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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, 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.

DIVISION'S RESPONSE TO PURDUE'S NOTICE OF SUPPLEMENTAL AUTHORITY

DCP Legal File No. CP-2019-005

DCP Case No. 107102

The Division of Consumer Protection ("Division") respectfully submits this response to Respondents Purdue Pharma L.P.'s, Purdue Pharma Inc.'s, and The Purdue Frederick Company's (collectively "Purdue") Notice of Supplemental Authority related to Purdue's Motion to Dismiss the Division's Citation and Notice of Agency Action. That Purdue did not immediately submit the decision it cites, which issued May 10, 2019, is understandable. The decision is readily distinguishable.

First, Purdue is wrong to describe *State of North Dakota v. Purdue Pharma, L.P., et al.*, case No. 08-2018-CV-01300 (May 10, 2019) ("N.D. Slip Op."), as pertaining to a "similar motion to dismiss." Purdue Notice at 2. Most obviously, the court did not rule on a motion to dismiss, but rather decided, based on the parties briefing and conduct at the hearing, that it would "treat Purdue's Motion as a motion for summary judgment." N.D. Slip Op. at 3.¹ It therefore addressed Purdue's preemption claims without a full record (as well as without the benefit of many of the arguments made, and facts alleged in the Citation, here).

Further, other courts, in ruling on motions to dismiss in actions by state attorneys general, have rejected the same preemption and causation arguments Purdue made in North Dakota. With respect to Purdue's preemption arguments, these decisions, attached as exhibits to the Division's opposition, include orders that specifically reject the contentions Purdue made in North Dakota. *See, e.g., In re Opioid Litigation*, No. 400000/2017, 2018 WL 3115102, at *8-9 (N.Y. Sup. Ct. June 18, 2018) (noting, among other things, that the Food and Drug Administration ("FDA") in 2013 granted in part the 2013 "PROP" citizen petition on which Purdue relied; that the partial

¹ The Division also notes that any discussion of recent summary judgment decisions is incomplete without disclosing that the Court in *Oklahoma, ex rel., Hunter* recently denied motions for summary judgment by other opioid manufacturers in that case. *See* Order Denying Motions for Summary Judgment, *Oklahoma, ex rel., Hunter v. Purdue Pharma L.P.*, No. CJ-2017-816 (Dist. Ct. Cleveland Cty. Okla. May 13, 2019).

denial of that petition did not meet the preemption standard for clear evidence that the FDA would have rejected a stronger warning; and that the FDA's response supported allegations that opioid manufacturers were making claims that were unsupported by substantial evidence); *Washington v. Purdue Pharma L.P.*, No. 17-2-25505-0 SEA (Wash. Super. Ct. May 14, 2018) (finding "that Purdue has not established that the FDA would have rejected proposed labels that were more conservative."). Furthermore, pursuant to today's Supreme Court decision in *Merck Sharp & Dohme Corp. v. Albrecht*, in order to meet the "clear evidence" standard for preemption of a failure to warn claim, Purdue would have to show that Purdue itself, not a third party, requested a change to its FDA approved label, fully informing the FDA of the justification for the change, but the FDA rejected the requested change. *Merck Sharp & Dohme Corp. v. Albrecht*, No. 17-290, slip op., (U.S. May 20, 2019). There is no indication that Purdue made such a request. Finally, unlike in the North Dakota case, the Division's claims are not based on failure to warn, but on affirmative deception, including through channels that are not regulated by the FDA and carry no warning or label at all.

Second, as Purdue appears to admit, the North Dakota court's conclusion regarding causation was based on its interpretation of the complaint in that case as seeking damages. The decision did not address standards or requirements for civil penalties.² As explained in the Division's Opposition to Purdue's Motion, claims for civil penalties and injunctive relief such as those at issue here do not require any showing of causation. In fact, the Tenth Circuit has held in the context of the Federal Trade Commission ("FTC") Act that it was error to "believe[] the FTC

² Even in the damages context, the North Dakota decision at best can be construed as accepting Purdue's invitation to join a split, irrelevant to this action, among courts addressing damages under the Federal False Claims Act ("FCA"), concerning whether a plaintiff must identify a representative example claim. *See Foglia v. Renal Ventures Mgmt.*, *LLC*, 754 F.3d 153, 156 (3d Cir. 2014) (Third Circuit case recognizing split and citing the First, Fifth, and Ninth Circuits as rejecting such a requirement).

had to present a 'parade' of consumer witnesses to establish its case." *F.T.C. v. Freecom Commc'ns, Inc.*, 401 F.3d 1192, 1206 (10th Cir. 2005). Finally, without reiterating the points made in its Opposition, the Division also notes, for example, that Purdue ignores that the central issue is whether the acts that Purdue cites as purportedly superseding causes are foreseeable. *See, e.g., Harris v. Utah Transit Auth.*, 671 P.2d 217, 219 (Utah 1983). The Division alleges throughout its complaint that the acts of third parties that contributed to the opioid crisis were not only foreseeable to Purdue, but indeed were the direct consequence of its deceptive marketing and unconscionable acts and practices.

DATED this 20th day of May, 2019.

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CERTIFICATE OF SERVICE

I certify that on May 20th, 2019 I served the Division's Response to Purdue's Notice of Supplemental Authority on the parties of record in this proceeding as set forth below:

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Dated this 20th day of May, 2019.

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