IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA, Plaintiff, v. PURDUE PHARMA L.P., *et al.*, Defendants.	Case No. CJ-2017-816 Judge Thad Balkman William C. Hetherington Special Discovery Master

DEFENDANTS JANSSEN PHARMACEUTICALS, INC. AND JOHNSON AND JOHNSON'S MOTION *IN LIMINE* NO. 17 TO EXCLUDE EVIDENCE OF ULTRAM, ULTRAM ER, AND ULTRACET

BRIEF IN SUPPORT

The State has structured its case against Janssen Pharmaceuticals, Inc. ("Janssen") and Johnson & Johnson ("J&J") around three prescription opioid medicines that the Drug Enforcement Administration ("DEA") classifies as Schedule II drugs—Duragesic, Nucynta, and Nucynta ER. The State's exhibit list, however, includes various documents referencing three different Janssen medicines with the active ingredient tramadol—Ultram, Ultram ER, and Ultracet. Those medicines were not mentioned once in the State's Petition, nor were they scheduled by the DEA until 2014. Even then, they were only placed in Schedule IV. They are not relevant to the State's claims against Janssen, as the district court overseeing the national opioid multi-district litigation ("MDL") in Ohio recognized by denying discovery about tramadol entirely.

The evidence is irrelevant. Ultram, Ultram ER, and Ultracet are not at issue in this case, and any evidence or argument about them must be excluded. *Id.* § 2402 ("Evidence which is not relevant is not admissible."). As just mentioned, drugs containing tramadol are not mentioned once in the State's Petition and were not even federally scheduled during the vast majority of the time period relevant to this litigation. When they finally were scheduled in 2014, they were classified as Schedule IV medications, which have a "low potential for abuse relative to the drugs or other substances in schedule III," which in turn have a "potential for abuse less than the drugs or other substances in schedules I and II." 21 U.S.C. § 812(b)(3)-(4). Given the absence of these medications in the State's Petition and the State's exclusive focus on Schedule II medications, Ultram, Ultram ER, and Ultracet are irrelevant. Indeed, the State's own expert, Dr. Daniel Clauw, testified that "in general" he "ha[s] not considered tramadol to be an opioid because … most of the effectiveness comes from … serotonin norepinephrine reuptake inhibition." Ex. C, Clauw

Dep. at 59:15-18. To the extent it is an opioid, he opined, "it is such a weak opioid, that it's hard to get into trouble with … given how weak the opioidergic effects of the drug are." *Id.*, at 59:18-22.

Confronted with a complaint that similarly focused on Duragesic, Nucynta, and Nucynta ER, the Special Master overseeing discovery in the MDL denied discovery into these and other non-Schedule II medications. Ex. A, Discovery Ruling No. 2, *In Re: National Prescription Opiate Litig.*, Case No. 1:17-MD-2804, Docket No. 693 (Jun. 30, 2018); *see also* Ex. B, S. Baglin Lr. to Special Master Cohen Re: Discovery Disputes, Appendix B. at 2 (Jun. 26, 2018) ("Janssen's three tramadol-based products—Ultram, Ultram ER, and Ultracet—cannot be relevant because those opioids were not even 'scheduled' at the time of the conduct alleged in the complaint. The [DEA] started to regulate these products as Schedule IV opioids on *August 18, 2014.*"). This Court should follow the same reasoning and exclude evidence about Ultram, Ultram ER, and Ultracet as irrelevant.

The evidence is a waste of time. Evidence and argument about Ultram, Ultram ER, and Ultracet would add nothing to the State's case, and represents a waste of the Court's and the litigants' time. *See* 12 O.S. § 2403. If the Court were to admit evidence and argument about Ultram, Ultram ER, and Ultraset, Janssen and J&J would need to rebut it by presenting their own evidence—all of which would have no bearing on the issues in this case. The Court should not create a trial within a trial on extraneous matters. *See* 12 O.S. § 2403; *Glaros v. H.H. Robertson Co.*, 797 F.2d 1564, 1573 (Fed. Cir. 1986) (exclusion warranted where admission "would have injected frolics and detours and would have required introduction of counter-evidence, all likely to create side issues that would have unduly distracted the jury from the main issues").

For all these reasons, the Court should grant this Motion *in Limine* and issue an order barring the State from introducing any evidence and argument about Ultram, Ultram ER, and Ultracet.

Respectfully submitted,

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CERTIFICATE OF MAILING

Pursuant to Okla. Stat. tit. 12, § 2005(D), and by agreement of the parties, this is to certify on May 15, 2019, a true and correct copy of the above and foregoing has been served via electronic mail, to the following:

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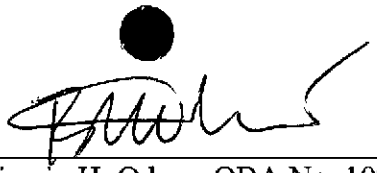

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Exhibit A

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	**CASE NO. 1:17-MD-2804**
	)	
	)	**SPECIAL MASTER COHEN**
THIS DOCUMENT RELATES TO: "*Track One Cases*"	)	
	)	
	)	**DISCOVERY RULING NO. 2**

The undersigned has received numerous emails and letters from plaintiffs and defendants raising various discovery issues. Having reviewed carefully the parties' positions, the Special Master now enters the following discovery rulings.

Scope of Products Subject to Discovery

Plaintiffs have requested discovery related to a wide array of opioids that are manufactured, sold, or distributed by the defendants, including branded products, generic products, and lower-strength products that have been sold "without problem" for decades. The *distributor* defendants have not objected to these requests – the distributors have agreed to produce discovery for all opioid products requested by plaintiffs. To various degrees, however, the *manufacturer* defendants do object to the breadth of the plaintiffs' requests. For example:

- Teva has no objection to plaintiffs' requests based on identity of the opioid product; thus, Teva is producing discovery related to all opioids, including unbranded and generic products.

- Purdue is willing to produce documents related to three of its branded opioid products (Oxycontin, Butrans, and Hyslinga ER), but objects to discovery of documents related to (a) any other branded opioid product (e.g. Targiniq ER), and (b) any unbranded or generic opioid product.
- Janssen is willing to produce documents related to three of its newer branded opioid products (Duragesic, Nucynta, and Nucynta ER), but objects to discovery of documents related to, among others, two branded, decades-old, combination opioid products (41-year-old Tylenol [acetaminophen] with codeine; and discontinued-in-2014, 32-year-old Tylox [acetaminophen with oxycodone]).

At this juncture, plaintiffs are in dispute on this issue with Endo, Mallinckrodt, Allergan, Janssen, and Purdue.

The main reason offered by defendants to support their objections is that plaintiffs' complaints do not sufficiently allege theories of liability based on the manufacture, sale, or distribution of *generic* drugs. This is simply untenable. Plaintiffs' complaints certainly focus upon branded drugs, such as Oxycontin; but the allegations clearly also support claims premised on the manufacture, sale, and distribution of generic drugs. *See, e.g., City of Cleveland v. Purdue Pharma*, case no. 18-OP-45132, second amended complaint ¶5 (docket no. 508) ("*Cleveland Complaint*") (attributing the huge number of deaths caused by opioid overdose to drugs including "brand-name prescription medications such as OxyContin, Opana ER, Vicodin, Subsys, and Duragesic, as well as generics like oxycodone, hydrocodone, and fentanyl"); *id.* at ¶45, 49, 65, 78, 87, 824 (referring to individual generic drugs produced by each manufacturer defendant).

A second reason defendants offer to support their objections is that some of the drugs at issue

are low-potency products that were launched decades before there was any "opioid crisis" (which plaintiffs allege began in the "late 1990s);"[1] therefore, these drugs are at best barely relevant to plaintiffs' claims and the burden of production exceeds its likely benefit. The Special Master concludes this argument is well-taken. Tylenol with codeine has been available in the United States since the 1970s, and is listed by the FDA as a Schedule III drug – meaning it has a lower potential for abuse than substances in Schedule II (such as hydromorphone, oxycodone, fentanyl, and morphine), which are at the alleged root of the "opioid crisis." Tylenol with codeine is clearly peripheral to plaintiffs' claims.

Accordingly, the Special Master **RULES** as follows. Defendants shall produce discovery related to all opioid products that are or ever were classified as Schedule II under the Controlled Substances Act. This includes branded, unbranded, and generic drugs. If a branded drug was launched before 1995, then defendants need to produce documents related to that drug, and its non-branded and generic equivalents, only if the documents were created on or after January 1, 1995.

Geographic Scope of Discovery

The plaintiffs in the Track One cases are all located in the Northern District of Ohio, but Plaintiffs' discovery requests are largely national in scope. With regard to certain categories of documents, most defendants do not lodge objections based on geographic scope. Thus, for example, most of the manufacturer defendants have agreed to produce nationwide information on their marketing, advocacy, and regulatory activities. But several defendants object to production of other types of information outside of Ohio – for example, sales information for each customer pharmacy,

[1] *See, e.g., Cleveland Complaint* ¶¶4-7, 690-91, & 789.

notes on sales calls, compensation of sales representatives, and so on. Other defendants have taken a more surgical approach: manufacturer Mallinckrodt, for example, has agreed to provide "documents relating to diversion" on a national basis, but "documents that pertain to marketing" only in sales districts encompassing Ohio and its border states of Michigan, Indiana, Kentucky, West Virginia, and Pennsylvania. The bases for defendants' geographic scope objections are burden and relevance.

The Special Master now **RULES** as follows. Defendants must produce on a national basis documents related to marketing and promotion, brand planning and strategy, sales training and sales bulletins, prescriber educational materials, distribution monitoring, advocacy groups, speakers bureau programs, continuing medical education, diversion, suspicious order reports, adverse event reports, and regulatory activity.[2] The defendants' policies and actions regarding all of these subjects are (and were) primarily centralized and over-arching, applying broadly to their opioid products. This discovery is referred to below as Category One Discovery.

The ruling above is relatively easy; the harder question is the extent to which defendants must produce documents related to decentralized, customer-specific materials, such as sales call notes and transactional data. (This discovery is referred to below as Category Two Discovery.) As noted earlier, most defendants seek to limit geographic production of these materials to Ohio, where plaintiffs in the Track One cases are located. In response, plaintiffs argue this information should be produced more broadly – at least regionally, if not nationally – as materials connected to locations outside of Ohio are likely to reveal information relevant to the Ohio plaintiffs' claims. For

[2] This list is illustrative, not exhaustive. The Special Master has carefully considered whether each of the topics in this list should be included.

example, plaintiffs allege there is "abundant evidence . . . establish[ing] that prescription opioids migrated between cities, counties, and states, including into Ohio from West Virginia, Kentucky, Illinois, Georgia, and Florida." *Cleveland Complaint* ¶633. The Special Master agrees that tracing opioid migration to Ohio from other locations, especially high-supply areas, is relevant to plaintiffs' claims.

The Special Master concludes it is appropriate to enter a compromise ruling: defendants shall produce customer-specific information for the States of Ohio, Pennsylvania, West Virginia, Kentucky, Illinois, Georgia, and Florida. This restriction will provide plaintiffs with sufficient discovery to test their "migration" theory and pursue their claims, while limiting the burden on defendants. To the extent defendants must produce this discovery in stages, production of Ohio information shall occur first.

Scope of Prior Productions

Numerous defendants have produced documents in connection with other, earlier litigation matters or governmental investigations. In regard to these "prior productions," the Court ordered as follows in CMO-1:

> all Defendants shall review documents previously produced pursuant to any civil investigation, litigation, and/or administrative action by federal (including Congressional), state, or local government entities involving the marketing or distribution of opioids and shall produce to the PEC non-privileged documents relevant to the claims in this MDL proceeding.

Docket no. 232 at 15, ¶9.k.ii. Initially, some defendants agreed to produce only those prior productions that had occurred after a date-certain, such as January 1, 2006. Those defendants have correctly abandoned that position. But some defendants now assert they do not have to produce

certain prior productions for other reasons – for example, because a prior production in patent litigation did not "involv[e] the marketing or distribution of opioids," or because the prior production was made in *private* civil litigation as opposed to litigation with a governmental entity.

The Special Master now **RULES** as follows. The above-quoted language in CMO-1 was meant to be comprehensive. Defendants' objection that they are not obligated to produce in the MDL prior productions made in private ("non-governmental") litigation is not well-taken. If a defendant produced discovery in *any* prior litigation that involved the marketing or distribution of opioids, that discovery must be produced in the MDL.[3] That said, the Special Master agrees that defendants need not produce discovery of prior productions made in cases, such as patent litigation, that only tangentially addressed marketing and distribution of opioids.

The Special Master adds that defendants must produce prior productions made in personal injury cases, because those productions are highly likely to include materials relevant to distribution and marketing of opioids. More specifically, the Special Master notes that MDL lead plaintiff counsel Paul Hanly has engaged in prior litigation against manufacturer Purdue involving claims that Purdue's sale and marketing of Oxycontin led to personal injuries to hundreds of plaintiffs.

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[3] Defendants apparently read the language in CMO-1 to mean they are only required to produce in the MDL prior productions made in "litigation . . . by federal (including Congressional), state, or local government entities," and not by private entities. The underlined clause, however, was meant to make fully *expansive* the requirement relative to administrative actions, not to *restrict* the requirement relative to litigation or investigations.

Purdue's prior discovery productions in those cases is relevant and discoverable in the MDL.[4] To lower Purdue's discovery burden, rather than requiring Purdue to re-produce its prior productions made to Hanly's firm, these prior productions "shall be deemed produced to all Plaintiffs in MDL 2804 and shall be made immediately available to the PEC by any parties or counsel in possession of same, at no cost to the party or counsel in possession." *See* docket no. 232 at 15, ¶9.k.i (CMO-1) (taking this approach with prior productions made in *City of Chicago v. Purdue Pharma L.P.*, case no. 17-OP-45169).

List of Prior Productions

The Special Master earlier directed each defendant to produce to plaintiffs a "list of all prior productions in any civil investigation, litigation, and/or administrative action involving the marketing or distribution of opioids," so that the parties and the Court could "understand precisely what is the universe of prior productions at issue." Email to counsel, June 13, 2018. 6:06 pm. However, many of those defendants that responded – some still have not – did not include in their lists prior productions made in private, non-governmental civil litigations. The Special Master now **ORDERS** *every* defendant to produce to plaintiffs, on or before July 10, 2018, a list of *every* prior production in *any* earlier litigation, investigation, or administrative action that touches upon the marketing or distribution of opioids, *without exception*. This separate requirement is meant only to

[4] Mr. Hanly has stated repeatedly that Purdue's earlier discovery in his personal injury cases is clearly relevant to the claims in the MDL, and Purdue has not contested that assertion – although it has withheld permission for Mr. Hanly to share his discovery in the MDL. This is unacceptable. It would be very odd and unsound for two different MDL lead plaintiffs' counsel – say, Mr. Hanly and Mr. Farrell – to attend a deposition of Purdue where Mr. Hanly is aware of relevant documents (but cannot use them), and Mr. Farrell is not.

obligate each defendant to produce a *list*, not to produce each and every single one of those prior productions. Among other reasons, this list is necessary for the plaintiffs and the Court to engage in the mechanism set out at CMO-1, ¶9.k.iii ("to the extent the PEC believes there are other documents that were produced by a Defendant in another proceeding that are discoverable in this proceeding, the PEC shall notify the Defendant and identify the specific document(s) and basis for requesting production, and the parties shall meet and confer to attempt to resolve the issue").

Temporal Scope of Discovery

Plaintiffs' discovery requests are made without any time limit, and plaintiffs generally seek documents dating back to 1995 or even earlier. Defendants object and seek to limit their responses to various other, later dates. For example, distributors McKesson, Amerisource, and Cardinal have each agreed to provide documents from January 1, 2013 forward, but not earlier; manufacturer defendant Teva has agreed to provide documents from January 1, 2006 forward, as well as certain categories of documents that pre-date 2006; and manufacturer defendant Endo has agreed to provide documents with a begin-date of two years prior to the launch of its opioid product Opana ER. The reasons distributors offer for limiting the begin-dates of their discovery production include: (a) statutes of limitations, (b) when their opioid products were launched, and (c) general relevance and burden.

The question of temporal scope is the most difficult of the issues addressed in this *Discovery Ruling*. Obviously, the earlier the cut-off date for document production, the more burdensome is the discovery request on defendants, and potentially the less relevant. Still, the Special Master rejects the defendants' contentions that the cut-off date should be set by strict reference to statutes

of limitations. *See Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 352 (1978) ("it is proper to deny discovery of . . . events that occurred before an applicable limitations period, unless the information sought is otherwise relevant to issues in the case"); *Ray v. Waste Mgmt. of Kentucky, LLC*, 2010 WL 11545747 at *1 (W.D. Ky. Dec. 15, 2010) (denying a motion to limit discovery to the limitations period, because discovery into earlier events could lead to relevant and admissible evidence). Moreover, it appears the statute of limitations for plaintiffs' claims of public nuisance may be equitably tolled. *See The Little Miami RR Co. v. Comm'rs of Greene Cty.*, 1877 WL 31 at *6 (Ohio Dec. 1, 1877) ("no length of time can legalize a public nuisance"); *cf. State v. Swartz*, 88 Ohio St. 3d 131, 134 (2000) (in the case of criminal nuisance, "a continuing nuisance can constitute a continuing course of conduct, thus tolling the limitations period").

With regard to relevance, plaintiffs argue convincingly that "baseline evidence" of what the opioid marketplace looked like before defendants undertook their allegedly fraudulent marketing activities, and before defendants allegedly purposely failed to report Suspicious Orders, is highly relevant. The amount and degree of "unnecessary prescriptions" and the extent of the "inappropriate increase" of opioid distribution must be measured against a time before the allegedly wrongful activity began; that is, the scope of the "opioid crisis" can only be assessed against pre-crisis conditions. Indeed, the U.S. Drug Enforcement Agency describes Suspicious Orders as "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b). This language necessitates comparisons with "normal" and "usual" circumstances. Plaintiffs provide data showing opioid prescriptions and distributions began to increase dramatically in 1995, which is when Purdue launched Oxycontin. In sum, the baseline level of opioid prescriptions and distributions, which existed at that juncture, is highly relevant.

Ultimately, the dispute over the temporal scope of discovery requires a balancing of burden, relevance, and need. The Special Master has undertaken that calculation with an eye toward providing plaintiffs with evidence they need but no more than that, and with as little burden on defendants as this measure allows. This requires imposition of different, tailored cut-off dates for discovery of different categories of information from different defendants. A single cut-off date for all discovery would be both over- and under-inclusive. Accordingly, the Special Master now **RULES** as follows.

Manufacturer Defendants

Except as stated in the next paragraph, the manufacturer defendants shall produce Category One Discovery and Category Two Discovery with a cut-off date of one year prior to the launch date of the opioid product in question. Thus, for example, Purdue must produce Categories One and Two Discovery related to Oxycontin going back to the date one year before it began selling Oxycontin; Purdue must produce Categories One and Two Discovery related to Hyslinga ER going back to the date one year before it began selling Hyslinga ER; and Mallinckrodt must produce Categories One and Two discovery related to Xartemis XR going back to the date one year before it began selling Xartemis XR. These dates are very different, as they are individualized to each drug.[5] Further, each manufacturer defendant must produce Categories One and Two discovery for generic opioids with a cut-off date of one year before it first sold that generic product.

Further, the manufacturer defendants shall produce transactional data (which is otherwise

[5] Purdue's Oxycontin was approved by the FDA in December of 1995, while Purdue's Hyslinga ER and Mallinckrodt's Xartemis XR were approved in 2014. The Special Master adds here that this "one year" requirement applies regardless of when the defendant acquired rights to the drug.

in Category Two) and Suspicious Order Reports (which is otherwise in Category One) with a cut-off date of January 1, 1996.

Distributor Defendants

The distributor defendants shall produce transactional data and Suspicious Order Reports with a cut-off date of January 1, 1996. The discovery cut-off for all other discovery is January 1, 2006.

Discovery of Prior Transcripts

Although this topic was disputed, the parties' most recent reports to the Special Master reveal there are no remaining disagreements regarding production of transcripts of testimony taken in prior opioid-related litigation or investigations.

Definition of "Marketing Activities"

Earlier, some of the defendants objected to the definition of "marketing activities" that plaintiffs included in their discovery requests. It appears most of the defendants have resolved their disputes with plaintiffs regarding this issue, but some defendants (e.g. Mallinckrodt) have lingering disagreements. The specific language at issue is as follows:

> "Marketing" refers to the action or business of promoting, selling, or providing information about Opioids or Opioid Products. "Marketing" includes both branded and unbranded Communications; branded and unbranded informational or educational programs; detailing by sales representatives (including electronic detailing); continuing medical education; publication of scientific medical or marketing articles, Scientific Research, studies or reports; websites (whether branded or unbranded); video or other visual media; sales blasts, messages, or other means used to sell or promote Opioids or Opioid Products for sale or distribution.

Requests for Production at 3.

The Special Master simply observes that this definition in the abstract does not appear to be over-broad or to require production by defendants of irrelevant information. The Special Master directs those parties who continue to have disagreements over the definition of marketing to meet and confer again while taking this observation into account.

Different Agreements

The Special Master is aware that certain defendants may have reached agreements with plaintiffs on certain issues that are different from the requirements stated above. For example, this *Discovery Ruling* directs the manufacturer defendants to produce relevant documents with a cut-off date of one year prior to the launch date of their opioid products, but Janssen earlier agreed to produce documents going back two-and-a-half years before its launch of Nucynta. The parties are free, but not required, to honor these prior agreements, and are free to negotiate different agreements going forward from the requirements set out herein. But the Special Master hereby imposes consistent standardized rulings for all parties, so that there will be clarity going forward.

Pharmacies

The discussion above addresses discovery disputes plaintiffs have had with the manufacturer and distributor defendants. The Special Master has not received position papers on these topics from the retail pharmacy defendants, as their meet-and-confers with plaintiffs are ongoing. Nonetheless, the Special Master expects the pharmacy defendants will adhere to the rulings set out above and will not bring a similar dispute to the undersigned unless there is very good cause for a different

outcome.

Other Issues

The Special Master is aware there are other discovery disputes brewing, including a complete absence of scheduling of 30(b)(6) depositions. The parties are **ORDERED** to: (1) submit on or before July 6, 2018 an agreed schedule for at least some 30(b)(6) depositions, or risk sanctions; and (2) continue to meet and confer on all other outstanding disputes.

RESPECTFULLY SUBMITTED,

/s/ David R. Cohen
David R. Cohen
Special Master

Dated: June 30, 2018

Exhibit B

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VIA E-MAIL

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Re: ***In re: Nat'l Prescription Opiate Litig., MDL No. 2804***

Dear Special Master Cohen:

I write on behalf of Defendants Janssen Pharmaceuticals, Inc. and Johnson & Johnson in response to your June 20, 2018 request for a short submission on six discovery disputes. For Janssen, there are only three issues that require continued meet-and-confer discussions: 1) the scope of Janssen opioids subject to discovery; 2) the temporal scope of discovery; and 3) the geographic scope of discovery.

Plaintiffs sent Janssen a position statement on June 22, 2018 outlining their positions on these issues. *See* Appendix A. In response to their letter and as our own position statement, we have enclosed our response. *See* Appendix B.

Please let us know if you have any questions of if you would like additional information.

Respectfully,

/s/ Seth Baglin

Seth Baglin
Counsel
for O'MELVENY & MYERS LLP

SB

APPENDIX A

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June 22, 2018

VIA E-MAIL
Sabrina H. Strong
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Re: *In re Nat'l Prescription Opiate Litig.*: Response to June 12, 2018 Letter to Special Master Cohen

Dear Ms. Strong:

I am writing in response to your June 12, 2018 letter to Special Master Cohen concerning the status of meet and confers in relation to the discovery responses served on behalf of Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. ("Defendants") in the above-referenced matter. In view of the notice issued by Special Master Cohen requesting position statements from the Defendants on identified discovery issues on or before June 25, 2018, this letter will address certain, but not all, of the important discovery issues that Plaintiffs consider unresolved. Plaintiffs will separately address our disputes concerning Defendants' deficient written discovery responses.

Although your letter of June 12th suggested that the parties were not at an impasse as to prior productions and transcripts, Plaintiffs consider multiple issues addressed in your letter as still being unresolved.

As you are aware, the parties previously met and conferred concerning Defendants' production of documents made in prior governmental investigations. Defendants agreed to produce all prior productions with the exception of productions made in OIG investigations. Mr. Baglin addressed that it was still unknown as to which of Defendants' prior counsel produced OIG productions, but, in any event, that such productions would be largely encompassed in Defendants' other productions. He agreed to advise us of those litigations, and whether Janssen had been able to locate the documents. We have yet to hear from you on that topic. In addition, Janssen has not produced a list of all prior investigations and litigation in which Defendants provided productions and/or testimony, as required by Special Master Cohen. Mr. Baglin indicated during the meet and confer on June 8, 2018 that such a list would be forthcoming. At present, the list has not been produced.

With respect to the scope of opioid products subject to discovery, Plaintiffs believe that Defendants' limitation of the scope of its production to include only

Duragesic, Nucynta, and Nucynta ER to be unwarranted and inconsistent with Plaintiffs' allegations. Plaintiffs' allegations are in fact broader than characterized by Defendants. Specifically, at ¶ 83 of the *County of Summit* complaint, Plaintiffs alleged: "J&J, Janssen Pharmaceuticals, OMP, and Janssen Pharmaceutica and their DEA registrant subsidiaries and affiliates (collectively, "Janssen") are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally, and in Summit County. ***Among the drugs*** Janssen manufactures or manufactured are the following: . . . " (Emphasis added) The complaints additionally allege a number of facts concerning opioids generally, without reference to any specific drugs. Such allegations, by way of example, include the following:

- ¶ 84: "Janssen made thousands of payments to physicians nationwide, including, upon information and belief, in Ohio, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids."

- ¶ 85: "Information from the U.S. Department of Justice's Office of the Inspector General shows that J&J made payments to prescribers, but does not indicate which drug was being promoted when J&J made these payments."

- ¶ 86: "Janssen's employees are required to read, understand and follow its Code of Conduct for Health Care Compliance. J&J imposes this code of conduct on Janssen as a pharmaceutical subsidiary of J&J. Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen."

- ¶ 88: "J&J made payments to thousands of physicians nationwide . . . ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids."

- ¶ 212: "Janssen likewise misrepresented the addiction risk of opioids on its websites and print materials. One website, *Let's Talk Pain*, states, among other things, that 'the stigma of drug addiction and abuse' associated with the use of opioids stemmed from a 'lack of understanding about addiction.'"

- ¶ 214: "Janssen unbranded website, *www.PrescribeResponsibly.com*, states that concerns about opioid addiction are 'overestimated' and that 'true addiction occurs only in a small percentage of patients.'"

- ¶ 215: "Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults*, which, as seen below, described as "myth" the claim that opioids are addictive, and asserted as fact that '[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.'"

- ¶ 234: "Janssen, on its website *www.PrescribeResponsibly.com*, states that the risk of opioid addiction 'can usually be managed' through tools such as opioid agreements between patients and doctors.44 The website, which directly provides screening tools to prescribers for risk assessments, includes a '[f]our question screener' to purportedly help physicians identify and address possible opioid misuse."

- ¶ 250: "Janssen also currently runs a website, *www.PrescribeResponsibly.com*, which claims that concerns about opioid addiction are 'overestimated,' and describes pseudoaddiction as 'a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately the inappropriate behavior ceases.'"

- ¶ 268: "Despite the lack of evidence of improved function and the existence of evidence to the contrary, the Marketing Defendants consistently promoted opioids as capable of improving patients' function and quality of life because they viewed these claims as a critical part of their."[1]

- ¶ 275: "Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as 'a fact' that 'opioids may make it easier for people to live normally.' This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. It assures patients that, '[u]sed properly, opioid medications can make it possible for people with chronic pain to "return to normal."'"

- ¶ 276: "In addition, Janssen's *Let's Talk Pain,* website featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to 'continue to function,' falsely implying that her experience would be representative."

- ¶ 288: "Janssen sponsored *Finding Relief: Pain Management for Older Adults* (2009), which listed dose limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased doses from opioids. *Finding Relief* described the advantages and disadvantages of NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving 'stomach upset or bleeding,' 'kidney or liver damage if taken at high doses or for a long time,' 'adverse reactions in people with asthma,' and 'can increase the risk of heart attack and stroke.' The only adverse effects of opioids listed are 'upset stomach or sleepiness,' which the brochure claims will go away, and constipation."

- ¶ 443: "The Marketing Defendants collectively spent more than $14 million on the medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. The 2011 total includes . . . $4.9 million by Janssen . . . ."

[1] The Second Amended Complaint defines "Marketing Defendants" to include Janssen.

- ¶ 881: "Each of the RICO Marketing Defendants and the other members of the Opioid Marketing Enterprise conducted and participated in the conduct of the Opioid Marketing Enterprise by playing a distinct role in furthering the enterprise's common purpose of increasing profits and sales through the knowing and intentional dissemination of false and misleading information about the safety and efficacy of long-term opioid use, and the risks and symptoms of addiction, in order increase the market for prescription opioids by changing prescriber habits and public perceptions and increase the market for opioids."

- ¶ 945: "The RICO Marketing Defendants, through the Opioid Marketing Enterprise, made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use, including: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition the RICO Marketing Defendants named 'pseudoaddiction'; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse."

The foregoing general allegations, in and of themselves, render information regarding Janssen's other opioid products, including generics, manifestly relevant. Indeed, throughout our meet and confer on June 8, 2018, Defendants acknowledged producing and/or licensing prescription opioid products *other than the three products* for which the Defendants are willing to engage in discovery. Plaintiffs seek discovery concerning each opioid product that Defendant licensed, manufactured and/or marketed.

The temporal scope of discovery also remains unresolved. Defendants have taken the position that, with the exception of certain, limited categories of documents concerning Duragesic, the relevant scope of discovery includes the period from January 1, 2006 forward. Plaintiffs continue to take issue with this limitation. We do not agree that Janssen's marketing efforts to promote Duragesic have no bearing whatsoever on its conduct with respect to Nucynta. To the contrary, Janssen no doubt incorporated information learned from its prior efforts in its Nucynta marketing. Further, any differences between Janssen's marketing of Nucynta and its earlier marketing of Duragesic may support Plaintiffs' allegations concerning misleading marketing. Plaintiffs seek the production of pre-2006 documents concerning Duragesic that fall outside of Defendants' FDA-related communications and NDA. Additionally, during our most recent meet and confer, Defendants agreed to investigate the existence of its prior productions, consider the burden of producing such prior productions, and follow-up with Plaintiffs within one week. One week has passed, and this issue remains unresolved.

Similarly, the geographic scope of Janssen's production also remains unresolved. During the June 8 meet-and-confer, we objected to Janssen's refusal to produce evidence of payments to third parties outside of Ohio on the grounds that the location of an individual or entity is not determinative as to whether that individual's or entity's statements were available to Ohio prescribers and consumers. Mr. Baglin agreed to consider this request. Has Janssen concluded its

review concerning the production of third-party payment information extending beyond the State of Ohio, which payments may have supported marketing or educational efforts reaching prescribers in Ohio? If such information exists, will Janssen produce all such documents?

The foregoing issues remain unresolved as of this date. We appreciate your continued attention to these matters.

Sincerely,

/s/ Mark A. Linder
Mark A. Linder

cc: David Ackerman
Evan Janush

APPENDIX B

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VIA E-MAIL

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Re: *In re Nat'l Prescription Opiate Litig.:* Response to June 22, 2018 Letter

Dear Mark:

I write in response to your June 22, 2018 letter discussing the status of our meet and confers, specifically, Janssen's discovery responses. Many of these issues were also addressed in the June 25 discovery chart Special Master Cohen requested.

At the outset of your letter, you appear to indicate that an unresolved issue equates to an impasse. We disagree and believe that continued good-faith meet and confers about the proper scope of discovery are likely to resolve our few remaining issues. To that end, each outstanding issue is addressed below, and we look forward to additional meet and confer discussions on these topics as necessary to resolve any remaining disputes.

I. Prior Productions

Janssen has determined that it is able to produce the OIG investigation previously referenced during our last meet and confer. Janssen is currently working on its list of prior litigations and investigations, and we expect to be in a position to provide you with that list by July 6, 2018.

II. Scope of Opioid Products

Plaintiffs' twice-amended, 331 page complaint mentions only three Janssen opioid products: Nucynta, Nucynta ER, and Duragesic. Plaintiffs presumably based their allegations on a pre-suit investigation into Janssen's marketing and sales of potentially relevant opioid products.[1] Plaintiffs' complaint includes 20 paragraphs containing a reference to one of the three identified products—in other words, 20 opportunities to have pled other opioids relevant to this litigation.

[1] Plaintiffs also presumably would have checked any number of websites that list opioid products manufactured by Janssen, including Janssen's own website or the FDA, all of which list the products Plaintiffs now belatedly claim are somehow relevant.

Yet plaintiffs identified only the three named opioids as the Janssen opioids at issue from the very outset:

> "¶ 83. J&J, Janssen Pharmaceuticals, OMP, and Janssen Pharmaceutica and their DEA registrant subsidiaries and affiliates (collectively, "Janssen") are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally, and in Summit County Among the drugs Janssen manufactures or manufactured are the following:

Product Name	Chemical Name	Schedule
Duragesic	Fentanyl	Schedule II
Nucynta	Tapentadol hydrochloride, immediate release	Schedule II
Nucynta ER	Tapentadol hydrochloride, extended release	Schedule II

During our June 8, 2018 meet and confer, I discussed the other opioid products manufactured by Janssen—none of which has any connection to Plaintiffs' allegations. I explained that Janssen's three tramadol-based products—Ultram, Ultram ER, and Ultracet—cannot be relevant because those opioids were not even "scheduled" at the time of the conduct alleged in the complaint. The FDA started to regulate these products as Schedule IV opioids on *August 18, 2014*. Moreover, there are no Schedule IV opioids, regardless of manufacturer, identified in the complaint.

The only other two opioids that Janssen manufactured are short acting acetaminophen combination products: Tylenol with codeine and Tylox. But these are equally irrelevant as they long pre-date the allegations of the complaint. Tylenol with codeine is a Schedule III opioid first approved by the FDA on August 17, 1977—i.e., it is a 41-year old opioid indicated only for the "management of mild to moderate pain." Similarly, the FDA approved Tylox on May 13, 1986, for the treatment of acute pain. Janssen discontinued Tylox in 2012 when the FDA reduced the maximum allowable dosage of acetaminophen in combination products.

The breadth and scope of Janssen's opioid products is publicly available information from a myriad of sources. Plaintiffs have no basis to argue that the Janssen products discussed in the two preceding paragraphs were not, or could not have been, known to Plaintiffs with minimal investigation at the time they drafted their complaint. That Plaintiffs chose not to include these medications in their complaint belies any assertion that they are relevant to your claims.

Although Plaintiffs may now superficially claim that their allegations are "in fact broader than characterized by Defendants," the paragraphs cited for support only show why Janssen was

correct to base its document collection, processing, and review on the three opioids named in the complaint:

- Payment Allegations:
    - ¶ 84: "Janssen made thousands of payments to physicians nationwide, including, upon information and belief, in Ohio, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids. ***Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least $1 billion in annual sales.***"[2]
    - ¶ 85: "Information from the U.S. Department of Justice's Office of the Inspector General shows that J&J made payments to prescribers, but does not indicate which drug was being promoted when J&J made these payments."
    - ¶ 88: "J&J made payments to thousands of physicians nationwide . . . ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids."
    - Response: Janssen is producing all Ohio-related payments having to do with Duragesic, Nucynta and Nucynta ER. If those payments also related to unbranded activities that Plaintiffs believe support the inclusion of other Janssen opioids, then the payment information will be captured in Janssen's production.
- Unbranded Materials Allegations:
    - ¶ 212: "Janssen likewise misrepresented the addiction risk of opioids on its websites and print materials. One website, *Let's Talk Pain*, states, among other things, that 'the stigma of drug addiction and abuse' associated with the use of opioids stemmed from a 'lack of understanding about addiction.'"
    - ¶ 214: "Janssen unbranded website, *www.PrescribeResponsibly.com*, states that concerns about opioid addiction are 'overestimated' and that 'true addiction occurs only in a small percentage of patients.'"
    - ¶ 215: "Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults*, which, as seen below, described as "myth" the claim that opioids are addictive, and asserted as

[2] Plaintiffs omitted the bolded and italicized sentence from their letter, ignoring that paragraph's own limitation to the three opioids identified in the complaint.

fact that '[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.'"

- ¶ 234: "Janssen, on its website *www.PrescribeResponsibly.com*, states that the risk of opioid addiction 'can usually be managed' through tools such as opioid agreements between patients and doctors.44 The website, which directly provides screening tools to prescribers for risk assessments, includes a '[f]our question screener' to purportedly help physicians identify and address possible opioid misuse."

- ¶ 250: "Janssen also currently runs a website, *www.PrescribeResponsibly.com*, which claims that concerns about opioid addiction are 'overestimated,' and describes pseudoaddiction as 'a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately the inappropriate behavior ceases.'"

- ¶ 275: "Janssen sponsored and edited a patient education guide *entitled Finding Relief: Pain Management for Older Adults* (2009), which states as 'a fact' that '*opioids may make it easier for people to live normally*.' This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. It assures patients that, '[u]sed properly, opioid medications can make it possible for people with chronic pain to "return to normal."'"

- ¶ 276: "In addition, Janssen's *Let's Talk Pain*, website featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to 'continue to function,' falsely implying that her experience would be representative."

- ¶ 288: "Janssen sponsored *Finding Relief: Pain Management for Older Adults* (2009), which listed dose limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased doses from opioids. Finding Relief described the advantages and disadvantages of NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving 'stomach upset or bleeding,' 'kidney or liver damage if taken at high doses or for a long time,' 'adverse reactions in people with asthma,' and 'can increase the risk of heart attack and stroke.' The only adverse effects of opioids listed are '*upset stomach or sleepiness*,' which the brochure claims will go away, and constipation."

- Response: These materials were made available in 2009 in advance of Janssen's launches of Nucynta and Nucynta ER, the only opioid medications Janssen promoted after 2009. As stated above, Tylenol with codeine is a 41-year old opioid and Tylox is a 32-year old opioid. Neither is indicated for chronic pain

or has any connection to Plaintiffs' allegations. And at the time of these unbranded publications, the low-potency pain relievers Ultram, Ultram ER, and Ultracet were not even FDA-scheduled medications.

- Marketing Allegations:
  - ¶ 86: "Janssen's employees are required to read, understand and follow its Code of Conduct for Health Care Compliance. J&J imposes this code of conduct on *Janssen as a pharmaceutical subsidiary of J&J. Documents posted on J&J's and* Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen."
    - Response: The documents cited by Plaintiffs in this paragraph relate to Janssen's general corporate code of conduct, and not to any specific opioids that allegedly contributed to opioid abuse. These documents do not make Ultram, Ultram ER, Tylenol with codeine, or Tylox subject to discovery.
  - ¶ 268: "Despite the lack of evidence of improved function and the existence of evidence to the contrary, the Marketing Defendants consistently promoted opioids as capable of improving patients' function and quality of life because they viewed these claims as a critical part of their."
    - Response: Again, there is no connection between the subject matter of this paragraph—that Opioids were promoted as improving patient function—and Ultram, Ultram ER, Tylenol with codeine or Tylox.
  - ¶ 443: "The Marketing Defendants collectively spent more than $14 million on the medical journal advertising of opioids in 2011, nearly triple what they spent in *2001. The 2011 total includes . . . $4.9 million by Janssen . . . .*"
    - Response: Plaintiffs' other allegations provide context that the increase in spending referenced in ¶ 443 relates to the launch of Nucynta in 2009 and the launch of Nucynta ER in 2011. *See, e.g.*, ¶ 458: "Janssen's quarterly spending dramatically rose from less than $5 million in 2000 to more than $30 million in 2011, *coinciding with the launch of Nucynta ER* (with yearly spending at $142 million for 2011)." (emphasis added). By 2011, all of Janssen's other opioids had lost patent exclusivity and had their market share marginalized by generics. Therefore, the increase in spending is the result of Nucynta, not Janssen's other opioids that had generic equivalents.
  - ¶ 881: "Each of the RICO Marketing Defendants and the other members of the Opioid Marketing Enterprise conducted and participated in the conduct of the Opioid Marketing Enterprise by playing a distinct role in furthering the enterprise's common purpose of increasing profits and sales through the knowing

and intentional dissemination of false and misleading information about the safety and efficacy of long-term opioid use, and the risks and symptoms of addiction, in order increase the market for prescription opioids by changing prescriber habits and public perceptions and increase the market for opioids."

- ¶ 945: "The RICO Marketing Defendants, through the Opioid Marketing Enterprise, made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use, including: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition the RICO Marketing Defendants named 'pseudoaddiction'; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse deterrent formulations provide a solution to opioid abuse."

- Response: These paragraphs relate solely to 2009–2012 marketing and sales activities during which Janssen launched Nucynta and Nucynta ER. As a result, the only responsive documents to this paragraph would relate to those unbranded marketing and educational activities and Nucynta—not a 41-year-old opioid product, not a 32-year-old opioid product, and certainly not an opioid product that was not even within the FDA's scheduling regime during the time of those activities.

III. Temporal Scope of Discovery

Janssen has offered to meet and confer with Plaintiffs on request-by-request time periods in an effort to compromise while still recognizing that discovery must be tethered to Rule 26's proportionality requirements. To date, Janssen has not heard from Plaintiffs on this proposal.

IV. Geographic Scope

Janssen is determining the extent to which payments outside of Ohio nonetheless relate to marketing and sales activities within the state of Ohio. Janssen will produce Ohio-specific payment data today, and this production will help inform our next meet and confer on the subject.

Respectfully,

/s/ Seth Baglin

Seth Baglin
Counsel
for O'MELVENY & MYERS LLP

Exhibit C

IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel.,
MIKE HUNTER,
ATTORNEY GENERAL OF OKLAHOMA,
Plaintiff,

Case Number
CJ-2017-816

VS.
(1) PURDUE PHARMA L.P.;
(2) PURDUE PHARMA, INC.;
(3) THE PURDUE FREDERICK COMPANY;
(4) TEVA PHARMACEUTICALS USA, INC.;
(5) CEPHALON, INC.;
(6) JOHNSON & JOHNSON;
(7) JANSSEN PHARMACEUTICALS, INC.;
(8) ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC., f/k/a JANSSEN PHARMACEUTICALS, INC.;
(9) JANSSEN PHARMACEUTICA, INC., f/k/a JANSSEN PHARMACEUTICALS, INC.;
(10) ALLERGAN, PLC, f/k/a WATSON PHARMACEUTICALS, INC.;
(11) WATSON LABORATORIES, INC.;
(12) ACTAVIS, LLC; and
(13) ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.,

Defendants.

VIDEO DEPOSITION OF DANIEL J. CLAUW, M.D.
STATE OF OKLAHOMA 3230(C)(5) WITNESS
TAKEN ON BEHALF OF THE DEFENDANTS
ON MARCH 26, 2019, BEGINNING AT 7:57 A.M.
IN OKLAHOMA CITY, OKLAHOMA

Reported by: Cheryl D. Rylant, CSR, RPR
Video Technician: Gabe Pack

PAGES 1 - 327

Q. In this excerpt that you read, Dr. Krebs is reporting on a systematic review of 11 studies, correct? 09:03

A. I'm sorry, I need to go back, because this first paragraph doesn't actually tell what the -- it -- 09:03

Q. Sure. 09:04

A. It looks like it actually starts -- the -- the description of what they're talking about looks like it starts in the preceding paragraph. 09:04

Q. Sure. Feel free to go back and read whatever you need. 09:04

A. The other thing here I would point out is that the studies that consider tramadol to be an opioid skew a lot of the results about the effects of opioids and chronic pain. I -- in most of the things that I write, I don't -- I consider tramadol to be a serotonin norepinephrine reuptake inhibitor. Its opioid effects are so weak, that it wasn't actually even a scheduled drug when it was first approved. So I -- I have, myself -- tramadol is the only drug that could be considered an opioid that I have ever prescribed I -- that I can remember prescribing newly for someone with chronic pain. So I would really hold tramadol out and say that -- that all the 09:04 09:04 09:04 09:04 09:04 09:04 09:50 09:04 09:04 09:04 09:04 09:05

statements I'm making about opioids and chronic pain don't include tramadol --

Q. You don't --

A. -- because it is such a weak opioid. And it is extremely hard to get to the dosages of tramadol that I alluded to where -- where -- that are really problematic, because it is just such a weak opioid, that you'd have side effects from the serotonin norepinephrine before you would have enough of an opioid effect to cause you problems. So -- so I -- so a lot of these meta-analyses are distorted by including tramadol as an opioid, and I think this one as well. I'd have to actually find -- you'd have to give me this actual article rather than the -- the Kroenke, Krebs, Bair synopsis of the article to actually look and see how many of the people -- how many of these studies were actually of tramadol versus other stronger opioids.

Q. You believe, from reading the article, at least some of these studies were on tram -- about tramadol?

A. It says that.

Q. Do you know how many?

A. No, because you didn't give me the article. That's what I said, is --

Q. Okay.

A. -- if you want me to opine on the article, give me the article, not a review article that -- that synthesizes the article. 09:06

Q. And, as I understand it, you consider studies that rely on or treat tramadol as an opioid to be skewed? 09:06

A. Yes. 09:06

Q. All studies that rely on or treatment tramadol as an opioid? 09:06

MR. LEONOUDAKIS: Objection, form. 09:06

THE WITNESS: You have to look at each study to -- to what the hypothesis is, what the question is trying to ask and answer. But in general, I have not considered tramadol to be an opioid because I think most of the effectiveness of tramadol comes from the serotonin norepinephrine reuptake inhibition. And, again, it is such a weak opioid, that it's hard to get into trouble with some of the -- the plethora of issues that you have with opioids, given how weak the opioidergic effects of this drug are. 09:06 09:50 09:06 09:07 09:07 09:07

Q. (By Ms. Laurendeau) You would agree that tramadol is an opioid, though, correct? 09:07

A. Tramadol has opioid activity. 09:07

Q. Is it appropriate to classify it as an opioid? 09:07

MR. LEONOUDAKIS: Objection, form, outside the scope. 09:07

THE WITNESS: I think I've ans -- I've said that I don't typically put it in that category. When I write review articles, I put -- I put it in the category -- I typically will put it in the category of a serotonin norepinephrine reuptake inhibitor or allude to the fact that it's an outlier, that tramadol, although it's weakly -- a weak opioid, it has been, for example, shown in some trials in fibromyalgia to be effective. But -- but I really believe that it's the serotonin norepinephrine reuptake component of the drug that's leading to the effectiveness in fibromyalgia, not the weak opioid. 09:07 09:07 09:07 09:07 09:07 09:07 09:07 09:07 09:07 09:50 09:07

Q. (By Ms. Laurendeau) Other researchers sometimes put tramadol in the category of opioids, correct? 09:08 09:08 09:08

A. Correct. 09:08

Q. It appears from this book chapter that that's what Dr. Krebs did in the chapter she wrote on Treatment of Chronic Pain Syndromes, correct? 09:08 09:08 09:08

A. Correct. 09:08

Q. You would disagree with Dr. Krebs' 09:08