims both the drug substance and the drug product (and is eligible for listing on either basis) is required only to specify that it claims either the drug substance or the drug product. Orange Book users should not rely on an Orange Book patent listing, regardless of when first published, to determine the range of patent claims that may be asserted by an NDA holder or patent owner.

#### Patent and Exclusivity for: N022272

Product 001 OXYCODONE HYDROCHLORIDE (OXYCONTIN) TABLET, EXTENDED **RELEASE 10MG** 

Patent Da	ta					
Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested
001	7674799	03/30/2025		DP		Υ
001	7674800	03/30/2025	DS			Υ
001	7683072	03/30/2025	DS			Υ
001	7776314	04/19/2025		DP		Υ
001	8309060	11/20/2023		DP	U-1556	
001	8808741	08/24/2027			U-1556	Ж
001	8894987	03/29/2030		DP		
001	8894988	08/24/2027		DP		
001	9060976	08/06/2022		DP		
001	9073933	03/30/2025	DS			
001	9492389	08/24/2027		DP		
001	9492391	08/24/2027			U-1556	
001	9492392	08/24/2027		DP		
001	9492393	08/24/2027			U-1556	
001	9522919	03/30/2025	DS	DP		
001	9675610	06/16/2023		DP		
001	9763933	08/24/2027		DP		
001	9770416	08/24/2027		DP		
001	9775808	08/24/2027		DP		

#### **Exclusivity Data**

<b>Product No</b>	<b>Exclusivity Code</b>	<b>Exclusivity Expiration</b>
001	NPP	08/13/2018

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## Orange Book: Approved Drug **Products with Therapeutic Equivalence Evaluations**

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#### Patent and Exclusivity for: N022272

Product 002 OXYCODONE HYDROCHLORIDE (OXYCONTIN) TABLET, EXTENDED **RELEASE 15MG** 

Patent Dat	ta					
Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested
002	7674799	03/30/2025		DP		Υ
002	7674800	03/30/2025	DS			Υ
002	7683072	03/30/2025	DS			Υ
002	7776314	04/19/2025		DP		Υ
002	8309060	11/20/2023		DP	U-1556	
002	8808741	08/24/2027			U-1556	
002	8894987	03/29/2030		DP		
002	8894988	08/24/2027		DP		
002	9060976	08/06/2022		DP		
002	9073933	03/30/2025	DS			
002	9492389	08/24/2027		DP		
002	9492391	08/24/2027			U-1556	
002	9492392	08/24/2027		DP		
002	9492393	08/24/2027			U-1556	
002	9522919	03/30/2025	DS	DP		
002	9675610	06/16/2023		DP		
002	9763933	08/24/2027		DP		
002	9770416	08/24/2027		DP		
002	9775808	08/24/2027		DP		

#### **Exclusivity Data**

<b>Product No</b>	<b>Exclusivity Code</b>	<b>Exclusivity Expiration</b>
002	NPP	08/13/2018

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View a list of all exclusivity codes (results\_exclusivity.cfm)

## Orange Book: Approved Drug **Products with Therapeutic Equivalence Evaluations**

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#### Patent and Exclusivity for: N022272

Product 003 OXYCODONE HYDROCHLORIDE (OXYCONTIN) TABLET, EXTENDED **RELEASE 20MG**