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

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

Pursuant to the ALJ's bench order during the May 21, 2019 hearing, Purdue submits this Supplemental Brief relating to *North Dakota ex rel. Stenehjem v. Purdue Pharma, L.P.*, No. 08-2018-CV-01300 (N.D.D. Ct. May 10, 2019), *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S.— (2019), and *In re Bajio, LLC*, DCP Case No. 83998 (Utah Div. Consumer Prot. Jan. 12, 2017).[1]

[1] Purdue also incorporates the Supplemental Brief submitted by the Individual Respondents.

I. *NORTH DAKOTA EX REL. STENEHJEM V. PURDUE PHARMA, L.P.*

In *North Dakota*, the court dismissed consumer protection claims almost identical to those alleged here.[2] The court first held that the State of North Dakota failed to plead causation because its "claims—no matter how styled—have to account for the independent actor (i.e., the doctor) who stands between Purdue's alleged conduct and the alleged harm." *Slip Op.* ¶ 55. The Division's Citation suffers from the same flaws as the North Dakota Complaint. The Division "does not identify any [Utah] doctor who ever received any specific purported representation made by Purdue, or who wrote a medically unnecessary prescription because of those alleged statements." *Id.* ¶¶ 50–51. Moreover, OxyContin's labeling "discloses the risks Purdue allegedly concealed," and, even if it did not, Purdue cannot be the "proximate cause of a patient's injury if the prescribing physician had independent knowledge of" those risks. *Id.* ¶¶ 54–55.

Instead, the Division argues that it is not required to allege that ***any*** harm resulted from Purdue's alleged conduct because it does not seek restitution. In part because the State sought restitution, the *North Dakota* court did not address whether causation was an element *per se* under North Dakota's CPA. Nonetheless, the court ***also*** entered judgment on the State's ***civil-penalty and injunctive-relief claims*** because, *inter alia*, the State specifically alleged causation and harm in its Complaint, *id.* ¶¶ 45–46, ***just as the Division alleges here.*** Indeed, the Division conceded that any such harm is relevant to determining the amount of any civil penalties. (Citation ¶ 29.)[3]

The *North Dakota* court also held that federal law preempted the State's claims based on

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[2] It is irrelevant that the court construed Purdue's motion as one for summary judgment because the relevant documents—OxyContin's FDA-approved labeling and the FDA's response to citizen petitions—may be considered on a motion to dismiss. (*See* Purdue's Reply at 3–4.)

[3] Additionally, as explained in Purdue's Motion, under the facts alleged here, the Division must show causation to establish a connection to a consumer transaction under the UCSPA.

the same alleged representations at issue here, including those regarding the safety and efficacy of opioids for the long-term treatment of chronic pain, (*id.* ¶¶ 49–68, 83–92), maximum dosing, (*id.* ¶¶ 69–72), 12-hour dosing, (*id.* ¶¶ 73–82), pseudo-addiction, (*id.* ¶¶ 51–53, 58–59), and the manageability of addiction risk. (*Id.* ¶ 54.) Because "the FDA retains authority to reject labeling changes," a manufacturer cannot be liable under state law where there is "clear evidence that the FDA would not have" permitted the manufacturer to change its labeling or marketing materials to add the warnings that a plaintiff's claims would require. *Wyeth v. Levine*, 555 U.S. 555, 571 (2009); *accord Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 488–89 (2013). After extensively reviewing OxyContin's FDA-approved labeling and the FDA's denial of PROP's Citizen Petition, which raised the same issues at the core of the Division's claims, the *North Dakota* court found that Purdue's "marketing practices . . . were consistent with the FDA-approved product labeling" and "the FDA *would not* have approved changes to Purdue's labels to comport with the State's claims." *North Dakota*, No. 08-2018-CV-01300, *slip op.* ¶¶ 29–35. Here, as in *North Dakota*, because "the FDA does not yet believe the state of the data supports additional warnings or altered labeling when presented with the issues asserted by the [Division], it would have been impossible for Purdue to comply with what the [Division] alleges was required under [Utah] law while still respecting the FDA's unwillingness to change the labeling and warnings, both on its labels for opioids and in its advertising." *Id.* ¶ 40.

II. ***MERCK SHARP & DOHME CORP. V. ALBRECHT***

The Division argues incorrectly that *North Dakota* was somehow made "obsolete" by the decision in *Albrecht*. In *Albrecht*, the U.S. Supreme Court held that *Wyeth*'s clear-evidence rule is a question of law that refers "to the ***type*** of [FDA action] that a manufacturer must show" to trigger

preemption, not a standard of proof. *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S.—, 2019 WL 2166393, at *6 (2019). The Court explicitly declined to specify the "methods" by which the FDA must disapprove of a labeling change to trigger *Wyeth* preemption, noting only that the FDA's actions must "lie within the scope of the authority Congress has lawfully delegated." *Id.* at *8.

Nonetheless, the Division erroneously argues that the FDA's decision not to change labeling triggers *Wyeth* preemption only if the ***manufacturer itself*** proposed the change, and that the FDA's labeling decisions—including its rejection of the PROP petition—thus do not preempt the Division's claims. The Division's argument ignores the Court's warning that it was ***not deciding*** what methods of disapproval are sufficient to establish preemption. Indeed, *Albrecht* did not involve a citizen petition, and the Court did not even decide whether the facts before it—FDA actions in response to a manufacturer's application—preempted state-law claims, let alone whether other agency actions—such as the denial of a citizen petition—would be sufficient. Significantly, Justices Alito, Kavanaugh, and Chief Justice Roberts raised this ***exact concern*** about misreading the Court's opinion, fearing that the majority's "discussion of the law and the facts may be ***misleading*** on remand." *Id.* at *12 (Alito, J., concurring) (emphasis added). Preemption "does not depend on whether ***the relevant drug manufacturer, as opposed to some other entity or individual***, brought the new information to the FDA's attention," or "require the FDA to communicate . . . that a label change is unwarranted." *Id.* (emphasis added). Instead, "if the FDA declines to require a label change despite having received and considered information regarding a new risk . . . the FDA [has] determined that a label change was unjustified." *Id.* As explained above, the FDA considered and rejected prior requests to change the OxyContin labeling,[4] and has

[4] The Division's assertion that the PROP petition "did not concern *warnings*, but *use* of" opioids is irrelevant

"require[d] Purdue to conduct additional studies . . . before any changes or additional warnings [will] be included." *North Dakota*, No. 08-2018-CV-01300, *slip op.* ¶ 30. Moreover, the Division has not pointed to any evidence that was not brought to the FDA's attention.

Additionally, the Division limited its claims to alleged misrepresentations that are "inconsistent" with OxyContin's labeling, (*see* May 21, 2019 Hr'g Tr. at 99, 102–03), and "made through channels that the FDA does not review." (Pl.'s Supp. Br. at 3.) The Division's Citation and Initial Disclosures, however, are not so restricted. At the very least, the Division's claims should be limited to non-branded marketing materials that are inconsistent with Purdue's FDA-approved labeling and branded marketing materials.[5] Finally, although counsel conceded that the Division does not claim Purdue deceived the FDA, (Hr.'g Tr. at 100), the Division contends that its claims are not preempted because Purdue "cannot show[] that i[t] fully disclosed all pertinent information to the FDA." (Pl.'s Supp. Br. at 6.) That claim is both abandoned and preempted. *See Buckman*, 570 U.S. at 488–89. Accordingly, the Division's claims must be dismissed to the extent they are based on: (1) representations consistent with the FDA's responses to the PROP and Connecticut petitions; (2) branded marketing materials submitted to the FDA under 21 CFR § 314.81; or (3) the contention that Purdue withheld or failed to disclose information from the FDA.

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and incorrect. First, the FDA does not limit uses of medications without changing the label's warnings or contraindications. Second, the PROP petition was submitted pursuant to the FDA's authority "to regulate labeling," and sought to "implement[] the label changes proposed in th[e] petition" and limit "the marketing of opioids."

[5] Despite insisting that it relies only on representations that "go beyond" or "contradict" OxyContin's labeling and marketing materials, the Division ***again*** conspicuously fails to identify ***even one example***. Instead, it points to statements by the FDA and CDC, including the FDA's responses to the 2008 Connecticut Attorney General petition and the PROP petition ***rejecting*** warnings regarding maximum dosing and 12-hour dosing. (Pl.'s Supp. Br. at 3.)

III. *IN RE BAJIO, LLC*

In *In re Bajio, LLC*, the ALJ held the Division lacked statutory authority to bring a citation for purely past conduct under the pre-May 2018 version of § 13-2-6(3) unless it had reason to believe at the time of the Citation that the respondent was currently violating the UCSPA. *Id.* at 5, 8.[6] Here, Purdue's right not to be subjected to an administrative proceeding vested when it ceased all direct marketing in February 2018. Although the Division says it has reason to believe Purdue continues to violate the UCSPA, it has not pleaded any ***facts*** to support that conclusory allegation.[7]

In *Bajio*, the ALJ also invited the Division to "pursue legislative expansion of its U.C.A. § 13-2-6(3) enforcement powers." *In re Bajio*, DCP Case No. 83998, at 6. And that is precisely what happened. In May 2018, the Legislature purposefully expanded the scope of the Division's administrative enforcement power to reach, for the first time, a person who "***has violated*** or is violating" the UCSPA. The Legislature also expanded the Division's jurisdiction from "[a] person violating" the UCSPA to "[a] person who has violated, is violating, or has attempted to violate" the UCSPA. UTAH CODE ANN. § 13-2-6(4). These changes demonstrate that the Legislature did ***not*** understand the prior language to include cases where a person "has violated" the UCSPA.

Bajio also held, however, that the Division could bring UCSPA claims for purely past conduct under § 13-11-17(4)(a), which provides for a fine and cease-and-desist order "for each violation," "in addition to [the] enforcement powers" under § 13-2-6. This interpretation was not

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[6] To the extent the Division has previously brought administrative actions for purely past conduct, it did so in contravention of the statute's plain language. It is unsurprising that such a practice may have gone largely unchallenged, given the limited scope and monetary damages at stake in the great majority of the Division's prior administrative actions.

[7] And with good reason: the Division's outside lawyers have taken the position in a challenge to Purdue's confidentiality designations that "Purdue has itself ceased promoting opioids." (*See* Letter from David Ackerman (May 10, 2019), attached as **Exhibit A**.)

advanced by the Division here, and is contrary to the statute for two reasons. First, the Legislature knew that § 13-11-17(4)(a) existed, yet it still amended § 13-2-6(3). Second, if § 13-11-17(4)(a) were interpreted to dispense with the restrictions imposed by § 13-2-6, the Division could issue a cease-and-desist order and impose a fine ***without issuing a citation or holding a hearing at all*** because the citation and hearing requirements ***all come from § 13-2-6***. Under *Bajio*'s erroneous interpretation, there is no basis for determining which § 13-2-6 restrictions still apply and which ones do not. The Legislature could not have intended to allow the Division to pursue under § 13-11-17(4)(a) the same remedies that it can pursue under § 13-2-6 with ***none*** of the restrictions. This interpretation contravenes the canons of statutory interpretation: if the Division could simply issue cease-and-desist orders or impose fines under § 13-11-17, § 13-2-6 would be surplusage. *Lancer Ins. Co. v. Lake Shore Motor Coach Lines, Inc.*, 2017 UT 8, ¶ 13, 391 P.3d 218.

A better reading of the statute is that the issuance of a citation in compliance with § 13-2-6 is a precondition to imposing the remedies allowed by § 13-11-17(4)(a). This interpretation accounts for the "in addition to" language in § 13-11-17(4)(a) because § 13-2-6(3) ***by itself*** does not provide for fines, let alone one fine "for each violation." Instead, § 13-2-6(3)(g) allows fines only "[i]f the chapter violated allows for an administrative fine"—*e.g.*, ***if § 13-11-17 allows fines as an "addition[al] . . . enforcement power."*** It also provides for only one cease-and-desist order, not one "for each violation."

In sum, § 13-11-17(4)(a) does not provide a mechanism to initiate administrative actions. The Division could bring this action only through § 13-2-6(3), which does not allow actions for purely past conduct. Because it had no reason to believe Purdue violated the UCSPA after February 2018, the Citation should be dismissed.

CONCLUSION

For the forgoing reasons, the Citation should be dismissed in its entirety.

Dated this 30th day of May, 2019.

SNELL & WILMER L.L.P.

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CERTIFICATE OF SERVICE

I hereby certify that on May 30, 2019, I caused a copy of the foregoing to be served by electronic mail upon the following:

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EXHIBIT A

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"I will stand for my client's rights.
I am a trial lawyer."
–Ron Motley (1944–2013)

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May 10, 2019

VIA EMAIL

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Re: *In the Matter of: Purdue Pharma L.P., et al.*, DCP Case No. 107102 (Utah)
Challenge to Designation of Documents as Confidential Information

Dear Will,

Pursuant to paragraph 32 of the Agreed Protective Order, the Division of Consumer Protection challenges the confidentiality of the following documents, which were attached as exhibits to the Division's Memorandum in Opposition to the Sackler Respondents' Motion to Dismiss the Division's Notice of Agency Action and Citation:

Exhibit	***Bates Number***
3	PPLPC012000368569
4	PPLPC039000000157
5	PDD9316716146
6	PPLPC062000001559
8	PPLP004030117
9	PDD1701029146
10	PDD150191375
11	PDD9316706668
12	PDD9316704259
13	PPLPC012000174478
14	PPLPC012000174477
15	PPLPC012000174202
16	PPLPC012000174476

Exhibit	*Bates Number*
18	PPLPC012000234801
19	Friedman Dep. Dec.1996
20	Friedman Dep. July 2002
21	Friedman Dep. July 2002
22	Friedman Dep. July 2002
23	Friedman Dep. May 2004
24	Friedman Dep. July 2002
25	PDD9316100460
26	PPLPC042000016733
29	PDD9316304897
30	PDD9316304898
32	PPLPC061000049074
33	PKY180149256
34	PPLPC045000004928
35	PPLPC045000004928
36	PPLPC012000170948
37	PPLP004030162
39	PPLPC04500005405
40	PPLPC061000024965
41	PDD9316101579
42	PPLPC012000153272
43	PPLC45000006550
45	Friedman Dep. Aug 2001 (excerpt)
46	PPLPC012000023080
47	PPLPC019000112417

The Division contends that none of these documents qualifies as "Confidential Information" or "Highly Confidential Information" under the Agreed Protective Order because none of the documents contains information "the disclosure of which could reasonably be expected to result in unfair competitive injury" to

Purdue or any other Respondent. Specifically, the documents cited are nearly all more than 10 years old and Purdue has itself ceased promoting opioids.

Pursuant to paragraph 32 of the Agreed Protective Order, please advise within 7 calendar days whether Purdue will remove the designations from each document or, if Purdue will not remove the designations, state the reason(s) for maintaining the confidentiality designations.

Please contact me with any questions regarding this letter.

Sincerely,

/s/ David I. Ackerman

David I. Ackerman

cc: Counsel of Record