BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: National Prescription Opiate Litigation MDL No. 2804

Relates to: *City of Portland v. Purdue Pharma L.P., et al.*
D. Maine, Civil Action No. 2:18-cv-00282

City of Bangor v. Purdue Pharma L.P., et al.
D. Maine, Civil Action No. 1:18-cv-00298

City of Lewiston v. Purdue Pharma L.P., et al.
D. Maine, Civil Action No. 2:18-cv-00310

AMICUS AMERICAN HOSPITAL ASSOCIATION'S BRIEF IN SUPPORT OF DEFENDANTS MARK E. CIENIAWSKI, M.D. AND MICHAEL B. BRUEHL, M.D.'S MOTIONS TO PARTIALLY VACATE CONDITIONAL TRANSFER ORDERS (CTOs-47, -50, & -51)

Amicus American Hospital Association ("AHA") respectfully submits this *amicus curiae* brief in support of Defendants Mark E. Cieniawski, M.D. and Michael B. Bruehl, M.D.'s Motions to Partially Vacate Conditional Transfer Orders (CTOs-47, -50, & -51).[1] The American Hospital Association (AHA) represents more than 5,000 hospitals, health care systems, and other health care organizations, plus 43,000 individual members. AHA hospitals employ more than 270,000 affiliated physicians and two million nurses. AHA members are committed to improving the health of communities they serve and to helping ensure that care is available to and affordable for all Americans. AHA educates its members on health care issues and advocates to ensure that their perspectives are considered in formulating health policy. In recent years, the public health crisis created by the opioid epidemic has become a major focus for the

[1] Only Dr. Cieniawski is party to the motion in the *City of Portland* case regarding CTO-47; Dr. Bruehl is not a defendant in that case. Both Dr. Cieniawski and Dr. Bruehl are parties to the motions in the *City of Bangor* and *City of Lewiston* cases, regarding CTOs-50 and -51, respectively.

AHA, its members, and the physicians, nurses, and other caregivers who work at and with AHA hospitals and health systems.

Every day these caregivers contend with the powerful effects of opiate medications on the patients, families, and communities they serve. Prescription opioids can be a safe and necessary element of pain management for those who have experienced trauma or are suffering from cancer, sickle cell disease, or other conditions that cause debilitating pain. On the other hand, opioids carry significant risk for misuse, addiction, overdose, and death, and must be used judiciously.

AHA, its member hospitals, health systems, and other caregivers are on the front lines of combatting the abuse of opioid medications. Not only do AHA hospitals treat those who have been harmed by misuse of opioids, they also play a major role preventing opioid addiction and determining what doses are safe and reasonable when, in their medical judgment, their doctors must prescribe opioids to specific patients. These individualized medical decisions, however, have not been a focus of the ongoing MDL, which this Panel created to address the common national issues raised by the alleged conduct of "the *manufactur[ers] and distributor[s]*" of opioids. Transfer Order at 3, *In re: National Prescription Opiate Litigation*, 1:17-md-02804-DAP (JPML Dec. 12, 2017), ECF No. 1 ("Transfer Order") (emphasis added). And the allegations concerning Drs. Cieniawski and Bruehl are wholly outside this MDL's scope—the alleged "diversion of opiates … into illicit channels" and "improper marketing of such drugs." *Id.* The Amended Complaints in the *City of Bangor*, *City of Portland*, and *City of Lewiston* actions contain no substantive allegation suggesting either Dr. Cieniawski or Dr. Bruehl participated in marketing, promoting, or diverting opioids; indeed, they barely mention either physician at all. In *amicus*'s understanding, these doctors are merely local Maine primary care

physicians who were hospital employees and prescribed opioids only when they made an individualized clinical judgment that it was appropriate. The AHA respectfully submits that they are not proper defendants in this multi-district action, and so their motions to partially vacate Conditional Transfer Orders 47, 50, and 51 should be granted.

I. THE WIDESPREAD ABUSE OF OPIOIDS HAS A DEEP IMPACT ON AMERICAN HOSPITALS AND THE DOCTORS WHO WORK AT THEM

Opioid misuse and dependency present a major public health crisis. The United States Department of Health and Human Services has estimated that in 2016, 2.1 million people had an opioid disorder, resulting in over 42,000 deaths from overdose and approximately $504 billion in economic costs. United States Department of Health and Human Services, *What is the U.S. Opioid Epidemic?*, https://www.hhs.gov/opioids/about-the-epidemic/index.html.

Hospitals are at the forefront of the response to this issue. Emergency departments saw over 142,000 visits for opioid overdoses from July 2016 through September 2017—nearly 315 visits *per day* where physicians were routinely called upon to make lifesaving interventions.[2] For those they can save, hospitals and the physicians with whom they work closely play an important role in getting patients access to longer-term care and addiction treatment.

They also address the consequences of opioid addiction in infants born to opiate-dependent women. In 2013, 6.0 cases per 1,000 hospital births involved an infant born with Neonatal Abstinence Syndrome ("NAS"), a group of conditions caused by the infant's

[2] Alana M. Vivolo-Kantor et al., *Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses – United States, July 2016-September 2017*, CDC Morbidity and Mortality Weekly Report, Mar. 9, 2018, https://www.cdc.gov/mmwr/volumes/67/wr/mm6709e1.htm.

withdrawal from drugs he or she has been exposed to in the womb.[3] Infants with NAS require significantly more care than other infants, and hospitals typically provide that care.[4]

The heroic efforts to provide care for these patients consume immense resources.[5] At its most basic level, the volume of opioid patients in emergency rooms and NAS patients in NICUs occupy significant scarce hospital resources that could be provided to other patients. What's more, it is growing more and more expensive to treat overdose patients. According to one study, the average cost to hospital ICUs for such patients climbed from $58,517 in 2009 to $92,408 in 2015—a 58% increase.[6] And these skyrocketing financial costs of treating patients with opioid-associated health problems are often borne by hospitals, as many of these patients are uninsured or underinsured.[7]

Despite the dangers and costs associated with the misuse of prescription opiates, these medications remain a necessary and safe treatment option for a number of conditions that cause

---

[3] Jean Y. Ko et al., *Incidents Of Neonatal Abstinence Syndrome – 28 States, 1999-2013*, CDC Morbidity and Mortality Weekly Report, Aug. 12, 2016, https://www.cdc.gov/mmwr/volumes/65/wr/mm6531a2.htm.

[4] *See* NIH, *Dramatic Increases in Maternal Opioid Use and Neonatal Abstinence Syndrome*, https://www.drugabuse.gov/related-topics/trends-statistics/infographics/dramatic-increases-in-maternal-opioid-use-neonatal-abstinence-syndrome (noting that infants with NAS spend an average of 16.9 days in the hospital (often in intensive care units, or "NICUs"), compared to an average of 2.1 days for other infants).

[5] *See, e.g.*, Tyler N.A. Winkelman et al., *Incidence and Costs of Neonatal Abstinence Syndrome Among Infants with Medicaid: 2004-2014*, Pediatrics (March 2018), http://pediatrics.aappublications.org/content/early/2018/03/21/peds.2017-3520 ("Adjusting for inflation, total hospital costs for NAS births that were covered by Medicaid … [were] $462 million in 2014.").

[6] Jennifer P. Stevens et al., *The Critical Care Crisis of Opioid Overdoses in the United States*, Annals of the American Thoracic Society, 11 (Dec. 2017), http://www.thoracic.org/about/newsroom/press-releases/resources/opioid-crisis-and-icus.pdf.

[7] *See* Mary Rechtoris, *8 Statistics on Uninsured Adults with Opioid Addiction*, Becker's ASC Review (May 18, 2017), https://www.beckersasc.com/asc-coding-billing-and-collections/8-statistics-on-uninsured-adults-with-opioid-addiction.html ("Twenty percent of adults with opioid addiction lack insurance.").

debilitating pain. Thus, notwithstanding the dangers of opioid misuse and dependency, physicians can and must be able to retain the discretion to prescribe opioids to patients suffering severe and debilitating pain when other options are ineffective. If they could not do so, they could not responsibly carry out their professional responsibility to use sound medical judgment on their patients' behalf and provide effective, patient-centered care.[8]

Hospitals are aware that the opioid epidemic cannot be successfully dealt with by health care providers working independently, however. They are therefore collaborating with their communities to create coordinated responses. They are forming partnerships with other health care providers, state and local departments of health, law enforcement, schools, community organizations and others. Impressing the physicians with whom hospitals work closely into opioid litigation as defendants will only impede their valuable efforts to curtail the opioid epidemic and further burden them as they treat patients suffering from opioid-related conditions.

II. THE ONGOING MDL IS NOT FOCUSED ON INDIVIDUAL DOCTORS

The AHA knows that the Panel is well aware of the magnitude of the opioid crisis based on its work to date in this MDL. But the nature of this MDL is critical to Dr. Cieniawski and Dr. Bruehl's motion. As the AHA understands it, the focus of this MDL is not on individual prescribing physicians. This has been true from the MDL's initiation: This Panel's initial transfer order creating the MDL found that centralization of the cases into a single district was desirable because of the "common factual questions about … the manufacturing and distributor defendants' knowledge of and conduct regarding the alleged diversion of these prescription opiates, as well as the manufacturers' alleged improper marketing of such drugs" and the allegations that "[b]oth manufacturers and distributors" are alleged to "have failed to adhere to"

[8] *See* AMA Code of Medical Ethics 1.1.1 & 1.1.6, https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics-chapter-1.pdf.

standards under state and federal law "to prevent diversion of opiates … into illicit channels." Transfer Order at 3. Put another way, the MDL is focused on the nationwide promotion and distribution of opioid medication—not the individual prescribing decisions of local physicians.

The coordinated proceedings in the Northern District of Ohio have, unsurprisingly, followed this approach. The court's initial pretrial conference order set up a conference to "educate the Court … on supply-chain dynamics"—the fundamental issue with respect to nationwide, common factual issues regarding opiate distribution and marketing—not on individual prescribing habits. Minutes of Initial Pretrial Conference - 1/9/18 at 1, *In re: National Prescription Opiate Litigation*, 1:17-md-02804-DAP (N.D. Ohio Jan. 11, 2018), ECF No. 70. The court also established "negotiating teams to discuss settlement," comprising the major groups of parties in the litigation: Plaintiffs, Manufacturer-Defendants, Distributor-Defendants, State Attorneys General, and Chain Pharmacies. Amended Order at 1, *In re: National Prescription Opiate Litigation*, 1:17-md-02804-DAP (N.D. Ohio Feb. 12, 2018), ECF No. 124, *see id.* at 2; Order at 2, *In re: National Prescription Opiate Litigation*, 1:17-md-02804-DAP (N.D. Ohio Feb. 12, 2018), ECF No. 228 (N.D. Ohio April, 9, 2018). The Court also contemplated creating a future team for insurers. *See* Amended Order, ECF No. 124 at 2.

Nowhere did the court suggest that a team representing individual physicians would be necessary to participate in discussions to resolve the issues of the MDL, and the court has even separately stayed the cases as they relate to the handful of physician defendants who—unlike Drs. Cieniawski and Bruehl—are alleged to have participated in the *marketing* of opioids. Order Regarding Stay as to Physician Defendants, *In re: National Prescription Opiate Litigation*, 1:17-md-02804-DAP (N.D. Ohio May 9, 2018), ECF No. 407; *cf* Amended Order, ECF No. 124; Order, ECF No. 228. Individual doctors—even those alleged to have participated in the

marketing of opioids central to the MDL—are simply tangential to the MDL's focus on nationwide supply.

With one exception, the *City of Bangor*, *City of Portland*, and *City of Lewiston* actions are in keeping with the remainder of cases in the MDL. As discussed below, that exception is the handful of paragraphs addressing Drs. Cieniawski and Bruehl. Other than those allegations, the headings of the fact sections in the Amended Complaints demonstrate that their gravamen involves the marketing of opioids. *See* Amended Complaint, *City of Bangor v. Purdue Pharma L.P. et al.*, No. 1:18-cv-00298-NT ("*Bangor* Am. Compl.") (D. Maine Aug. 6, 2018), ECF No. 1-2; Amended Complaint, *City of Portland v. Purdue Pharma L.P. et al.*, No. 1:18-cv-00282-NT ("*Portland* Am. Compl.") (D. Maine July 20, 2018), ECF No. 6-32; Amended Complaint, *City of Lewiston v. Purdue Pharma L.P. et al.*, No. 1:18-cv-00310-NT ("*Lewiston* Am. Compl.") (D. Maine Aug. 13, 2018), ECF No. 1-2. In particular, after a "background" section, the five substantive sections of the complaints setting forth the alleged conduct all address *marketing* of opioids.[9] The sections of the Amended Complaints setting forth the purported consequences of the alleged misconduct similarly are addressed to the marketing of opioids.[10]

Lest there be any doubt that these Amended Complaints are not focused on prescribing physicians, the documents themselves describe prescribing physicians as *targets* of the alleged

[9] *See, e.g., Bangor* Am. Compl. at iv. ("Defendants Promoted Their Branded Products through Direct Marketing…."); *id.* ("Defendants Used 'Unbranded' Marketing…."); *id.* at v ("Defendants' Marketing Messages Are Misleading…."); *see also Lewiston* Am. Compl. at iv-v (same); *Portland* Am. Compl. at iv-v (same); *cf.* Transfer Order at 3 ("All of the actions [consolidated into the MDL] can be expected to implicate common fact questions as to the allegedly improper marketing and widespread diversion of prescription opiates.").

[10] *See, e.g., Bangor* Am. Compl. at vii. ("Defendants' … Marketing of Opioids … Caused Harm"); *id.* (Defendants' … Marketing Has Led to Record Profits"); *id.* ("Through Their Public Statements, Marketing, and Advertising, Defendants … Deprived Plaintiff Of … Knowledge…."); *see also Lewiston* Am. Compl. at vii (same); *Portland* Am. Compl. at vii (same).

misconduct, rather than as participants in it. Each states: "Each Defendant Engaged in Deceptive Marketing … that Targeted … Prescribers." *Bangor* Am. Compl. at v; *Portland* Am. Compl. at v; *Lewiston* Am. Compl. at v. Thus, the overwhelming majority of the *City of Bangor, City of Portland*, and *City of Lewiston* actions mirror the MDL: Their focus is on nationwide supply and marketing of opioids, rather than the conduct of individual physicians. The handful of allegations regarding Drs. Cieniawski and Bruehl, two local Maine prescribing physicians, therefore have no connection to the issues addressed by the MDL.

III. THE FACTUAL ALLEGATIONS ARE OUTSIDE THE SCOPE OF THE MDL AND, IN ANY EVENT, LEGALLY INSUFFICIENT

The City of Bangor's action is presented in a 280 page, 923 paragraph Amended Complaint. The City of Portland and City of Lewiston's Amended Complaints are nearly identical in size and scope. Those lengthy pleadings contain no substantive allegation that either Dr. Cieniawski or Dr. Bruehl participated in either marketing opioids or "diver[ting them] into illicit channels." Transfer Order at 3. The claims against these doctors thus involve no "common questions of fact" supporting their consolidation into multidistrict proceedings. 28 U.S.C. § 1407(a).

The only allegations addressing either Dr. Cieniawski or Dr. Bruehl in any of the Amended Complaints appear in the section identifying the parties. Neither doctor is discussed *once* in the substantive sections of the documents. The five paragraphs addressing each doctor allege in substance only that each was placed on probation by the Maine Board of Licensure. *See Bangor* Am. Compl. ¶¶ 119-128; *Lewiston* Am. Compl. ¶¶ 116-125; *Portland* Am. Compl.

¶¶ 119-123.[11] Neither doctor is alleged to have marketed opioids or diverted them to illicit channels.

Far from marketing or illicitly diverting opioids, the consent agreements with the Maine licensing board show that each defendant was treating the relevant patients in good faith. Dr. Bruehl was disciplined for prescribing "large doses" of opioids to a *single* patient who experienced "chronic pain … from her multiple abdominal surgeries" and the consent agreement notes that he did not believe the patient was abusing the medications. Consent Agreement at 2, In Re Michael B. Bruehl, M.D., Complaint No. CR16-24 (ME Board of Licensure in Medicine Nov. 8, 2016), http://www.maine.gov/tools/whatsnew/attach.php?id=726389&an=1. Dr. Cieniawski, similarly, was placed on probation for documentation and procedural issues related to a small number of patients for whom he and the other "physicians in [his] practice" concluded "nothing else worked" to treat their pain. Consent Agreement at 2, In Re Mark E. Cieniawski, M.D., Complaint No. CR15-163 (ME Board of Licensure in Medicine April 11, 2017), http://www.maine.gov/tools/whatsnew/attach.php?id=743129&an=1.

The only other allegation about each doctor is the conclusory assertion that each "was instrumental in promoting opioids for sale and distribution in Maine" or one of the plaintiff cities. *Lewiston* Am. Compl. ¶¶ 116,121; *see also Bangor* Am. Compl. ¶¶ 119, 124 (alleging the two physicians were "instrumental in promoting opioids for sale and distribution in Bangor"); *Portland* Am. Compl. ¶ 119 (alleging Dr. Cieniawski "was instrumental in promoting opioids for sale and distribution in Portland"). This allegation, wholly unsupported by the remainder of the complaint, is the paradigmatic conclusory allegation that is insufficient to withstand a motion to dismiss. *See, e.g., Ashcroft v. Iqbal*, 556 U.S. 662, 681 (2009) (conclusory allegations, including

[11] As noted above, *supra* note 1, Dr. Bruehl is not named or mentioned at all in the City of Portland's Amended Complaint.

that individual was "instrumental" in adopting and executing complained of policy, are "not entitled to be assumed true" on a motion to dismiss); *see also Flemming v. Smith*, No. 9:11-CV-00804 NAM, 2014 WL 3698004, at *6 (N.D.N.Y. July 24, 2014) ("Conclusory allegations that medical staff defendants were aware of a plaintiff's medical needs and failed to provide adequate care are generally insufficient to state [a claim]."). This allegation is plainly the kind of "bare assertion[]" that cannot survive a motion to dismiss. *Iqbal*, 556 U.S. at 681. Consequently, on these allegations, plaintiffs should not be permitted to drag two Maine doctors into an MDL in Ohio that is expressly related to the nationwide manufacture, advertising, and promotion of opioids.

IV. CONCLUSION

For the reasons stated above, Defendants Mark E. Cieniawski, M.D. and Michael B. Bruehl, M.D.'s Motions to Partially Vacate Conditional Transfer Orders (CTOs-47, -50, & -51) should be granted.

DATED: September 20, 2018

By: */s/ Christopher M. Lynch*

Chad Golder
Christopher M. Lynch
MUNGER, TOLLES & OLSON LLP
1155 F Sreet NW, 7th Floor
Washington, DC 20004-1361
Telephone: (202) 220-1100
Facsimile: (202) 220-2300
Email: chad.golder@mto.com
christopher.lynch@mto.com

Attorneys for Amicus American Hospital Association

CERTIFICATE OF SERVICE

I certify that on September 20, 2018, I electronically filed the foregoing ***AMICUS AMERICAN HOSPITAL ASSOCIATION'S BRIEF IN SUPPORT OF DEFENDANTS MARK E. CIENIAWSKI, M.D. AND MICHAEL B. BRUEHL, M.D.'S MOTIONS TO PARTIALLY VACATE CONDITIONAL TRANSFER ORDERS (CTOs-47, -50, & -51)*** using the CM/ECF system, which will send notification of such filing to all attorneys of record.

I certify under penalty of perjury that the foregoing is true and correct.

Dated this 20th day of September, 2018, at Washington, District of Columbia.

/s/ Christopher M. Lynch
Christopher M. Lynch
MUNGER, TOLLES & OLSON LLP
1155 F Sreet NW, 7th Floor
Washington, DC 20004-1361
Telephone: (202) 220-1100
Facsimile: (202) 220-2300
Email: chad.golder@mto.com
christopher.lynch@mto.com

Attorneys for Amicus American Hospital Association