COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, ss. SUPERIOR COURT
C.A. No. 1884-cv-01808 (BLS2)

COMMONWEALTH OF MASSACHUSETTS,	)
v.	)
PURDUE PHARMA L.P., PURDUE PHARMA INC., RICHARD SACKLER, THERESA SACKLER, KATHE SACKLER, JONATHAN SACKLER, MORTIMER D.A. SACKLER, BEVERLY SACKLER, DAVID SACKLER, ILENE SACKLER LEFCOURT, PETER BOER, PAULO COSTA, CECIL PICKETT, RALPH SNYDERMAN, JUDITH LEWENT, CRAIG LANDAU, JOHN STEWART, MARK TIMNEY, and RUSSELL J. GASDIA	)

THE COMMONWEALTH'S SURREPLY IN OPPOSITION TO PURDUE'S MOTION TO DISMISS THE FIRST AMENDED COMPLAINT

LEAVE TO FILE SURREPLY GRANTED MAY 29, 2019

During the month after the Commonwealth served its Opposition and before Purdue served its Reply, two courts issued decisions related to this case: a trial court in North Dakota and the Supreme Court of the United States. Purdue made the North Dakota decision the centerpiece of its Reply argument and said nothing at all about the subsequent decision of the U.S. Supreme Court. The Commonwealth respectfully submits this Surreply to address these two decisions that were not available at the time of its Opposition.

On May 20, 2019, the U.S. Supreme Court decided *Merck Sharp & Dohme Corp. v. Albrecht*, holding that an FDA preemption defense "requires the drug manufacturer to show that

it fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning." 2019 WL 2166393, at *7. *Merck* reinforces the Supreme Court's holding in *Wyeth v. Levine*, discussed in the Commonwealth's Opposition at 9-11, that the preemption defense requires "clear evidence" that "it was impossible for [the drug company] to comply with both federal and state requirements." 555 U.S. 555, 571 (2009).

Purdue's Reply, served after *Merck*, does not address the Supreme Court's opinion at all, nor how Purdue possibly could have "fully informed the FDA" of all the dangerous, deceptive, and unfair conduct alleged in the Commonwealth's Complaint. Purdue, at the very least, did not fully inform the FDA about: Purdue's finding that higher doses keep patients on opioids longer (FAC ¶¶ 90-91); Purdue's finding that it was "very likely" that patients face "dose-related overdose risk" (FAC ¶ 74); Purdue's finding that its savings cards kept patients on opioids far longer (FAC ¶¶ 93-94, 384); Purdue's conclusion that opioid "pain treatment and addiction are naturally linked" (FAC ¶¶ 445-47); Purdue's determination that its own "long-term script users" were "target end-patients" for overdose-rescue drugs (FAC ¶ 473); Purdue's decision to hire the top OxyContin prescriber in Massachusetts as paid a spokesperson even when he was losing his medical license for dangerous prescribing (FAC ¶¶ 117-22); or the fact that Purdue's targeting of prolific prescribers, even when they were known to be harming patients, caused Massachusetts prescribers to write far more dangerous prescriptions and many more Massachusetts patients to overdose and die (FAC ¶¶ 114-16, 413, 711, 713). Thus, under *Merck*, Purdue cannot rely on the FDA to excuse Purdue's repeated, deadly violations of Massachusetts law.

Merck also adds another reason why the Court should not follow the isolated example of *State of North Dakota v. Purdue Pharma*, Case No. 08-2018-CV-01300, Order Granting

Defendants' Motion to Dismiss (N.D. District Court May 10, 2019). On May 10, 2019 — without the benefit of the *Merck* decision that would come ten days later — a North Dakota trial court became the first court in the nation to dismiss a state Attorney General's case against Purdue. The North Dakota court asserted that Supreme Court precedent (before *Merck*) did not define the standard for FDA preemption and that, instead, the existing Supreme Court law "simply held that in the circumstances of [one] case, there was no evidence that the manufacturer tried to alter the label to include additional warnings, and, therefore, the state law claims were not preempted." *Id.* at pg. 9 (emphasis in original). Even assuming that description was a fair account of uncertainty in the law before *Merck*, it is not so today. *Merck* "requires the drug manufacturer to show that it fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning." 2019 WL 2166393, at *7. At the motion to dismiss stage, the pleadings in this case do not establish either that Purdue informed the FDA of its marketing misconduct or that the FDA told Purdue that the misconduct was required by federal law. Indeed, the misconduct in this case goes far beyond a drug label and encompasses deceptive tactics that the FDA would never plausibly require.

The North Dakota decision is an outlier that does not acknowledge or address the nationwide consensus from which it departs. The North Dakota court did not mention *State of Arkansas v. Purdue Pharma L.P.*, No. 60CV-18-2018 (Ark. Cir. Ct. Apr. 5, 2019); *State of Vermont v. Purdue Pharma L.P.*, No. 757-9-18 (Ver. Super. Ct. Mar. 19, 2019); *State of Tennessee v. Purdue Pharma L.P.*, No. 1-173-18 (Tenn. Cir. Ct. Feb. 22, 2019); *State of Delaware v. Purdue Pharma L.P.*, No. N18C-01-223 MMJ CCLD, 2019 WL 446382 (Del. Super. Ct. Feb. 4, 2019); *State of Minnesota v. Purdue Pharma L.P.*, No. 27-CV-18-10788

(Minn. Dist. Ct. Jan. 4, 2019); *Grewal, Attorney General of New Jersey v. Purdue Pharma L.P.*, No. ESX-C-245-17, 2018 WL 4829660 (N.J. Super. Ct. Oct. 2, 2018); *State of New Hampshire v. Purdue Pharma Inc.*, No. 217-2017-CV-00402, 2018 WL 4566129 (N.H. Super. Ct. Sep. 18, 2018); *State of Ohio v. Purdue Pharma L.P.*, No. 17 CI 261, 2018 WL 4080052 (Ohio C.P. Aug. 22, 2018); *State of Alaska v. Purdue Pharma L.P.*, No. 3AN-17-09966CI, 2018 WL 4468439 (Alaska Super. Ct. July 12, 2018); or *State of Oklahoma v. Purdue Pharma L.P.*, No. CJ-2017-816, 2017 WL 10152334 (Okl. Dist. Ct. Dec. 6, 2017).

Even though the Commonwealth discussed all ten of these decisions in its Opposition (at pages 6-8) and provided copies of them in an Appendix, Purdue, like the North Dakota court, does not acknowledge or address them either.

Dated: May 29, 2019

Respectfully submitted,
COMMONWEALTH OF MASSACHUSETTS

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CERTIFICATE OF SERVICE

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