IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.* Case No. 18-op-45090 and *The County of Cuyahoga v. Purdue Pharma L.P., et al.* Case No. 1:18-op-45004	**MDL No. 2804** **Case No. 17-md-2804** **Hon. Judge Dan A. Polster**

JANSSEN DEFENDANTS' TRIAL BRIEF

I. INTRODUCTION

Janssen fully recognizes the opioid crisis that exists in this country.[1] But one thing is clear: Janssen's medications did not cause or contribute to that crisis. Janssen marketed two Schedule II opioid pain medications during the period involved in this case: a fentanyl-based skin patch called Duragesic approved by the FDA in 1990 and a tapentadol-based tablet called Nucynta ER, designed to deter abuse that was approved in 2011—well into the opioid crisis. Even Plaintiffs' own experts admit that Duragesic and Nucynta ER made up *less than one percent* of the Counties' prescription opioid market. Janssen's medications had among the lowest rates of abuse and diversion of any Schedule II prescription opioid on the market. Nor can Plaintiffs blame the crisis on Janssen's marketing. Janssen will prove that its marketing was and remains supported by scientific medical evidence, offered in good-faith and without a scintilla of fraudulent intent.

Plaintiffs' accusations that Janssen was part of a criminal conspiracy or enterprise to defraud doctors about the risks of opioids are baseless and irresponsible. So are their arguments that Janssen failed to curb diversion of its opioid products. As the evidence will show, Janssen had a suspicious order monitoring ("SOM") program that fully complied with DEA regulations. The SOM program had a perfect DEA-inspection and compliance record.

Plaintiffs' attempts to hold Janssen responsible for the opioid crisis are misguided and will be rejected at trial.

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[1] This brief is submitted on behalf of all the Janssen defendants, and so "Janssen" refers to Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc., and Johnson & Johnson. Johnson & Johnson, however, is a parent company and did not sell or promote opioid medications.

II. THE PROBLEM OF CHRONIC PAIN

Chronic pain affects the lives of every American, either directly or indirectly through its staggering social costs. It plagues approximately 50 million Americans—or one in five adults—and causes an estimated $560 *billion* annually in medical and lost productivity costs.[2] More important than any monetary harms associated with chronic pain are its debilitating effects on every aspect of an afflicted person's life. Without proper treatment, chronic pain can have devastating consequences far beyond physical health—patients suffering from chronic pain have higher risks of unemployment, depression, suicide, and other psychological and social harms.[3]

Beginning in the 1970s, the medical community and the federal government began paying closer attention to the problem of untreated chronic pain. In 1977, a group of government researchers and federal regulators assembled at the request of the White House to research solutions to the problem. In 1981, they issued a report that found research and treatment options for chronic pain were lacking; they called on pharmaceutical manufacturers to give "attention to more potent analgesics [and] consider[] other routes of administration."[4]

There has since been widespread agreement among the medical community, federal regulators, and state officials that opioid medications can safely and effectively treat chronic pain long-term for some patients. The FDA has consistently endorsed the use of opioids to treat chronic pain[5] and after rigorous scrutiny has approved certain opioid medications (including

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[2] Trial Ex. DEF-18775, *CDC Morbidity and Mortality Weekly Report, Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults -- United States, 2016* (Sept. 14, 2018) at 2.
[3] *Id.* at 5.
[4] *See* Trial Ex. JA-1246, Rationale for the Development, Therapeutic Use, and Clinical Program for Transdermal Therapeutic System (Fentanyl) at 1.
[5] Trial Ex. JA-423, FDA Guide to Safe Use of Pain Medicine (Feb. 9, 2009) at 4 ("[S]tudies have shown that properly managed medical use of opioid analgesic compounds (taken exactly as prescribed) is safe, can manage pain effectively, and rarely causes addiction."); Trial Ex. JA-2271, Statement by Douglas Throckmorton, M.D., Deputy Center Director for Regulatory Programs in FDA (Apr. 9, 2019) at 1 (affirming FDA's commitment to "enabling appropriate access to [opioid analgesics] for patients living with serious pain").

Janssen's) as "safe and effective" for treatment of chronic pain.[6] Even the State of Ohio has taken steps to promote doctors' use of prescription opioids. In 1997, the Ohio Legislature enacted the Intractable Pain Act, which expanded physician prescribing authority to encourage treatment of chronic pain with opioids.[7]

III. JANSSEN MADE INNOVATIVE MEDICATIONS THAT MET PATIENT NEEDS AND DISCOURAGED ABUSE

Heeding calls for medications to address untreated chronic pain, for nearly three decades Janssen has supplied safe and effective, FDA-approved opioid medications that have provided patients with necessary relief and have never been widely abused or diverted. Plaintiffs have no evidence that Janssen's medications contributed to the opioid crisis.

Duragesic. Janssen began developing Duragesic in the 1980s in response to the growing awareness about the needs of pain patients.[8] Duragesic was first approved by the FDA in 1990[9] and was a breakthrough medicine. It was the first opioid medication in an extended-release adhesive patch that delivered a safe and controlled dose of pharmaceutical fentanyl for 72 hours without intravenous or subcutaneous administration.[10] The patch provided many important benefits—it eliminated the need for costly around-the-clock nursing staff; the slow, steady delivery reduced the chance of medication-dosing errors; and it provided a safe alternative to patients who have difficulty swallowing pills.[11] Duragesic was also exceedingly more difficult to abuse than other opioids: Unlike pills, patches cannot be crushed and snorted. The slow-

[6] *See* 21 U.S.C. §§ 355(d), 393(b)(2)(B) (FDA must approve medications as "safe and effective" before they can be sold in the United States).
[7] *See* O.R.C. § 4731.052(C).
[8] *See* Trial Ex. JA-1246, Rationale for the Development, Therapeutic Use, and Clinical Program for Transdermal Therapeutic System (Fentanyl) at 1.
[9] Trial Ex. JA-2322, 2018 Duragesic Label at 1.
[10] *See* Trial Ex. JA-1246, Rationale for the Development, Therapeutic Use, and Clinical Program for Transdermal Therapeutic System (Fentanyl) at 3.
[11] *Id.* at 3-4.

release mechanism made it less attractive to users seeking a quick high,[12] and extracting a nonlethal dose of fentanyl from the patch is extremely difficult, further discouraging and deterring abuse.[13]

Nucynta ER. In the early 2000s, reports of abuse of pure long-acting oxycodone pills began to rise sharply.[14] The number of people who admitted to using oxycodone pills for non-medical purposes also increased from 1999 to 2003.[15]

During this time, Janssen began to develop its Nucynta tablets—short-acting/immediate-release Nucynta and long-acting/extended-release Nucynta ER, on which Plaintiffs have specifically focused. Neither pill was sold until after Plaintiffs allege the opioid crisis began—Nucynta was FDA approved in 2008 and went to market in June 2009, and Nucynta ER was approved and released in 2011. In developing its Nucynta products, Janssen explicitly sought to respond both to patient needs and increased concerns related to opioid abuse by creating pills just as effective as other opioids, but with fewer side effects and abuse potential. Indeed, the Nucynta tablets were unique because their active ingredient, tapentadol, was designed with a dual action mechanism that worked both in the brain and at the site of pain to treat pain with fewer side effects than conventional opioids. Nucynta ER also had a specially designed tamper-resistant formulation that made it extraordinarily difficult to crush, grind, or dissolve. Janssen was so concerned with creating an abuse-deterrent, long-acting opioid that it delayed the release

[12] Trial Ex. JA-489, Duragesic Revised Risk Management Plan (Sept. 26, 2008) at 49; *see also* Trial Ex. JA-684, Assessment of the Abuse of Transdermal Fentanyl at 5 ("Transdermal fentanyl is less subject to abuse than other potent opioids because of its chemical formulation.").
[13] *See* Trial Ex. JA-2049, Examination of Transdermal Fentanyl Patch Systems Postings on Internet Bulletin Boards (Jun. 7, 2006) at 7 ("It appears that fear of fentanyl dose control, possibly derived in part from the difficulty in extracting known 'safely abusable' doses from Duragesic, is continuing to serve to keep the transdermal systems relatively unattractive as compared to heroin, which continues in the status of the most preferred opioid . . . .").
[14] Trial Ex. JA-3692, Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse, available at https://www.fda.gov/drugs/information-drug-class/timeline-selected-fda-activities-and-significant-events-addressing-opioid-misuse-and-abuse.
[15] *Id.*

of Nucynta ER until it had perfected the tamper-resistant coating. Nucynta ER was the first new opioid released with such a coating.

Duragesic and Nucynta ER Played No Part in the Opioid Crisis. Janssen has never suggested that its opioid medications, like all Schedule II opioids, do not carry potential risks of addiction, abuse, and fatal overdose. But its medications did not play any part in the crisis of abuse and diversion that Plaintiffs allege here. Both Duragesic and Nucynta ER were less subject to abuse and diversion than other opioids, and Janssen comprehensively warned of their risks in FDA-approved labels, patient medication guides, and educational materials.[16]

These efforts paid off. As overdose and diversion rates for oxycodone and hydrocodone pills skyrocketed, the Duragesic patch and Nucynta ER consistently ranked among the least abused and diverted opioid products—in Ohio or anywhere else.[17] The evidence at trial will confirm that opioid use disorder diagnoses and doctor-shopping episodes associated with Duragesic and Nucynta ER in Ohio were marginal. And as Plaintiffs' own expert Lacy Keller admits, Janssen's opioids accounted for a miniscule fraction of Summit and Cuyahoga counties' prescription opioid market—less than 1 percent.[18]

IV. JANSSEN'S MARKETING DID NOT CAUSE THE OPIOID CRISIS

Unable to claim that Janssen's rarely abused, rarely diverted medications caused the opioid crisis, Plaintiffs instead claim Janssen's marketing was false and misleading. The evidence will show otherwise. Janssen's marketing statements were all well supported by scientific evidence. In 2009—in the midst of the opioid crisis—the FDA itself stated that

[16] *See, e.g.*, Trial Ex. JA-1215, Duragesic Label 2005-02 at 1 (containing black-box warning of medication's risks); Trial Ex. JA-4697, Nucynta ER Risk Evaluation and Mitigation Strategy (discussing warnings in Nucynta ER medication guides and educational materials).
[17] Trial Ex. JA-2157, RADARS System Tapentadol Report (Apr. 7, 2015) at 16, 61 (showing opioid diversion and abuse rates over time).
[18] Dkt. 1914-4, L. Keller Rep. at 16, Tables 1 & 2 (showing market shares between 1997 and 2017).

"properly managed medical use of opioid analgesic compounds (taken exactly as prescribed) is safe, can manage pain effectively, and rarely causes addiction,"[19] language Janssen will show is virtually identical to the Janssen statements Plaintiffs now claim were false or misleading.

Branded Marketing. Janssen's branded marketing efforts focused only on its medications, which represented a negligible share of the prescription-opioid market and were not significantly abused, misused, or diverted. Janssen engaged in accurate, science-based marketing that was carefully reviewed by an internal Promotional Review Committee ("PRC"). Janssen's statements in its branded marketing aids used by sales representatives were entirely consistent with language approved by the FDA in the drugs' labels.

Unbranded Marketing. Beginning in 2008, Janssen created or sponsored certain educational materials that addressed the broad subject of pain management, including the use of prescription opioids where appropriate. Like its branded marketing, Janssen's unbranded statements were vetted by the PRC to ensure they were truthful and medically accurate. In addition, Plaintiffs' marketing-causation expert, Meredith Rosenthal, conceded that her statistical model—which considers branded detailing only—does not and cannot quantify the effects of unbranded marketing.[20] Moreover, since Janssen's unbranded marketing occurred *after* Plaintiffs claim the crisis began, they cannot be said to have been the cause of the crisis.

Statements by Third Parties. It will be undisputed that Janssen did not control key opinion leaders or professional advocacy organizations, nor did any funding Janssen provided influence their speech. Janssen did not conspire with other manufacturers—to the contrary, Janssen competed against them in selling medications less subject to abuse and diversion. When

[19] Trial Ex. DEF-20396, FDA Guide to Safe Use of Pain Medicine (Feb. 23, 2009) at 4.
[20] Dkt. 1984-4, M. Rosenthal Dep. at 145:6-22, 212:9-12.

manufacturers did associate, they operated lawfully under the oversight or direction of the FDA or coordinated for lawful, business reasons.

V. JANSSEN'S SUSPICIOUS ORDER MONITORING PROGRAM DID NOT CAUSE THE OPIOID CRISIS

Plaintiffs cannot pin the cause of the opioid crisis on any purported failures of Janssen to monitor its opioid distribution chain. Janssen had a robust suspicious order monitoring ("SOM") program that passed all DEA inspections. As a manufacturer of controlled substances, Janssen is heavily regulated by federal agencies, including the DEA. DEA regulations require Janssen to establish a SOM program that identifies orders of controlled substances of unusual size, frequency, or duration.[21] Janssen established a SOM program that monitored for all three types of suspicious orders. In exercising its oversight responsibility, and after multiple inspections of Janssen's distribution facilities by some fourteen separate investigators since 2006, the DEA never once raised a concern about Janssen's program.[22] Janssen's program so impressed DEA inspectors that one even commented that he "likes coming to places like" Janssen.[23] Notably, Janssen is the only manufacturer Plaintiffs do not name in their RICO supply chain enterprise claims, perhaps in recognition of how carefully Janssen monitors its opioid distribution.[24]

The purpose of SOM programs is to prevent diversion of controlled substances. Plaintiffs' diversion expert James Rafalski[25] testified that he could not identify a single instance of diversion of Duragesic or Nucynta in the Track One jurisdictions or a single order shipped from manufacturers to distributors that should have been reported as a suspicious order.[26]

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[21] *Id.*
[22] Trial Exs. JA-03534, JA-03465, JA-03417, JA-03531, JA-03532, JA-03466, JA-03533 (email correspondence with DEA investigators).
[23] Trial Ex. JA-03465, Email from Martha Warwick to Maryann Gribbin, et al. (July 30, 2013) at 8 ("[DEA Investigator Billy Lane] [o]verall likes coming to places like this.").
[24] Dkt. 2182, Pls.' Opp. to MSJ on Pls.' Civil Conspiracy, RICO and OCPA Claims at 3, 4.
[25] Dkt. 1969-18, Rafalski Dep. (May 13, 2019) at 18:17, 19:21-23, 20:6-11.
[26] *Id.* at 633:13-634:2; 635:2-13, 734:10-15; 735:19-736:1.

Plaintiffs maintain that they need not present proof about individual reporting lapses, but they also fail to provide aggregate proof of SOM failures.[27] And Plaintiffs' "data analyst" expert, Lacey Keller, offers no opinion that any of the orders she tallies were in fact "suspicious" under the Controlled Substances Act.[28]

VI. ALTERNATIVE CAUSES SUCH AS PUBLIC POLICY FAILURES AND ILLICIT DRUG USE DROVE THE OPIOID CRISIS

The evidence at trial will also show that Plaintiffs have ignored the multiple, alternative causes to the Counties' opioid crisis. The crisis has been marked by pervasive diversion and abuse of oxycodone and hydrocodone pills, unscrupulous doctors and internet pharmacies operating as drug-trafficking organizations, foreign criminal cartels that flooded the country with heroin and fentanyl illegally made in clandestine labs, and state and federal governments that struggled to ensure patients had access to necessary medications while addressing long-known problems of abuse, misuse, diversion, and overdose.

For example, Plaintiffs disregard that it was the State of Ohio that had far better insight and data regarding prescription drug abuse and diversion going back to the 1980s.[29] Yet the State struggled to strike the right balance between these risks and the benefits of essential pain medication. While doctors and pharmacists had called for the creation of a statewide prescription drug monitoring program for years, Ohio did not establish one until 2006—and the State waited an additional *nine years* to require opioid prescribers and pharmacists to check

[27] *E.g.*, Dkt. 2389, Plfs.' Opp. to Janssen Mot. for Summ. J. at 21
[28] Dkt. 1969-13, Keller Dep. (June 13, 2019) 51:6-52:15, 55:23-56:19, 124:17-22, 247:8-14.
[29] Changing social conditions no doubt contributed to the opioid crisis. Since at least 1979, well before Janssen manufactured opioids, overdose deaths have followed a clear upward trend, suggesting that broader societal factors, like worsening job opportunities, are influencing overdose deaths. Trial. Ex. DEF-19935, Hawre Jalal, et al., Changing Dynamics of Drug Overdose Epidemic in the United States from 1979 through 2016 (Sept. 21, 2018) at 1-2; Trial Ex. DEF-20504, Anne Case & Angus Deaton, Mortality and Morbidity in the 21st Century, Brookings Papers on Economic Activity (Spring 2017) at 397-98.

Ohio's prescription drug reporting system before prescribing or furnishing opioids.[30] The Ohio government similarly delayed in addressing pill mills, waiting until 2011 to enact legislation that more strictly regulated "pain management clinics" and the amount of controlled substances physicians can prescribe.[31] Following its enactment, opioid overdose deaths began to drop.[32]

Nor did the federal government always take adequate steps to combat prescription drug diversion. For example, the DEA's Office of Inspector General ("OIG") issued a report in 2002 concluding that the DEA's efforts to combat diversion of pharmaceutical drugs was insufficient—the DEA "dedicated only 10 percent of its field investigator positions to diversion investigations" and "[s]ince 1990, the number of diversion investigators as a percentage of total DEA investigators has *decreased* by 3 percent."[33] OIG also concluded that diversion investigations were hampered by the fact that diversion investigators lacked law enforcement authority, and relied on DEA Special Agent assistance to carry out their investigations.[34]

These government failures are important because corrupt prescribers have caused much of the harm at issue. Certain doctors wrote scores of medically improper opioid prescriptions without properly evaluating often cash-paying patients because it was extremely lucrative—not because of anything said in Janssen's marketing. For over a decade, neither federal law enforcement nor regulatory boards prioritized criminal over-prescribing for prosecution or disciplinary action, allowing a disproportionate share of medically unnecessary prescriptions to harm Summit and Cuyahoga residents.

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[30] O.R.C. § 4731.055.
[31] *See* O.R.C. § 4729.552.
[32] Trial. Ex. DEF-79, Ohio Department of Health, 2016 Overdose Data: General Findings at 2.
[33] Trial. Ex. DEF-17552, Mem. of Glenn A. Fine (Inspector General) to the DEA (2002) at ii.
[34] *Id.*

Moreover, illicit drug use accounts for much of the harm for which Plaintiffs blame Janssen. Indeed, Janssen will show that heroin use began increasing across the Counties in the 1990s. By the turn of the century, heroin availability in the Counties was "unreal."[35] At the same time, drug cartels began selling higher purity heroin, allowing abusers to smoke or snort it, thereby eliminating the stigma of using a needle to inject it.[36] Over the past several years, foreign drug cartels have flooded the nation with cheap heroin and illicit fentanyl. The availability of higher purity heroin and increased availability of illicit fentanyl have combined to cause the increase in reported drug-related mortalities across the county.[37] The evidence at trial will show that, although heroin abuse rates have remained relatively steady over the past several years, deaths attributed to those substances have spiked. Janssen's opioid products did not cause that increase—the activities of foreign drug cartels did.

VII. CONCLUSION

For the foregoing reasons, Plaintiffs will not be able to show at trial that Janssen contributed to the opioid crisis to any degree.[38]

[35] Trial Ex. DEF-17465, The Ohio Substance Abuse Monitoring Network, Surveillance of Drug Abuse Trends in the State of Ohio (January-June 2000) at 5.
[36] Trial Ex. DEF-17504, U.S. Dep't of Justice, Nat'l Drug Intelligence Center, Ohio Drug Threat Assessment (April 2001) at 9.
[37] *Id.*; Trial Ex. DEF-19736, Julie K. O'Donnell et al., *Overdose Deaths with Carfentanil and Other Fentanyl Analogs Detected (July 2016-June 2017)*, Morbidity & Mortality Weekly Report (Jul. 13, 2018).
[38] To the extent Plaintiffs claim that Janssen can be held liable for the opioid crisis due to the actions of its former subsidiary Noramco, this theory is not tenable. As Janssen has explained in its concurrently filed motions in limine, evidence about Noramco is inadmissible. In addition, Noramco's business was strictly regulated by the DEA.

Dated: September 25, 2019

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CERTIFICATE OF SERVICE

I, Charles C. Lifland, hereby certify that the foregoing document was served on September 25, 2019 via the Court's ECF system to all counsel of record, consistent with the Court's order.

/s/ Charles C. Lifland
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