PART A



IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

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

**DEFENDANTS JANSSEN PHARMACEUTICALS, INC. AND JOHNSON AND JOHNSON'S MOTION TO MOTION TO EXCLUDE TESTIMONY OF DR. ANDREW KOLODNY AND BRIEF IN SUPPORT**

THIS DOCUMENT WAS FILED IN ITS ENTIRETY APRIL 19, 2019,
UNDER SEAL PER COURT ORDER DATED APRIL 16, 2018

Defendants Janssen Pharmaceuticals, Inc. ("Janssen")[1] and Johnson & Johnson ("J&J") move this Court for an order excluding certain testimony of the State's purported expert witness, Dr. Andrew Kolodny, pursuant to 12 O.S. §§ 2702-2705. First, Dr. Kolodny's testimony that the Defendants' supposedly deceptive marketing caused an opioid epidemic in Oklahoma should be excluded, because Dr. Kolodny is not qualified to offer that opinion, the opinion is not helpful to the fact-finder, and there is no factual basis to support it. Second, the Court should exclude Dr. Kolodny's testimony regurgitating the State's theory and evidence supposedly showing that J&J should be held liable to the State based on its prior ownership of Noramco, because that testimony is neither appropriate subject matter for expert testimony nor will it help the fact-finder adjudicate this case in any way. Janssen and J&J thus respectfully request that their Motion to Exclude be granted, and for such other and further relief as the Court deems just and proper.

**BRIEF IN SUPPORT**

In support of this Motion, Janssen and J&J show the following:

## I. INTRODUCTION

An expert's opinion is inadmissible and must be excluded unless he has the qualifications and a reliable basis to offer that particular opinion, and the opinion will help the trier of fact decide the case. Dr. Kolodny is a trained psychiatrist and addiction medicine doctor. But Dr. Kolodny seeks to testify about far more than psychiatry or treatments for opioid addiction. Rather, Dr. Kolodny asks to opine as an expert about two additional topics on which he admittedly has *no* expertise to offer. The Court should not permit him to do so.

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[1] "Janssen" also refers to Janssen Pharmaceuticals, Inc.'s predecessors, Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc.

First, Dr. Kolodny seeks to testify that the Defendants undertook a deceptive marketing campaign that caused an opioid epidemic in Oklahoma. But Dr. Kolodny is not an expert in pharmaceutical marketing. Moreover, Dr. Kolodny's proffered causation opinion is not based on any scientific data or analysis, but on anecdote and speculation alone. He conducted no study of the impact of supposedly false marketing on opioid prescriptions in Oklahoma, much less any downstream harm from those prescriptions. He performed no regression analysis. He did not systematically survey Oklahoma doctors to understand why they exercised their independent medical judgment and wrote opioid prescriptions. And he could not identify a single prescriber who was misled by any of the Defendants' supposedly false marketing specifically. He simply assumed that all such prescriptions were caused by false marketing from the Defendants in this case, even though they are only a small subset of opioid manufacturers generally. Dr. Kolodny's speculation is an unreliable and unacceptable basis for an expert opinion on causation. And his claim that the Defendants' marketing was deceptive conflicts with many of their medications' FDA-approved labeling and purposes, rendering Dr. Kolodny's testimony to the contrary irrelevant, and unhelpful to the finder of fact, as a matter of law.

Second, Dr. Kolodny, a long-time opponent of opioid medications, seeks to offer his personal endorsement of the State's theory that J&J should be held responsible for allegedly causing an opioid crisis in Oklahoma because J&J's former subsidiary, Noramco, supplied raw material to other opioid manufacturers besides Janssen, making J&J the supposed "kingpin" of the Defendants' alleged deceptive scheme. Dr. Kolodny, however, simply proposes to regurgitate the State's evidence supposedly supporting that theory. But Dr. Kolodny's acting as a mouthpiece for the State's arguments does not involve the exercise of any expertise, specialized knowledge, or reliable analysis. Nor will it assist the fact-finder in understanding the State's evidence. Dr. Kolodny

should not be permitted to amplify the State's talking points by trying to imbue his lay opinions with the imprimatur of "expert" testimony when that testimony will not help the finder of fact in any way.

Under black letter Oklahoma law, Dr. Kolodny's opinions on these subjects are inadmissible and must be excluded.

## II. LEGAL STANDARD[2]

The Court has "a special obligation" to "prevent improper testimony from an expert witness." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999) (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993)); *accord Christian*, 2003 OK 10, ¶9, 65 P.3d at 598. Thus, the Court may admit expert testimony only if it satisfies several prerequisites. *See, e.g., Twyman v. GHK Corp.*, 2004 OK CIV APP 53, ¶¶21-28, 93 P.3d 51, 57. First, the expert must be qualified by "knowledge, skill, experience, training or education" to offer the *specific* opinion in question. 12 O.S. § 2702; *Alexander v. Smith & Nephew, P.L.C.*, 98 F. Supp. 2d 1287, 1292-93 (N.D. Okla. 2000). Second, the testimony must be relevant—it must "assist the trier of fact to understand the evidence or to determine a fact in issue." 12 O.S. § 2702. And third, the testimony must be reliable, meaning (a) the opinion is "based upon sufficient facts or data," (b) it is "the product of reliable principles and methods," and (c) "[t]he witness has applied the principles and methods reliably to the facts of the case." *Id.*; *see also Nelson*, 2016 OK 69, ¶13, 376 P.3d at 217. The party offering

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[2] Because Oklahoma's statutes governing expert testimony, 12 O.S. §§ 2702, 2703, 2704, and 2705, parallel the language of Federal Rules of Evidence 702, 703, 704, and 705 in all relevant respects, both state and federal jurisprudence regarding the admissibility of expert testimony is instructive. *See, e.g., Nelson v. Enid Med. Assocs., Inc.*, 2016 OK 69, ¶¶10-62, 376 P.3d 212, 217-31; *Christian v. Gray*, 2003 OK 10, ¶¶8-11, 65 P.3d 591, 598-99.

the expert testimony—here, the State—has the burden of showing by a preponderance of the evidence that the testimony meets all three preconditions. *Christian*, 2003 OK 10 ¶23, 65 P.3d at 603.

An opinion that is based only on speculative assumption or is not supported by reliable data must be excluded. *See, e.g.*, *Guidroz-Brault v. Mo. Pac. R.R. Co.*, 254 F.3d 825, 829 (9th Cir. 2001) (expert may not rely on "unsupported speculation and subjective beliefs" (citing *Daubert*, 509 U.S. at 590-91)). The Court thus must closely inspect how the expert arrives at his conclusions, and exclude "opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Under these basic evidentiary principles, Dr. Kolodny's testimony that the Defendants' supposedly deceptive marketing caused an opioid epidemic in Oklahoma, and that the Defendants must be held responsible for all related costs, is inadmissible and must be excluded.

## III. ARGUMENT

### A. The Court Should Exclude Dr. Kolodny's Testimony That The Defendants' Supposedly Deceptive Marketing Caused An Opioid Epidemic In Oklahoma

#### 1. *Dr. Kolodny Is Not An Expert In Pharmaceutical Marketing*

Dr. Kolodny is not qualified to testify about the Defendants' allegedly false marketing or its effect on Oklahoma doctors' prescribing behavior. Nevertheless, Dr. Kolodny seeks to opine that the Defendants, through their supposedly deceptive marketing and promotion of prescription opioid medications, caused an opioid epidemic in Oklahoma. *See, e.g.*, Ex. A, State's Dec. 21, 2018 Expert Witness Disclosure of Dr. Andrew Kolodny ("Kolodny Disc.") 3-8. For example, Dr. Kolodny intends to testify that the Defendants successfully manipulated Oklahoma doctors into over-prescribing opioid medications. Ex. B, Mar. 27, 2019 Deposition Transcript of Dr. Andrew Kolodny ("Kolodny Dep.") 85:4-24, 146:10-13. And he plans to opine that Oklahoma's "[i]ncreases in opioid-related morbidity and mortality" were "caused by Defendants' aggressive

and deceptive promotion of harmful and inappropriate opioid prescribing." Ex. A, Kolodny Disc. 3. Dr. Kolodny's "knowledge, skill, experience, training [and] education," however, do not qualify him to offer those particular opinions. 12 O.S. § 2702; *Whiting v. Boston Edison Co.*, 891 F. Supp. 12, 24 (D. Mass. 1995). To the contrary, Dr. Kolodny has no expertise in marketing generally, to say nothing of pharmaceutical marketing specifically. Dr. Kolodny's proposed testimony about pharmaceutical marketing and its effects, therefore, is improper lay opinion masquerading as expert testimony.

Courts across the country regularly hold that an expert must have specialized expertise to opine on the effects of marketing. This is especially so in a heavily regulated and complex environment like the pharmaceutical industry. For example, in *Pfizer Inc. v. Teva Pharmaceuticals USA, Inc.*, 461 F. Supp. 2d 271 (D.N.J. 2006), the court held that a rheumatologist was not qualified to opine about how pharmaceutical marketing affected doctors' choice between different drugs. *Id.* at 276. While the rheumatologist's medical expertise may have allowed him to opine on *general* factors that influence doctors' prescribing decisions, he was not qualified to opine on the *specific* effects of particular marketing efforts because he lacked "specialized expertise regarding sales or market analysis" and "had conducted no scientific studies or surveys concerning purchasing practices of other doctors in his field." *Id.*

Dr. Kolodny likewise lacks the necessary qualifications to opine about the influence of pharmaceutical marketing on opioid prescribing in Oklahoma. Although Dr. Kolodny asserts that he is an expert in "marketing tactics of opioid manufacturers and their deceptive marketing and sales tactics," Ex. B, Kolodny Dep. 81:22-24, that assertion is baseless. By his own admission, Dr. Kolodny's so-called expertise is based on nothing more than his personal crusade against the use of prescription opioids, and when pressed he conceded that "[a]ctually, I don't know if marketing

is a fair term to use" and that he only "guess[es] to some extent [he does] have that marketing experience." *Id.* at 82:18-19, 83:24-25. He does not. Dr. Kolodny has no training, education, or specialized knowledge in economics, marketing, or sales. Ex. A, Kolodny Disc. 9-10; Ex. B, Kolodny Dep. 81:1-19. And Dr. Kolodny concedes that he has no expertise in statistical analysis. Ex. B, Kolodny Dep. 86:21-23 ("Q. Are you a statistician, Doctor? A. No, I'm not a statistician.").

It would make little sense to qualify a doctor as an expert on the impact of pharmaceutical marketing, if any, simply because he is a doctor and, consequently, sometimes receives such marketing. Were it otherwise, any casual television viewer would be qualified as an expert on the impact of cereal or toothpaste ads on consumer behavior. And any lawyer would be an expert on legal-vendor marketing. Marketing is its own discipline. The Court should not open this floodgate by qualifying doctors as experts in other disciplines, absent their specific expertise in that particular space. The Court should take Dr. Kolodny at his word that he is no economist, no statistician, and no expert in marketing.

Dr. Kolodny also admits that he has only very limited experience, and only in his capacity as a doctor, with pharmaceutical companies' marketing efforts. Ex. A, Kolodny Disc. 9-10; Ex. B, Kolodny Dep. 81:25-84:4. Indeed, Dr. Kolodny is a psychiatrist and addiction medicine doctor, not a pain specialist, so he would not have been a target of opioid marketing efforts at all. Regardless, like the rheumatologist in *Pfizer*, Dr. Kolodny's training and experience as a doctor do not cure his conceded lack of qualifications in marketing. Absent specialized expertise, a physician is not qualified to give "broad opinions on the prescribing practices ... of all physicians." *Pfizer*, 461 F. Supp. 2d at 276. Indeed, "[a] blanket qualification for all physicians to testify as to anything medically-related would contravene the Court's gate-keeping responsibilit[y]" to ensure that all expert testimony is both relevant and reliable. *Alexander*, 98 F. Supp. 2d at 1293. The Court should

disqualify Dr. Kolodny from testifying about the Defendants' marketing and its supposed effects in Oklahoma.

2. *Dr. Kolodny's Testimony About The Supposed Deceptiveness Of The Defendants' Marketing Is Irrelevant And Unreliable*

Even if Dr. Kolodny were qualified to opine about the alleged impact of the Defendants' marketing (he is not), his testimony still would be inadmissible because it will not assist the fact-finder "to understand the evidence or to determine a fact in issue." 12 O.S. § 2702. Dr. Kolodny seeks to testify that the Defendants "deceptively" marketed opioids as a means of treating chronic pain because, Dr. Kolodny believes, opioid medications should not be prescribed for long-term pain management at all. *See, e.g.*, Ex. A, Kolodny Disc. 3-5; Ex. B, Kolodny Dep. 130:10-131:16. But, as the Court well knows, the FDA approved numerous opioid medications for exactly that purpose. And as a matter of law, pharmaceutical manufacturers may market their medicines consistent with the FDA-approved labels for those medicines. *See, e.g.*, *Wyeth v. Levine*, 555 U.S. 555, 592 (2009) ("Initial approval of a label amounts to a finding by the FDA that the label is safe for purposes of gaining federal approval to market the drug."). As such, Dr. Kolodny's personal opinion about the supposed impropriety of the Defendants' FDA-approved labels, and their marketing of opioid medications for FDA-approved purposes, is irrelevant and inadmissible in this case.

3. *Dr. Kolodny Provides No Reliable Basis For His Opinion That The Defendants Caused An Opioid Epidemic In Oklahoma*

Dr. Kolodny's testimony about pharmaceutical marketing and its supposed effects in Oklahoma is also inadmissible for the independent reason that it is unreliable. Having no training or experience in marketing or statistics, Dr. Kolodny uses none of the tools a qualified expert would use to analyze the effects of pharmaceutical marketing. But as the Oklahoma Supreme Court has emphasized, an "expert's opinion on causation must be more than *ipse dixit*." *Christian*, 2003 OK

10, ¶36, 65 P.3d at 607. Rather, the testimony must be "based upon a reliable method for determining causation," and his "conclusion" must be "analytically appropriate to that method." *Id.*

Dr. Kolodny has not relied upon or performed any relevant, reliable scientific study to support his conclusions about the supposed effects of the Defendants' marketing. This failure violates the rule that an expert must provide empirical data or analysis to support his assertion of a causal connection between pharmaceutical marketing practices and prescribing decisions. For instance, in *Pfizer*, the court held that a physician could not offer an opinion about the effects of pharmaceutical marketing on prescriptions when that physician "had conducted no scientific studies or surveys concerning purchasing practices of other doctors in his field." 461 F. Supp. 2d at 276. Similarly, in *Advanced Medical Optics, Inc. v. Alcon, Inc.*, the court rejected a doctor's opinion about the causes of sales of a particular medical device because the doctor based his opinions only on personal observations of his colleagues' preferences and did not perform any research to find out if their views were widely shared. Ex. C, No. 03-1095-KAJ, 2005 WL 782809, at *4 (D. Del. Apr. 7, 2005).

Dr. Kolodny's testimony is a classic example of an unreliable causation opinion. He admits that he failed to "do[] a study proving that A is causing B[.] I haven't done that ... ." Ex. B, Kolodny Dep. 156:3-157:9. Nor has he done any meaningful, systematic survey of Oklahoma doctors, including what marketing they received, whether they believed it was false, whether it influenced their prescribing behavior, and how it did. Dr. Kolodny instead offers bare speculation about a supposed relationship between the Defendants' marketing and prescribing trends in Oklahoma, which is not a legitimate basis for opining about causation. Dr. Kolodny broadly asserts, for example, that "[t]he medical community began prescribing opioids more aggressively in response

to" the Defendants' marketing; that the "Defendants' marketing actions led the medical community and others to believe that long-term use of opioids rarely led to addiction"; and that the "Defendants' widespread and deceptive marketing and promotion of opioids ... caused the opioid crisis that currently plagues Oklahoma." *See* Ex. A, Kolodny Disc. 3-5, 8. But he provides no actual data or analysis that supports those opinions. For this reason alone his opinions must be excluded.

Tellingly, rather than conduct any statistical or other analysis of Oklahoma doctors, Dr. Kolodny relies upon a decade-old study conducted in Utah purportedly finding that most individuals in Utah who died of a prescription opioid overdose during a two-year period had been prescribed the opioid medication for chronic pain. Ex. B, Kolodny Dep. 152:11-153:4. That study might supply *some* basis for a link between opioid *prescription* and opioid *prescription* overdose, but it *in no way* provides a link between opioid *marketing* and opioid prescription or overdose. Indeed, it does not come close to supporting Dr. Kolodny's causation opinion, because it does not say anything about causation in general, let alone that the Defendants' supposedly false marketing caused an increase in opioid prescriptions in Oklahoma specifically. *See, e.g., Lebron v. Sec'y of Fla. Dep't of Children & Families*, 772 F.3d 1352, 1368-70 (11th Cir. 2014) (excluding as unreliable expert testimony about Florida TANF recipients where testimony was based on studies of TANF recipients in Illinois and California and there was no "qualified expert to comment on the extent to which these results can be extrapolated to the population at issue in this case").

Equally unhelpful is Dr. Kolodny's reliance on national studies purportedly showing a relationship between doctors accepting payments from *unidentified* drug manufacturers and their prescribing more opioids. Ex. B, Kolodny Dep. 85:9-14. For one thing, the State does not allege that the Defendants paid doctors in Oklahoma to prescribe more opioids. For another, Dr. Kolodny in no way links those studies to any of the Defendants here, much less to their allegedly false

marketing at issue in this case. Absent any reliable modeling, survey, or study of Oklahoma prescribers and what supposedly false marketing, if any, they relied upon in writing prescriptions, Dr. Kolodny's opinion is inadmissible.

Dr. Kolodny also attempts to draw a correlation between personal anecdotes about opioid marketing and an increase in opioid prescribing in Oklahoma. But Dr. Kolodny admits that he could not identify even one Oklahoma doctor who was exposed to what he alleges was deceptive marketing. *Id.* at 108:23-109:14 ("Q: Has any Oklahoma doctor that you've spoken with told you that they were influenced by Janssen promotional materials for opioids? A: No."). Nor is he aware of any Oklahoma doctors whose prescribing habits were influenced by the Defendants' supposedly misleading marketing campaign. *Id.* at 111:5-112:11. Dr. Kolodny "believe[s] it's very likely that in Oklahoma a doctor expressed to [him] their experience hearing from a well-known key opinion leader about opioid prescribing," but none "that [he] can recall clearly," and certainly none that he can identify as related in any way to any particular Defendant. *Id.* at 108:5-22. The same is true regarding his claims that the Defendants encouraged misleading continuing medical education courses. Dr. Kolodny admitted that he "can't recall a specific conversation, but [he] think[s] it's very likely that a doctor in the state of Oklahoma did discuss with [him] deceptive [continuing medical education] that they were exposed to." *Id.* at 110:7-14. Given this effective concession that he has no reliable methodology or factual basis for his opinions, they must be excluded.

Of course, even a well-supported, mathematically-calculated correlation (which Dr. Kolodny still does not offer) is not causation—yet another fatal flaw in Dr. Kolodny's so-called method. *Correlation* is insufficient, without more, to establish a *causal* relationship between the Defendants' allegedly false marketing and an opioid crisis in Oklahoma—axiomatically, "correlation does not equal causation." *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 885 (10th Cir.

2005) (rejecting expert opinion that breast implants cause disease because opinion was based "solely on differential diagnosis and case studies"). Rather, two events may be "closely related but bear no causal relationship because they are both caused by a third, unexamined variable." Fed. Judicial Ctr., Reference Manual on Scientific Evidence 309 (3d ed. 2011). Thus, "'[a]n expert's failure to enumerate a comprehensive list of alternative causes and to eliminate those potential causes'" renders his specific-causation testimony inadmissible. *Hall v. ConocoPhillips*, 248 F. Supp. 3d 1177, 1193 (W.D. Okla. 2017) (quoting *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1310 (11th Cir. 2014)).

Dr. Kolodny's testimony is a textbook example of ignoring alternative possible causes. Dr. Kolodny admitted that other factors, aside from the Defendants' marketing, could explain Oklahoma doctors' decisions to prescribe more opioids. Ex. B, Kolodny Dep. 169:10-170:3. Yet Dr. Kolodny's causation opinion does not even try to account for how any other potential alternative causes, such as prior clinical experience, medical studies, the failure of prior medication regimes, insurance (and Medicaid) reimbursement rules, and improper physician motives, might have influenced opioid prescribing in Oklahoma. This further shows that Dr. Kolodny has no reliable basis to contend that the Defendants' supposedly false marketing in this case caused Oklahoma's opioid epidemic. *See, e.g.*, Ex. D, *Combs v. Shelter Mut. Ins. Co.*, No. 05-CV-474-JHP, 2007 WL 4748227, at *3 (E.D. Okla. Feb. 16, 2007) (excluding expert testimony because expert was "not a statistician" and opinions were not based on sufficient facts and data); *Fish v. Kobach*, 309 F. Supp. 3d 1048, 1058 (D. Kan. 2018) (barring expert's opinion on statistical data because, despite being an experienced pollster, the expert was not a trained statistician).

Dr. Kolodny's cherry-picked anecdotes about pharmaceutical marketing in Oklahoma cannot save his causation opinion either. Dr. Kolodny initially suggested that he had spoken to hundreds of doctors in Oklahoma who prescribe opioids. Ex. B, Kolodny Dep. 101:17-22. On further questioning, however, Dr. Kolodny admitted that he spoke directly with only about ten Oklahoma doctors. *Id.* at 101:23-102:9. And of those ten doctors, Dr. Kolodny could not recall whether any told him that they were influenced by the Defendants' marketing, except possibly one, who "*might have*" said that "he *may have felt* that there had been *some* influence." *Id.* at 103:2-14 (emphasis added). Even then, anecdote is not data, so one doctor's "personal experience" with pharmaceutical marketing is an insufficient basis for Dr. Kolodny to opine on the causes of other doctors' prescribing decisions. *See, e.g., Pfizer*, 461 F. Supp. 2d at 277-78 ("The fact that [a doctor] received frequent visits from Pfizer representatives, and that several of *his* patients requested Celebrex prescriptions does not alone support a conclusion that Celebrex's prescriptions were heavily influenced by advertising and promotion."). Regardless, Dr. Kolodny could not identify what that marketing was or whether it was false in some way.

Dr. Kolodny's unsupported say-so about the effects of the Defendants' marketing in Oklahoma is unreliable and must be excluded. (And for similar reasons that will be elaborated in Janssen's motion for summary judgment, even if the Court admitted Dr. Kolodny's testimony (it should not), that testimony is insufficient to create a material fact dispute about causation.)

### B. Dr. Kolodny Should Be Barred From Parroting The State's "J&J As Kingpin" Theory

#### 1. *Dr. Kolodny's Personal Opinion That J&J Is Especially Culpable Is Unscientific And Not Proper Subject Matter For Expert Testimony*

Rather than offering evidence-based expert opinion, Dr. Kolodny primarily seeks to express his personal view that J&J, in particular, should be held responsible for Oklahoma's opioid epidemic, because it previously owned Noramco, a federally-regulated supplier that sold federally-

regulated raw materials to both Janssen and other opioid manufacturers. But expert testimony is admissible only if it involves "scientific, technical, or other specialized knowledge" that will "assist the trier of fact to understand the evidence or to determine a fact in issue." 12 O.S. § 2702. Thus, "where the normal experiences and qualifications of laymen ... permit them to draw proper conclusions from the facts and circumstances," a purported expert's opinions about those facts and circumstances will not help the fact-finder and therefore are inadmissible. *Gabus v. Harvey*, 1984 OK 4, ¶18, 678 P.2d 253, 256.

Dr. Kolodny's testimony that J&J is an especially culpable "kingpin" is not expert opinion; it is the State's *argument*. This narrative did not appear in Dr. Kolodny's expert disclosure. It was only once the State itself revealed the theory that Dr. Kolodny apparently discovered it. *Compare* Ex. E, State De-Design. Mot. 4 (Feb. 26, 2019) (first accusing J&J of "act[ing] as the kingpin behind this Public Health Emergency, profiting at every stage"), *with* Ex. F, Andrew Kolodny (@AndrewKolodny) Twitter (Mar. 12, 2019, 5:45 am), https://twitter.com/andrewkolodny/status/1105449861657317376 ("Many will be surprised to learn that JnJ, same company that makes band aids and baby shampoo, has been an opioid 'kingpin.'"). The State's theory has since become the centerpiece of Dr. Kolodny's "expert" testimony. *See* Ex. B, Kolodny Dep. 204:10-208:14. Indeed, Dr. Kolodny levied the State's "kingpin" refrain against J&J over and over again throughout his depositions. *See, e.g., id.* at 131:12-16, 155:20-156:2, 204:22-206:15.

But it requires no scientific or other technical expertise for Dr. Kolodny to simply repeat the State's narrative about why liability should be extended to J&J. Parroting factual narratives is not the same thing as providing "expert" testimony. *See, e.g.*, Ex. G, *Wells v. Allergan, Inc.*, No. 12-973, 2013 WL 7208221, at *2 (W.D. Okla. Feb. 4, 2013) ("regurgitating the evidence through

various factual narratives" "improperly assumes role of Plaintiffs' advocate and invades the province of the jury"); Ex. H, *Baldonado v. Wyeth*, No. 04 C 4312, 2012 WL 1802066, at *4 (N.D. Ill. May 17, 2012) (precluding expert from offering a "narrative history" of the defendant's promotion of hormone therapy); *Highland Capital Mgmt., L.P. v. Schneider*, 379 F. Supp. 2d 461, 469 (S.D.N.Y. 2005) ("[A]n expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based upon record evidence."); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 551 (S.D.N.Y. 2004) (excluding expert testimony reciting the regulatory history of a drug because there was nothing technical or scientific about the testimony but "merely a narrative of the case which a juror is equally capable of constructing" (quotation omitted)).

Nor is parroting the legal arguments of a party's lawyers. That is why courts consistently reject attempts by supposed "experts" to act merely as a party's megaphone. *See, e.g.*, Ex. I, *Raley v. Hyundai Motor Co.*, No. Civ-08-376-HE, 2010 WL 199976, at *4 (W.D. Okla. Jan. 14, 2010) (excluding expert's testimony that "would essentially have the expert offering opinions that are, in substance, the arguments of counsel"); Ex. J, *FDIC v. First Heights Bank*, No. 95-CV-72722-DT, 1998 U.S. Dist. LEXIS 21506, at *15 (E.D. Mich. Mar. 3, 1998) (expert testimony should be "developed through the expert's own knowledge, skills and investigation rather than the regurgitated opinion of the attorney"); *Marbled Murrelet v. Pac. Lumber Co.*, 880 F. Supp. 1343, 1364-65 (N.D. Cal. 1995) (experts' testimony "crafted by" defendants' attorneys lacked objectivity and credibility); *Occulto v. Adamar of New Jersey, Inc.*, 125 F.R.D. 611, 616 (D.N.J. 1989) (expert must not "participate as the alter-ego of the attorney who will be trying the case"). Dr. Kolodny should not be allowed to act as the State's mouthpiece here.

### 2. *Dr. Kolodny's Opinion That J&J Is A "Kingpin" Is Irrelevant*

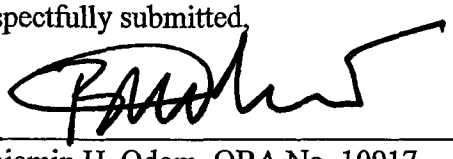
Further, even if Dr. Kolodny's testimony about J&J's supposedly heightened culpability were a proper subject matter for expert testimony, that testimony still would be inadmissible because it is in no way helpful to the fact-finder in this case. Like the State, Dr. Kolodny theorizes that J&J should be held responsible for the entirety of the opioid crisis in Oklahoma based on its past affiliation with a former subsidiary, Noramco, which produces a raw material used in opioid medications that it sold both to Janssen and other pharmaceutical manufacturers. Ex. B, Kolodny Dep. 205:10-19. But, as a matter of law, the State cannot hold Janssen and J&J liable based on their former relationship to Noramco given the "general principle of corporate law deeply ingrained in our economic and legal systems that a parent corporation ... is not liable for the acts of its subsidiaries." *United States v. Best Foods*, 524 U.S. 51, 61 (1998) (quotation omitted); *see also Gilbert v. Sec. Fin. Corp. of Okla., Inc.*, 2006 OK 58, ¶¶22-25, 152 P.3d 165, 175; *Gulf Oil Corp. v. State*, 1961 OK 71, ¶¶10-14, 360 P.2d 933, 936. Dr. Kolodny's attempt to do the same is therefore irrelevant to this case, and his testimony repeating the State's "J&J as kingpin" theory is inadmissible and must be excluded.

## IV. CONCLUSION

For all these reasons, the Court should grant Janssen and J&J's Motion to Exclude and issue an order barring the State from introducing Dr. Kolodny's testimony about both (1) the effects of the Defendants' marketing in Oklahoma and (2) his personal view that J&J is especially responsible for allegedly causing an opioid epidemic in Oklahoma.

Dated: April 16, 2019

Respectfully submitted,



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## CERTIFICATE OF MAILING

Pursuant to 12 O.S. § 2005(D), and by agreement of the parties, this is to certify on April 16, 2019, a true and correct copy of the above and foregoing has been served via electronic mail, to the following:

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# EXHIBIT A

**Exhibit J - Dr. Andrew Kolodny, M.D.**

**A. Dr. Kolodny is expected to testify about the following subject matters:**

- **Defendants' multi-faceted campaign to deceive the medical community, policymakers and the public about the risks and benefits of opioid analgesics, including but not limited to:**
  - The promotion of aggressive and inappropriate opioid prescribing by Defendants' sales representatives and Defendants' branded and unbranded marketing materials.
  - The scientific basis, or lack thereof, for Defendants' marketing claims.
  - False claims that opioid under-prescribing was contributing to a crisis of untreated chronic pain.
  - The promotion of aggressive and inappropriate opioid prescribing by key opinion leaders, professional societies, pain organizations, the Pain Care Forum, sales representatives, and others.
  - The financial and business relationships between Defendants and the individuals and organizations that have promoted aggressive and inappropriate opioid prescribing.
  - The creation, history, cause and effects of the present opioid crisis.
  - The need for abatement measures to end the opioid crisis.
- **The impact of Defendants' deceptive campaign to increase opioid prescribing, including but not limited to:**
  - Trends in opioid prescribing in the United States and the State of Oklahoma.
  - Trends in opioid-related morbidity and mortality in the United States and the State of Oklahoma.

- Trends in opioid-related health and social problems in the United States and the State of Oklahoma

- **Actions taken by Defendants to preserve the status quo of aggressive and inappropriate opioid prescribing, including but not limited to:**
  - Lobbying, advocacy, media relations and consumer/patient outreach and influence by the Pain Care Forum and other industry groups, and Defendants' participation and/or influence in same.
  - Misinforming and influencing the medical community and the public about the nature of the opioid crisis, both directly and through industry-funded groups and individuals.
  - Defendants intentional and purposeful targeting of certain types of physician and prescribers, and pharmacies relying on market research, IMS data, and other material.
- **The nature and science of opioids.**
- **Adverse effects of opioid use, including physiological dependence, tolerance, opioid use disorder, addiction, neuroendocrine dysfunction, immune suppression, withdrawal symptoms, and hyperalgesia.**
- **The appropriate treatment of opioid use disorder and opioid addiction.**
- **The lack of evidence supporting effectiveness of long-term opioid use and the likelihood of iatrogenic addiction.**
- **Certain measures required to abate the opioid crisis in Oklahoma and amount of time necessary.**

**B. Dr. Kolodny is expected to testify about the following facts, and/or opinions, among others:**

1. The State of Oklahoma has experienced a sharp increase in the prevalence of opioid use disorder, an increase in opioid-related overdose deaths, and an increase in other opioid-related health and social problems. Families and communities across the State are suffering the devastating impact of this public health crisis.
2. Increases in opioid-related morbidity and mortality was caused by Defendants' aggressive and deceptive promotion of harmful and inappropriate opioid prescribing. As opioid prescribing increased, rates of addiction and overdose deaths increased in parallel.
3. The medical community began prescribing opioids more aggressively in response to Defendants' multi-faced, deceptive campaigns.
4. Defendants delivered their deceptive marketing messages through branded marketing, unbranded marketing, sales representatives, biased journal articles and studies, medical "education," paid "key opinion leaders," paid speakers, and purportedly unbiased organizations, among other tactics.
5. Defendants' scheme to influence targeted clinicians, pharmacists, hospitals, consumers, state agencies, and state legislatures to carry out their deceptive marketing campaign.
6. The purpose of Defendants' deceptive marketing campaign was to change the way that the medical community viewed opioids as a class of drug, in order to increase and/or maintain sales of their drugs. During the century before Defendants' deceptive marketing campaign, the medical community correctly viewed narcotic analgesics as dangerous and addictive medications that should be mainly be reserved for short-term, severe acute pain (such as in the hospital setting or following surgery), and for easing suffering at the end of life from conditions like metastatic cancer.

7. Defendants set out to change this accurate appreciation of opioid risks and limitations of long-term use by coopting a "compassionate care" message that led prescribers to believe that tens of millions of Americans were unnecessarily suffering because of an overblown and irrational fear of using opioids. Defendants, individually and in collaboration with each other and others, attempted to create a belief that America had a crisis of untreated chronic non-cancer pain caused by under-prescribing of opioids. In short, Defendants sought to create and/or aggressively expand a market for opioid analgesics where no such market had previously existed. Thus, Defendants aggressively promoted the use of opioids generally, as a class of drugs, to treat pain in a wide variety of common, moderately painful conditions—something that had not been done in nearly a century due to the highly addictive nature of opioids. To do this, Defendants sought to convince healthcare providers, pharmacists, consumers, and others that opioids were less addictive than they actually are and more effective than they actually are. They sought to convince healthcare providers that they had an ethical and professional duty to treat pain with opioids. That is what Defendants' deceptive marketing campaign did.

8. The campaign to increase opioid prescribing minimized the risks of opioid analgesic use, especially the risk of addiction. Defendants' marketing actions led the medical community and others to believe that long-term use of opioids rarely led to addiction. For example, Defendants and their collaborators cited a one paragraph letter to the editor of a medical journal on the topic of hospital use of opioids, and other publications, to falsely suggest that the risk of addiction with long term use of opioids was less than 1%. In reality, opioid use disorder is common in patients on long-term opioids.

9. Defendants' campaign to increase opioid prescribing minimized the serious difficulty and discomfort patients experience when attempting to discontinue opioid use. Physiological opioid dependence was deceptively characterized as natural and benign. In reality, physiological dependence on opioids is not natural or benign. It begins within the first few days of use and can result in severe withdrawal symptoms that include worsening of pain when opioids are discontinued. Physiological dependence makes it difficult for many patients to discontinue opioids.
10. In their campaign to increase opioid prescribing generally, Defendants stated and suggested that tolerance to opioids did not limit long-term effectiveness. In reality, tolerance results in reduced analgesic effect unless the dose is increased.
11. Defendants' campaign to increase opioid prescribing stated and suggested that prescribing dangerously high doses of opioids is appropriate and that there should be no ceiling or upper dose limit. In reality, as the opioid dose increases so do risks, including the risk of addiction and death.
12. Defendants' campaign and marketing was not supported by medical evidence and the truth is that Defendants, at the time they were claiming addiction was rare and the long term benefits were great, did not know what the risk of addiction was with the long term use of opioids nor whether it carried the claimed benefits.
13. Defendants promoted the dangerously false idea that patients exhibiting behaviors likely to be caused by addiction were instead suffering from "pseudo-addiction," meaning the patient was engaging in drug-seeking behavior because her opioid dose was too low not because she was potentially addicted. Prescribers were taught to respond to "pseudo-addiction" by increasing the dose. In reality, drug seeking behavior should be viewed as a

red flag for the possibility of addiction and giving a higher dose of opioids to these patients is an exceptionally dangerous practice. The concept of "pseudo-addiction" was manufactured and perpetuated by Defendants as an effort to overcome prescribers well-founded concerns about addiction and abuse of opioids, concerns which Defendants viewed as a barrier to sales.

14. In advance of MS Contin going off patent and in conjunction with the launch of OxyContin, Defendant Purdue Pharma was aware of and exploited the mistaken belief that oxycodone (the opioid in OxyContin) is less potent than morphine (the opioid in MS Contin) to promote the use of oxycodone for common, moderately painful conditions. Purdue marketed OxyContin as less potent than MS Contin in an effort to expand the market of long-acting opioids beyond the cancer-pain market that MS Contin had already dominated. In reality, oxycodone is significantly more potent than morphine.

15. Defendants funded, supported, collaborated with, influenced and in some cases created, pain patient organizations to collaborate with Defendants, each other, and others for the purpose of advocating communicating with the media, public, consumers, health care providers and others and aggressively promote use of their products. These organizations have produced print, video and web-based materials that minimize opioid risks, especially the risk of addiction, and exaggerate the benefits of opioid use. In their materials, non-opioid medications like Tylenol and Advil are presented as if they are more dangerous than opioids.

16. Defendants funded professional organizations that have promoted opioid use and issued guidelines, consensus statements, booklets, videos and web-based materials promoting aggressive and inappropriate opioid prescribing.

17. Defendants paid a cadre of Key Opinion Leaders (KOLs) to influence their health professional colleagues with deceptive educational messages that minimize opioid risks and exaggerate the risks on non-opioid analgesics.

18. Defendants funded and utilized deceptive medical education programs sponsored by the pain organizations and KOLs and speakers they funded and by medical education communication companies they employ. These educational programs minimize opioid risks, exaggerate opioid benefits, and falsely imply that opioids are safe and effective for long-term use.

19. Defendants, other pharmaceutical companies, and the non-profit groups they fund, participate in an organization called the Pain Care Forum (PCF), which actively lobbies against efforts that might reduce opioid prescribing, and engaged in numerous coordinated activities designed to make opioids more readily available and to remove restrictions on access and prescribing. Each Defendant considered the PCF to be a key advocacy and marketing tool and utilized the PCF to sell more opioids.

20. Defendants purchase data on clinician prescribing practices to inform their marketing strategies and to determine compensation for sales representatives. Defendants used this and other market research to target prescribers and pharmacies in order to convince them to prescribe and purchase their opioids. Defendants secretly targeted and detailed physicians, mid-levels, nurses, pharmacists, and staff—anyone who could influence total opioid prescriptions.

21. Defendants deceptive marketing campaign successfully changed the medical community and stakeholders' accurate appreciation of opioid risks and benefits, and the damage of this campaign is still visible in the medical community.

22. Defendants' widespread and deceptive marketing and promotion of opioids—both their specific opioid products and opioids generally—caused the opioid crisis that currently plagues Oklahoma.

23. Oklahomans die every week from opioid-related overdoses, and more and more Oklahomans become opioid-addicted every week.

24. As the opioid crisis worsened in the U.S. and Oklahoma, Defendants impeded a public health response to the problem. In an effort to preserve the status quo of aggressive prescribing and maintain revenue, Defendants made false statements to medical providers, policymakers, and the media about the nature of the opioid crisis. Defendants falsely framed the opioid crisis as if all opioid-related harms were limited to recreational abusers of diverted opioids. In reality, millions of pain patients were becoming addicted to aggressively prescribed opioids, and thousands of pain patients receiving legitimate prescriptions were dying from overdoses.

25. Defendants' multi-faceted campaign to increase opioid prescribing included a compensation structure for their employees and sales staff that incentivized encouragement of aggressive opioid prescribing and disincentivized reporting of pill mills and other forms of diversion.

26. Defendants, working in a coordinated manner within the Pain Care Forum and utilizing the same Key Opinion Leaders, mischaracterized measures to reduce inappropriate prescribing as "barriers to compassionate pain care" including triplicate prescription pads, patient registries, mandatory use of prescription drug monitoring programs, hydrocodone up-scheduling and many other efforts, even though these interventions would have improved care for patients and reduced opioid-related harms.

27. The devastating impact of the opioid crisis will affect the state of Oklahoma, its families and communities for decades. It must be abated. Among the many interventions required to bring the opioid crisis under control, there is a need to reduce the number of Oklahomans becoming opioid-addicted by sponsoring a counter-detailing educational campaign. This counter-detailing campaign must correct the misinformation that led to opioid overprescribing. There is also a need to ensure access to effective opioid addiction treatment for the hundreds of thousands of Oklahomans now suffering from opioid addiction.

C. **Dr. Kolodny's training, experience and basis for his opinion:**

- Medical degree from Temple University School of Medicine
- General internship at Mount Sinai School of Medicine
- Residency in Psychiatry at Mount Sinai School of Medicine
- Fellowship in Public Psychiatry from Columbia University School of Medicine
- Fellowship in Health Policy, United States Senate
- Board certification in Psychiatry & Neurology
- Board certification in Addiction Medicine
- Research Professor at NYU Global School of Public Health
- Senior Scientist at Brandeis University Heller School for Social Policy and Management
- Course Director, Columbia University School of Public Health
- Co-Founder, Physicians for Responsible Opioid Prescribing
- Past positions:

- Medical Director in the Office of Executive Deputy Commissioner, New York City Department of Health and Mental Hygiene
- Chairman, Department of Psychiatry, Maimonides Medical Center
- Chief Medical Officer, Phoenix House, a national non-profit addiction treatment agency
- President, Physicians for Responsible Opioid Prescribing

- Current positions:
  - Co-Director, Opioid Policy Research Colloborative, Brandeis University
  - Course Director, Opioid Crisis, Columbia University School of Public Health
  - Executive Director, Physicians for Responsible Opioid Prescribing.
- In addition to his skill, knowledge, education, experience, and training, the basis for the facts and opinions upon which Dr. Kolodny will testify is his review of the relevant medical literature, public documents, the documents produced by the parties in this case, and the deposition testimony provided in this case. Because discovery is ongoing, Dr. Kolodny reserves the right to amend or supplement the facts and opinions upon which he is expected to testify as additional information is made available.

**D. Dr. Kolodny's Compensation**

Dr. Kolodny is being compensated at the following rate: $725 per hour for testimony and preparation.

**E. Dr. Kolodny's Qualifications**

Dr. Kolodny's qualifications are reflected in the *curriculum vitae* attached as Exhibit J-1.

## F. Dr. Kolodny's Publications

A list of Dr. Kolodny's recent publications is contained in the *curriculum vitae*, see Exhibit J-1.

## G. Dr. Kolodny's Prior Testimony

A list of cases Dr. Kolodny has testified in at trial or deposition in the preceding four (4) years is attached in Exhibit J-2.

# EXHIBIT J-1

# CURRICULUM VITAE

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**Licensure**: New York State Medical License

**Certification:** American Board of Psychiatry & Neurology
American Society of Addiction Medicine

**Education**

BA, 1994 Queens College, City University of New York

MD, 1999 Temple University School of Medicine

**Training**

1999-2003 Internship & Residency in Psychiatry, Mount Sinai School of Medicine

2003 Fellow in Congressional Health Policy, United States Senate

2003-2004 Fellow in Public Psychiatry, Columbia University

**Professional experience**

2016-Present Director, Opioid Policy Research Collaborative,
Heller School for Social Policy & Management
Brandeis University

2013-2016 Chief Medical Officer & Senior Vice President, Phoenix House Foundation, New York, NY

2008 -2013 Chair, Department of Psychiatry, Maimonides Medical Center
Brooklyn, NY

2006-2008 Vice Chair, Department of Psychiatry, Maimonides Medical Center
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| 2003-2005 | Medical Director for Special Projects, Office of the Executive Deputy Commissioner, Mental Hygiene Division, New York City Department of Health and Mental Hygiene |

**Professional service**

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| 2014-Present | Executive Director, Physicians for Responsible Opioid Prescribing (PROP) |
| 2015-2016 | Advisor- Opioid Policy, The National Association of Attorneys General. |
| 2015-2016 | Advisor- Opioid Policy, Office of Massachusetts Attorney General |
| 2014-2016 | Advisor- Opioid Policy, Office of Kentucky Attorney General |
| 2010-2013 | President, Physicians for Responsible Opioid Prescribing (PROP) |
| 2012 | Advisor, New York City Mayor's Task Force on Prescription Drug Abuse |
| 2011- 2012 | New York State Governor's Inter-agency Workgroup on Prescription Drug Abuse |
| 2006-2014 | Medical Advisory Panel, New York State Office of Alcoholism & Substance Abuse Services, Albany, NY |
| 2003-2009 | Chair, Public Psychiatry Committee, New York County District Branch, American Psychiatric Association |
| 2004-2005 | President, New York Regional Chapter of the American Association of Psychiatric Administrators |
| 2003 | Health Policy Fellow, Office of Senator Joseph I. Lieberman, United States Senate, Washington, D.C. |
| 2001-2003 | Steering Committee on Practice Guidelines, American Psychiatric Association, Washington, DC |

**Academic appointments and teaching**

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| 2014-Present | Research Professor, Global Institute of Public Health, New York University |
| 2014-Present | Senior Scientist, Heller School for Social Policy and Management, Brandeis University |
| 2007-Present | Adjunct Assistant Professor in Health Policy and Management, Mailman School of Public Health, Columbia University |
| 2006-2012 | Clinical Assistant Professor of Psychiatry, SUNY-Downstate Medical Center, Brooklyn, NY |
| 2005-Present | Voluntary Faculty, Public Psychiatry Fellowship Program, Columbia University Department of Psychiatry |
| 2005-Present | Lecturer, Buprenorphine Certification Training, American Psychiatric Association |
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| 2013 | Drug-Fighter of the Year, Dynamite Youth Center Foundation |
| 2011 | Annual Honoree, Brooklyn Housing & Family Services |
| 2006 | Annual Lecture Honoree, American Association of Psychiatric Administrators |
| 2005 | Outstanding Service Award, NYC Department of Health and Mental Hygiene |
| 2003 | Mildred Hope Witkin Award, Mount Sinai School of Medicine |
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| 1998 | Honors in Clinical Internal Medicine, Temple University School of Medicine |
| 1998 | Honors in Clinical Psychiatry, Temple University School of Medicine |
| 1994 | Jonas Salk Award, City University of New York |
| 1993 | Ford Foundation Diversity Initiative Award |

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Principal Investigator, *Utilization of the New York State Prescription Drug Monitoring Program to Reduce Risky Prescribing.* Funded by the United States Food and Drug Administration, 2012-present.

Principal Investigator, *Treatment of Opioid Addicted Chronic Pain Patients with Buprenorphine.* Funded by Maimonides Medical Center Research Foundation, 2012-2013.

Co-investigator, *Pilot Study of Buprenorphine Maintenance for Opioid Addicted Jail Inmates.* Funded by National Institute on Drug Abuse, 2005.

Co-investigator, *Substance Abuse, HIV, & Hepatitis Prevention for Minority Populations and Minority Reentry Populations in Communities of Color*, funded by the Substance Abuse and Mental Health Services Administration, 2005.

Study Psychiatrist, *Citalopram in the Treatment of Sexual Compulsivity Among Men Who Have Sex with Men;* funded by the U.S. Center for Disease Control, 2001-2003.

Research Associate, *Ethnic Conflict Between Korean Immigrants and African Americans*; funded by the Ford Foundation, 1993-1995.

**Publications**

Lin D, Lucas E, Murimi IB, Kolodny A, Alexander GC. Potential financial conflicts of interest and federal opioid guidelines: A Cross Sectional Study. JAMA Intern Med. 2017 Jan 17. Epub ahead of print.

Kolodny A. Chronic Pain Patients Are Not Immune to Opioid Harms (letter). J Pain Palliat Care Pharmacother. 2016 Dec;30(4):330-331.

Hwang CS, Turner LW, Kruszewski SP, Kolodny A, Alexander GC. Primary Care Physicians' Knowledge And Attitudes Regarding Prescription Opioid Abuse and Diversion. Clin J Pain. 2015 Jun 22.

Kolodny A, Courtwright DT, Hwang CS, Kreiner P, Eadie JL, Clark TW, Alexander GC. The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction. Annual Rev Public Health. 2015 Mar 18;36:559-74.

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—The North American Opioid Addiction Epidemic. Keynote Lecture. International Medicine in Addiction Conference. Melbourne, Australia. March 21, 2015.

—The North American Opioid Addiction Epidemic. World Health Organization. Geneva, Switzerland, Nov 6, 2014.

—Overview of the Opioid Analgesic Epidemic. National Governors' Association Meeting. Frankfort, Kentucky, January 15, 2013.

—Common Threads: Pain and Addiction. Moderator and Lecturer, 43rd Annual Scientific Conference of the American Society of Addiction Medicine (ASAM) Atlanta, Georgia, April 19, 2012.

—An Iatrogenic Epidemic—Lessons from the Opioid Experiment, Keynote Speaker at the Seventh Annual Conference of The Addiction Institute of New York, March 2, 2012.

—Treating Patients with Mental Illness and Multiple Medical Problems: Building Patient-Provider Alliances. Grand Rounds Lecture, New York State Office of Mental Health (OMH). Lecture was broadcasted to OMH facilities in the New York State area, June 22, 2011.

—The Challenges and Rewards of Psychiatric Administration. Speaker at American Association of Psychiatric Administrators Annual Membership Luncheon, Toronto, Canada, May 23, 2006.

—How to Implement Buprenorphine Treatment in Your Program. Moderator, Discussant, Workshop, Annual Conference for Alcohol and Substance Abuse Providers of New York State, January 31, 2006.

—Buprenorphine: A New Approach to Tackle the Public Health Consequences of Untreated Opioid Addiction. Grand Rounds Lecture for St. Luke's Roosevelt Hospital, Department of Psychiatry, January 18, 2006.

—The History of Heroin Treatment: from Methadone to Buprenorphine. Bicentennial Celebration lecture for the New York City Department of Health and Mental Hygiene, New York, NY, August 24, 2005.

—When ACT Meets Medicaid: Financing, Fidelity and Philosophy. Program Director, American Association of Psychiatric Administrators New York Regional Chapter Annual Conference, New York, NY, June 3, 2005.

—Psychiatric Consequences of Methamphetamine Use. Plenary lecture, Understanding and Treating an Emerging Health Crisis, NYU Kimmel Center, New York, NY June 16, 2006.

# EXHIBIT J-2

**Dr. Kolodny's Prior Testimony**

1. 2018 - The estate of Jessica Sparrow v. Willam Hough, M.D.
2. 2018 - Jerome Cassell v. Christopher Clough PA, Dr. O'Connell's Pain Care Centers & Insys Therapeutics
3. 2018 – Mackenzie Colby v. Christopher Clough, PA, et al.
4. 2018 - John Perusse v. Christopher Clough, PA, et al

# EXHIBIT B

## [FILED UNDER SEAL]

IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel.,
MIKE HUNTER, ATTORNEY GENERAL
OF OKLAHOMA,
Plaintiff,
vs. No. CJ-2017-816
PURDUE PHARMA L.P.;
PURDUE PHARMA, INC.;
THE PURDUE FREDERICK
COMPANY;
TEVA PHARMACEUTICALS
USA, INC.;
CEPHALON, INC.;
JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-McNEIL-JANSSEN
PHARMACEUTICALS, INC., n/k/a
JANSSEN PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICA,
INC., n/k/a JANSSEN
PHARMACEUTICALS, INC.;
ALLERGAN, PLC, f/k/a
ACTAVIS PLC, f/k/a ACTAVIS, INC.,
f/k/a WATSON PHARMACEUTICALS, INC.;
WATSON LABORATORIES, INC.;
ACTAVIS LLC; and
ACTAVIS PHARMA, INC.,
f/k/a WATSON PHARMA, INC.,

Defendants.
_____/

VIDEOTAPED DEPOSITION OF ANDREW KOLODNY, M.D.
TAKEN ON BEHALF OF THE DEFENDANTS
ON MARCH 27, 2019, BEGINNING AT 9:24 A.M.
IN OKLAHOMA CITY, OKLAHOMA

VIDEOTAPED BY: Kaleb Pianalto
REPORTED BY: Jane McConnell, CSR RPR CMR CRR

[redacted]

Q And that's why you're out there making tweets like the one that we discussed, right?

A It's why I've been tweeting and speaking publicly and writing papers about the opioid crisis for many years so that people will understand what's happened here.

Q So, Doctor, you are a psychiatrist, correct?

A That's correct.

Q Do you have a degree in economics?
A No. I've never formally studied economics.
Q You have no training in health economics?
A No training in economics.
Q Have you ever published a peer-reviewed article in that area?
A I've never published an article on health economics.
Q Do you have a degree in marketing?
A I do not have a degree in marketing.
Q How about sales?
(Cell phone interruption.)
A I'm sorry. I meant to power this off.
I've never earned a degree in sales.
Q Have you had a marketing job or a sales job?
A I've never worked as a sales -- no, I've never really worked in marketing.
Q Do you consider yourself an expert in sales and marketing?
A I consider myself an expert in the marketing tactics of opioid manufacturers and their deceptive marketing and sales tactics.
Q On what do you base your expertise?

A I base that expertise on I'd say probably since 2006, although I worked on the opioid crisis before 2006. Since 2006 I became -- starting around 2006 I became especially interested in the role that marketing and marketing disguised as education was playing in fueling aggressive prescribing of opioids, and that as that prescribing was increasing, we were seeing adverse public health consequences associated with that aggressive marketing.

So I do have a background working in public health. And when it became clear that marketing was having a negative public health consequence, I became interested in those marketing tactics and began to study them.

Q Have you ever developed a marketing campaign?

A Actually, I don't know if marketing is a fair term to use, but I did work for New York City's Department of Health and Mental Hygiene. This was in the early 2000s, and my chief responsibility was to reduce deaths from drug overdose in New York City.

We believed that better access to a medication called buprenorphine could help reduce

drug overdose deaths. There was pretty good access to methadone maintenance that had been around in New York City for awhile. We had a reason to believe that many opioid-addicted people in New York City didn't want to have to go to a methadone maintenance clinic.

So we launched what we called the buprenorphine initiative, and I was in charge of the buprenorphine initiative. And the buprenorphine initiative involved trying to increase access to this medicine, actually trying to get doctors to prescribe buprenorphine.

And we utilized health department staff to do what we call academic detailing where they visited doctors and provided education about treatment of opioid addiction. I guess you could call that marketing. I did have quite a bit of experience.

The goal of the buprenorphine initiative I think was to get -- I think our goal was to see 60,000 New Yorkers receiving treatment for opioid addiction within -- by 2010 and I think that was a goal we set in maybe 2004.

So I guess to some extent I do have that marketing experience.

Q Anything else?
A In marketing?
Q Yes.
A I don't think so.
Q And have you -- have you ever done a study to measure the impact of pharmaceutical sales in marketing campaigns?
A I have studied -- I'm sorry. Can you ask that question one more time?
Q Have you ever done a study to measure the impact of pharmaceutical sales in a marketing campaign?
MR. PATE: Object to form.
A So I have done research on the impact of marketing on our opioid addiction epidemic and on the change in opioid prescribing and have published on that.
Q (BY MR. LIFLAND) Have you done a study?
MR. PATE: Object to form.
A Could you define what you mean by "a study"?
Q (BY MR. LIFLAND) I don't mean have you read literature from other people's studies that they have done on what they think the impact of a marketing campaign is.

I'm asking have you conducted such a study yourself?

MR. PATE: Object to form.

A I don't think I've conducted my own study. I have published on this subject. I have studied this subject, and I am very familiar with studies of this subject and have worked with these authors who have done some of these studies.

Studies, for example, that have shown that in counties in the United States, including Oklahoma, where doctors were paid more by drug companies, mostly dinners, where doctors took more money from drug companies, more opioids were prescribed.

And another more recent study that was published just a few months ago that showed that where doctors took the most money from drug companies in those counties, more people were dying of prescription opioid overdoses than in counties where doctors took less money from drug companies.

So I have not conducted my own unique study, but I have studied this topic extensively, and I've written on this topic. So I do feel that I'm an expert on this subject.

Q (BY MR. LIFLAND) You didn't design those

studies, did you?

MR. PATE: Object to form.

A No. I did not design those studies.

Q (BY MR. LIFLAND) And you said you didn't conduct them?

A I did not conduct those studies.

Q So you read them, correct?

A I've read them and I've communicated with the authors who did before they worked on those studies, and I've published on some of this work.

Q So you've published describing them?

MR. PATE: Object to form.

A I've published describing -- not this very -- I haven't written about this recent study, but I have published articles on the topic of marketing influence on opioid prescribing.

Q (BY MR. LIFLAND) Based on studies that you did not yourself design and conduct, correct?

MR. PATE: Object to form.

A That's correct.

Q (BY MR. LIFLAND) Are you a statistician, Doctor?

A No, I'm not a statistician.

Q Are you a regulatory expert?

A I am not a regulatory -- well, I'm not

sure what that would mean. I think that I do have a fair amount of expertise in regulation of narcotics in the United States. So I think when we talk about regulation of controlled drugs, I do have a fair amount of expertise.

Q Are you an analytical chemist?

A No.

Q Are you an immunologist?

A No.

Q Are you an epidemiologist?

A I teach epidemiology. I teach at the Mailman School of Public Health, and I do research in epidemiology.

I'm not sure that there is a formal degree in epidemiology, but I certainly have expertise in the epidemiology of opioid addiction in the United States.

Q What was the last epidemiology study that you designed?

A There's a study I've designed that I'm working on right now with a student at Columbia University. This is a study on the epidemiology of opioid addiction in the United States.

What we're doing is we're analyzing data, treatment episode data that comes from the federal

a clinical trial.

Q So you don't think it's possible to study efficacy of a drug other than by a clinical trial?

A You can perform a -- I suppose it would be possible to perform a study, but to really demonstrate whether a drug is efficacious or not, I don't believe it's really possible to demonstrate whether a drug is efficacious or not without performing a double blind, randomized, controlled trial.

So could you do a study? Yes. But I don't think it would really answer a question about whether the drug is efficacious.

Q What about whether the drug was effective?

A Effectiveness of a drug could be done with -- could be demonstrated without a clinical trial.

Q And have you done such a study for opioids?

A No. I haven't done effectiveness studies on opioids.

MR. LIFLAND: Let's take a short break for lunch.

VIDEOGRAPHER: We're going off the record at 12:02 p.m.

(Break taken from 12:02 p.m. to 12:46 p.m.)

VIDEOGRAPHER: We're back on the record at 12:46 p.m.

Q (BY MR. LIFLAND) Doctor, have you ever practiced medicine in Oklahoma?

A No.

Q Have you ever treated chronic pain patients in Oklahoma?

A No.

Q Have you treated patients for addiction in Oklahoma?

A No.

Q In fact, you're not licensed to practice medicine in Oklahoma, right?

A Correct.

Q Have you spoken with doctors in the state of Oklahoma who have prescribed opioids?

A I have.

Q How many doctors?

A Probably hundreds if "speaking to" includes giving talks.

Q Excluding that.

A You mean like direct conversations?

Q Direct conversations.

A I don't know, but I would say less than 10, but hard to say.

Q So less than 10 you've had direct conversations about opioid prescribing?

A I would say maybe about 10 actually. It's very difficult to say because I've talked with lots of doctors about opioids, and some could have been from Oklahoma. But I would say probably under 10 in the past couple of years.

Q Do you remember which doctors you spoke to?

A I don't remember all of their names. I've certainly talked with some of the experts whose names I remember. I've talked with Dr. Jason Beaman about opioids, I've talked with Dr. Scott Anthony about opioids, and there are a few others whose names I'm forgetting and some I remember speaking to, but I would never be able to remember their name.

Q Who is Scott Anthony?

A He's a pain doctor here in Oklahoma.

Q When did you speak to these doctors?

A I've talked with Dr. Beaman on many occasions. Dr. Scott Anthony, I met him once and talked with him and some of the other doctors on

different occasions.

Q Did any of the doctors you spoke with tell you that they were influenced by sales reps to prescribe opioids?

A I can't recall, but I think that Dr. Anthony might have -- I think he may have felt that there had been some influence, but I do not recall a specific conversation with a doctor in the state of Oklahoma where that doctor told me that they were not influenced.

I think if I were to put that question to doctors in Oklahoma, I think some would recognize that they were influenced and some might not recognize that they were influenced.

Q I asked whether one of the doctors you talked to told you they were influenced.

A I think --

MR. PATE: Objection; asked and answered.

A Yeah. I think that Dr. Anthony might have mentioned that.

Q (BY MR. LIFLAND) What did he say?

A I think he may have indicated that he felt like he was influenced, but I'm not certain. I don't really recall, but I think he might have mentioned it.

Q Did he say who influenced him?

A I don't -- I don't recall.

Q Did any doctor tell you that a Janssen sales rep influenced them to prescribe opioids?

A I don't recall a doctor in the state of Oklahoma ever telling me about being influenced by a specific visit or visits from the sales force for any particular drug company.

What I do think may have been discussed with Dr. Scott Anthony and others were the other ways in which Johnson & Johnson and Purdue and Teva influenced prescribing. I don't think the -- I don't recall talking about visits from specific drug reps.

Q When you said Dr. Anthony and others, which others?

A Well, like I said, I talked -- I've given talks about the opioid crisis in Oklahoma, and I have had doctors come up to me after my talk, thank me for the talk, and explain how what I presented helped them better understand the influence that opioid manufacturers had on opioid prescribing, and they may have talked about the influence on their own practice.

And most of my talk is -- I don't really

that I've had aside from events, what we're talking about here, I don't recall a doctor telling me that they overprescribed because of the visits from drug reps, and I don't --

Now, the fact that they might not have mentioned that or I didn't ask, I don't know how relevant that is.

I'm sorry. You're allowed to ask the questions and I'm answering them. I don't recall that coming up.

Q (BY MR. LIFLAND) And you don't recall a doctor telling you that at an event, do you?

A Telling me at an event that the sales force --

Q That a Janssen sales rep influenced their prescribing decisions.

A At the events what doctors would frequently talk with me about or vent about is the broader aspects of this campaign.

Q That's not my question. My question is sales reps.

A Yes, yes.

Q You don't recall that, being told that by a doctor?

A That's correct. I don't recall people

coming up to tell me voluntarily on their own that sales reps influenced them.

Q And you didn't ask them?

A I didn't ask them.

Q Did any of these 10 Oklahoma doctors that you talked to outside of events tell you that they were influenced by key opinion leaders?

A That would be something that would -- I hear frequently when I give a talk and I think probably heard in Oklahoma.

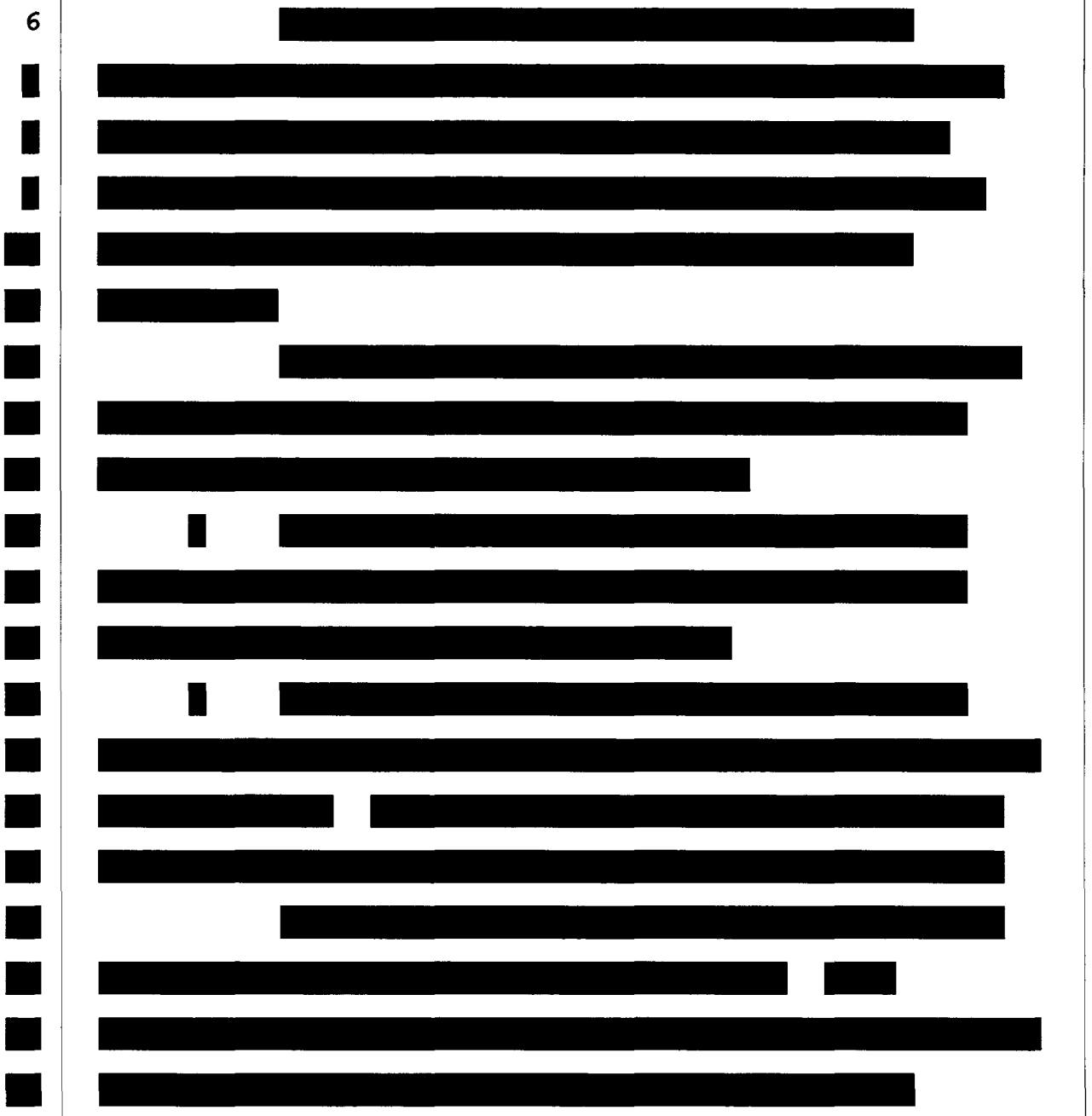
What people will say is they remember when one of the well-known key opinion leaders was in town and they remember hearing from that individual. Yes, that is something that I do hear very -- I do not recall a specific event or individual, but I believe it's very likely that in Oklahoma a doctor expressed to me their experience hearing from a well-known key opinion leader about opioid prescribing.

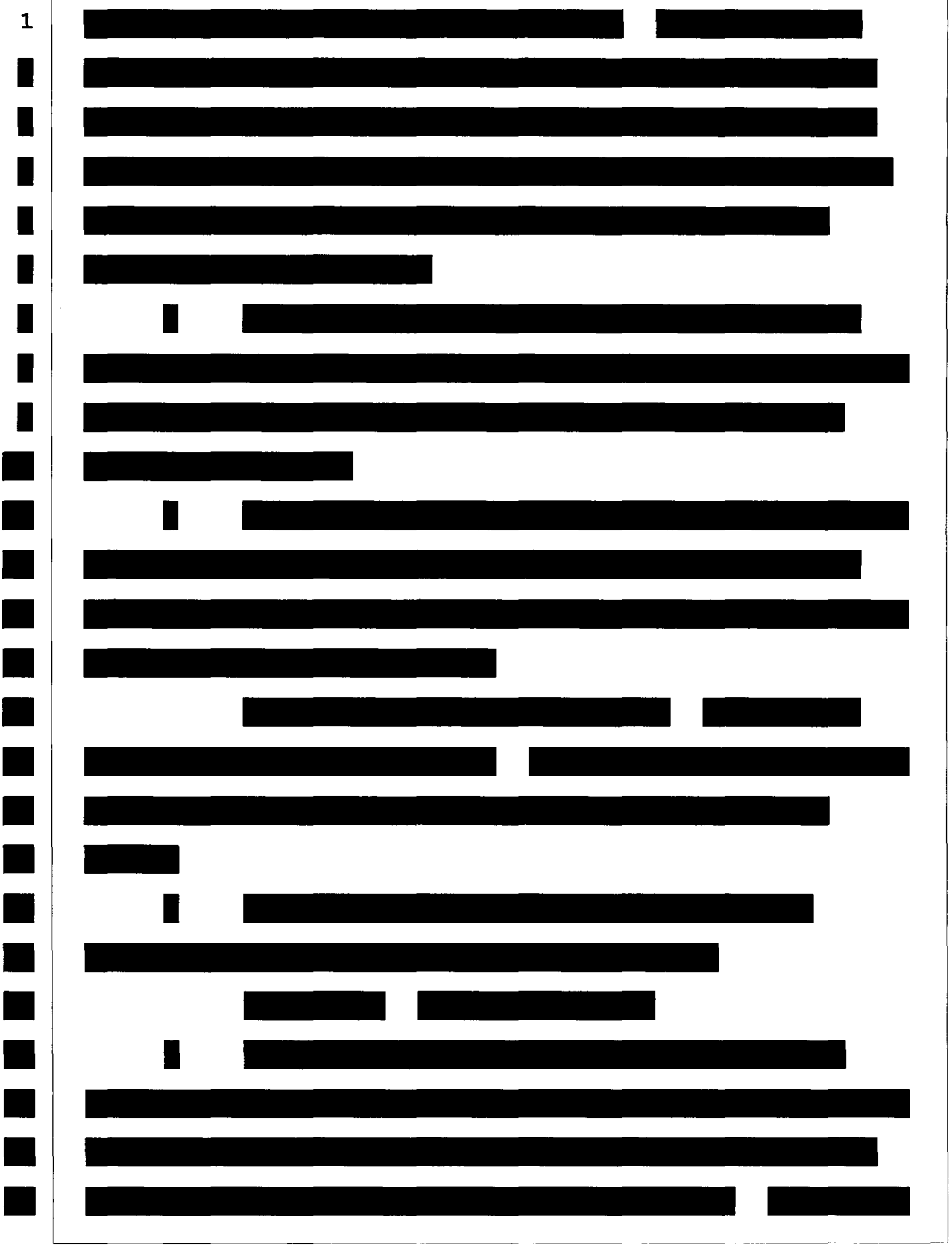
Q But you can't point to a specific one now that you can recall?

A Not that I can recall clearly.

Q Has any Oklahoma doctor that you've spoken with told you that they were influenced by Janssen promotional materials for opioids?

A No. I don't believe any doctor ever -- so I haven't had many conversations with doctors in Oklahoma other than giving talks, and I don't recall at a talk or outside of a talk a doctor volunteering to tell me about having seen deceptive material.





[redacted]

Q (BY MR. LIFLAND) Did any doctor, Oklahoma doctor who you spoke with tell you that they were influenced by what you called this multifaceted campaign?

A Yes. I do believe it's likely that I've heard from doctors in the state of Oklahoma about this deceptive campaign having an influence on them because, as I mentioned, I've on more than one occasion have given talks in Oklahoma where often at the end of the talk or sometimes in the Q&A a doctor will recall how this campaign that I lecture about influenced their prescribing. They're often angry about it and want to share their experience.

Q Can you recall a specific example?

A Of -- yes, I can recall a specific example of a doctor telling me that he believes he harmed patients by prescribing aggressively.

And I recall a doctor who did both primary care work and addiction treatment telling me about the experience of seeing a patient who he had treated for pain with opioids years later in an

addiction treatment setting and believing that his prescribing practices resulted in harm.

And I recall a doctor telling me about his belief that he had a patient who lost her life because of his prescribing practices.

So it's happened on --

Q Three in Oklahoma, right?

A I'm not sure I can remember that. Those examples I'm giving you were not Oklahoma physicians, just in my experience over the years conversations I've had --

Q How many talks --

A -- with doctors.

Q I'm sorry. How many talks have you given in Oklahoma?

A I believe three, but there might have been -- there might be one I'm not remembering.

Q So three talks total?

A Yes.

Q And the three doctors you just recalled might not have been at those talks --

A No.

Q -- they might have been out of the state?

A I know that those examples that I just gave you are doctors who I know are not in Oklahoma

because I remember those doctors and those conversations clearly.

Yeah. But I don't think your question was specifically about Oklahoma. I think you were --

Q No. It was. So you don't remember any in Oklahoma?

A I don't -- any what?

Q Any doctors who made those kind of comments to you after a talk in Oklahoma.

MR. PATE: Object to form.

A I do not recall a doctor in Oklahoma after hearing me talk telling me that he or she believes that his or her prescribing harmed people. That I don't remember.

But I do recall giving talks in Oklahoma and having doctors after that talk and during the Q&A even talk about their experience with this multifaceted campaign that led to very aggressive prescribing.

Doctors like to, for example, bring up the "pain is the fifth vital sign." They like to vent about how hospitals were financially incentivized through patient satisfaction surveys to encourage aggressive prescribing of opioids.

Q So it's your testimony that a patient who's getting chronic pain therapy cannot have an improvement in function?

MR. PATE: Object to form.

Q (BY MR. LIFLAND) That can't happen, is that your view?

A So --

MR. PATE: Object to form; misstates his testimony.

A Yeah. So I'm happy to explain again what I've just stated.

Q (BY MR. LIFLAND) I understand what you've just said. I'm asking you a different question.

Is it your view -- you say that there are studies that show patients in general don't do better. That's your position.

I'm asking you are there individual patients who can or is it zero patients who will do better in your view?

MR. PATE: Object to form.

Q (BY MR. LIFLAND) Do you really think you can say that?

MR. PATE: Object to form; asked and answered.

A What I would say is that putting a patient

on around-the-clock opioids, the term for that would be chronic opioid therapy, that means that the patient is taking it every day. If it's a Duragesic patch, they're always going to have that patch on. They're not putting that patch on when they need it. The idea with the Duragesic patch is you just wear that patch. If it's an extended-release oral opioid, you're taking it morning and night if it's a twice-a-day pill.

When opioids are prescribed in that manner, where they're taken around-the-clock for weeks and months and years, the best available evidence tells us that this -- that patients -- that the risks outweigh the benefits. We do not have evidence that this increases function. We have evidence that it's more likely to decrease function and even increase pain, a phenomenon called hyperalgesia.

Can I say that -- is it my testimony that no patient on chronic opioid therapy could ever benefit or have improved function? No, that's not my testimony.

Certainly in the short run a patient on chronic opioid therapy could have an improvement in their function. In the first weeks, yes. If the

dose is titrated up, they can continue to get pain relief.

But in general, this is a dangerous practice that lacks evidence to support it. When you're talking about any treatment for which -- which is dangerous, even a surgical intervention, if you don't have evidence that this particular treatment is going to help someone and you have evidence that it's dangerous, those are treatments that we should prescribe rarely. I wouldn't say never. I would say rarely.

Unfortunately, chronic opioid therapy for these common chronic conditions in the United States is prescribed commonly, and it's because of a deceptive campaign that your client, I believe, was a kingpin in.

Q (BY MR. LIFLAND) Doctor, you know there's data out there, in fact, that Janssen has developed data that supports the proposition that some patients will improve and their functionality will improve on chronic opioid therapy.

You said there was no evidence. You may be talking about a specific kind of evidence, but there's data out there that supports that. You wouldn't disagree with that?

MR. PATE: Object to form.

A You'll have to ask me that question again. I'm sorry.

Q (BY MR. LIFLAND) You'd agree that there's data that supports that patients can do well over a long period of time on chronic opioid therapy?

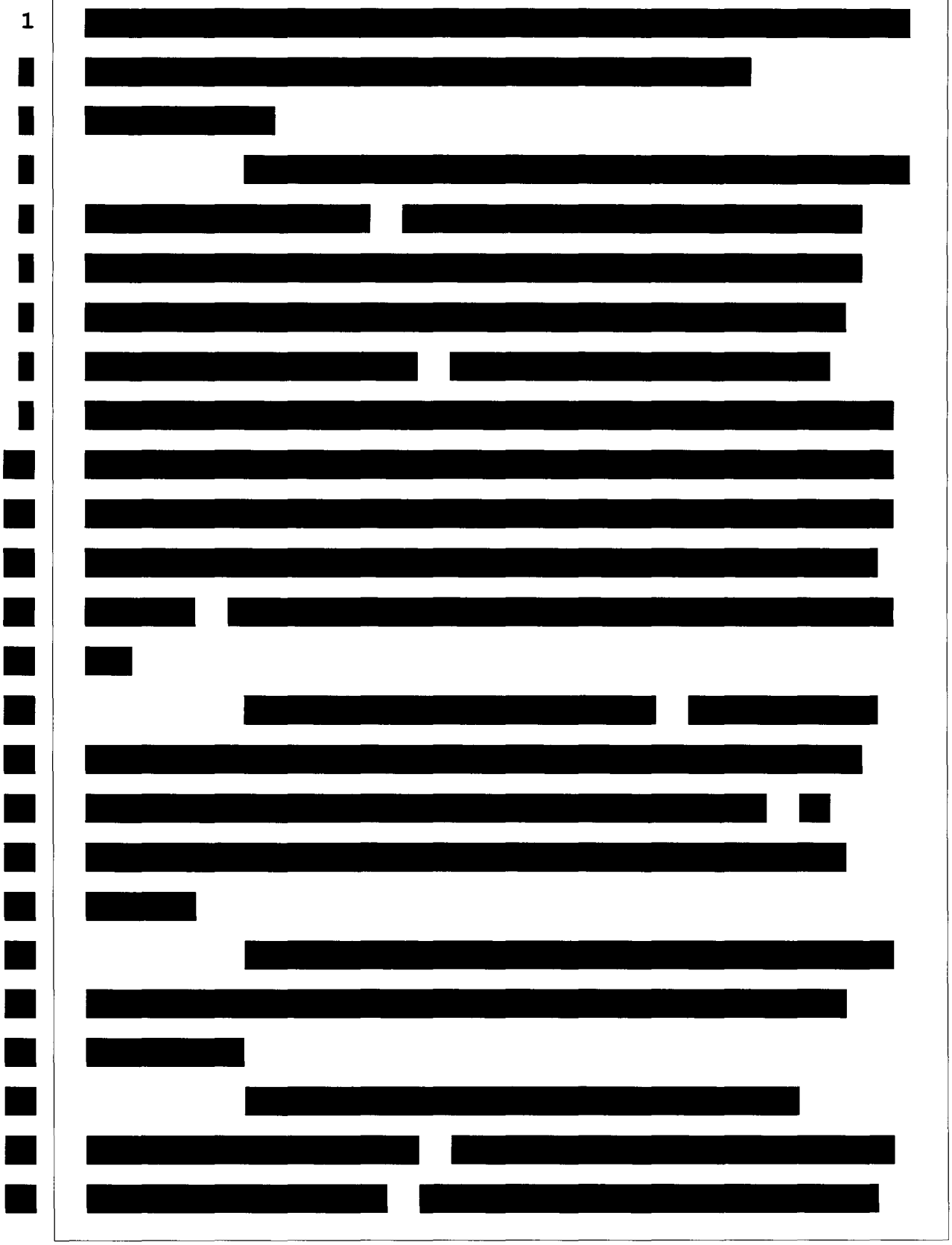
MR. PATE: Object to form.

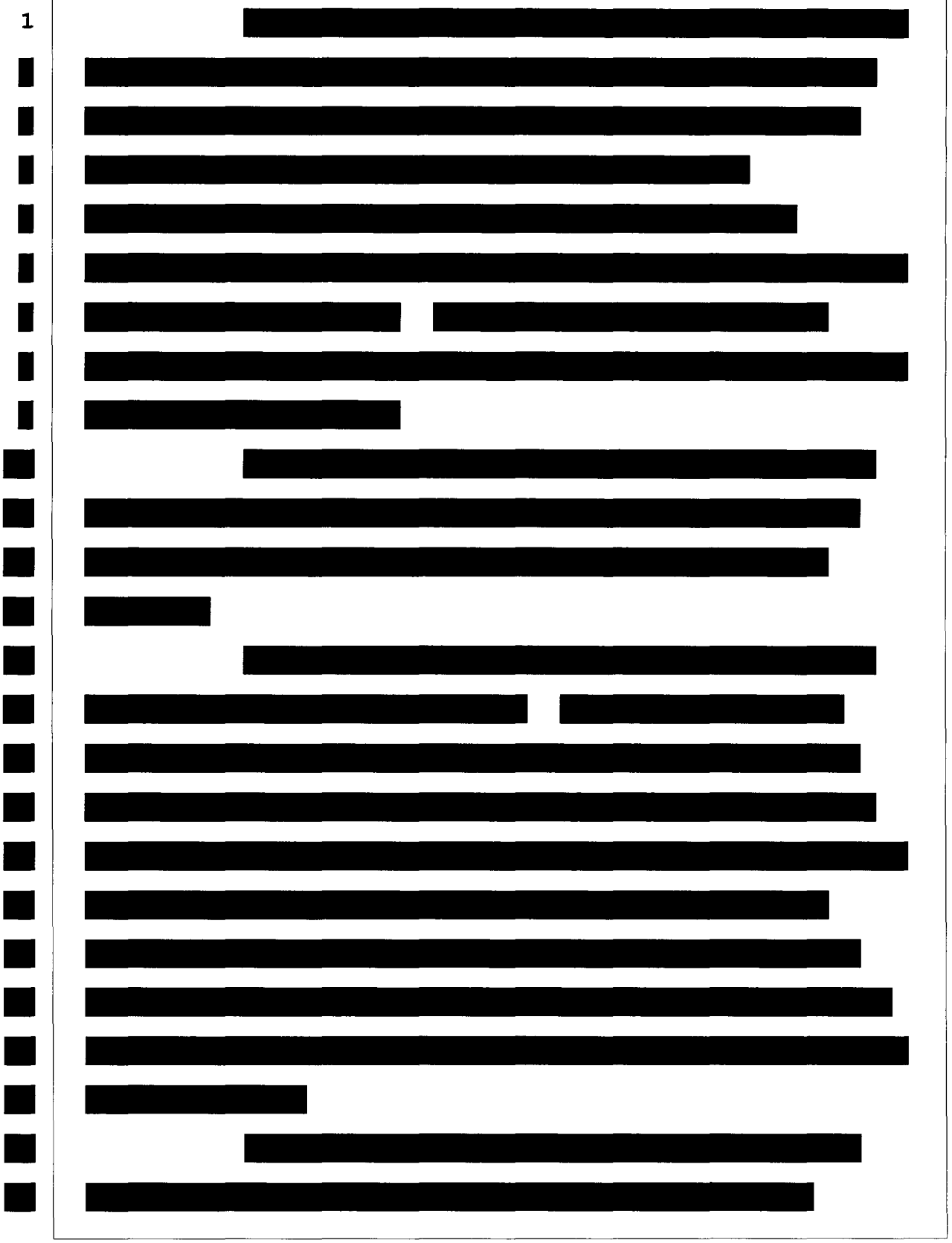
A Is there data that someone could point to to argue that a patient -- to bolster a claim that a patient can take opioids around-the-clock for years and do well, is there data that somebody could point to to support that claim? Yes. I'm sure there's some kind of data out there that somebody could point to.

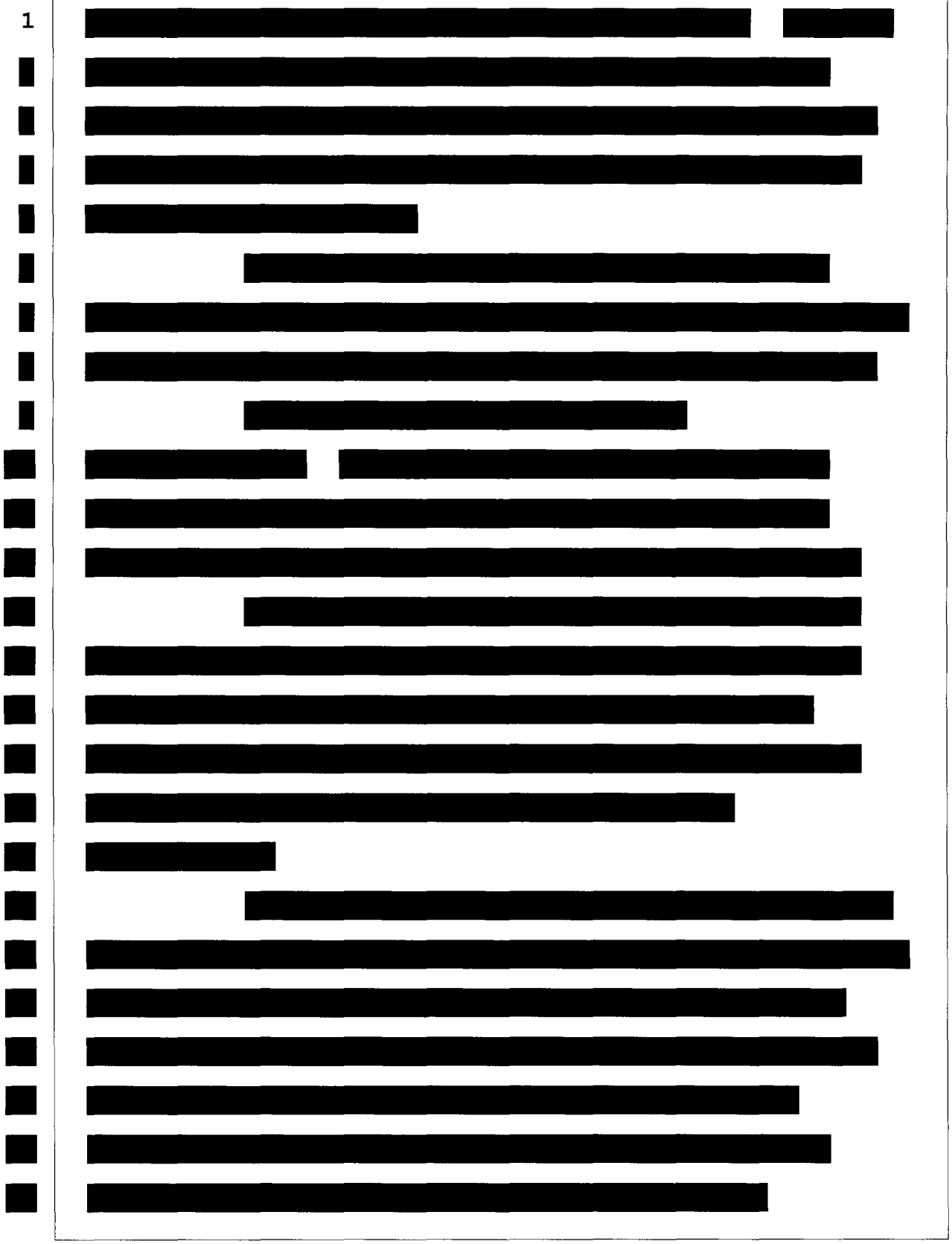
Whether or not it's true or whether or not this is data that is being appropriately used I think is unlikely.

When the -- when the federal government in 2015 sponsored a review of all of the available evidence on long-term effectiveness for opioid therapy, this is a 2015 review published, the first author is Roger Chou.

The conclusion of this review that obtained every published study was that they could not -- the authors could not find evidence,







overdosing and dying from opioid overdoses are people who are misusing both licit and illicit opioids?

A No, I would not agree with that.

Q In fact, that's what the CDC is saying right now, that it's the rise of illegal drugs that's driving what we're seeing in the country today?

MR. PATE: Object to form.

A Yeah. So we talked a little bit earlier about my research and to the different populations that are affected by the opioid crisis, and it's not just different populations or different demographic groups, but geographic areas have been affected very differently.

So it is certainly true that on the east coast the opioid most likely to result in an opioid overdose death would be an illicit opioid fentanyl. That is not -- certainly not true in Oklahoma. Prescription opioids kill far more people.

What I would -- I think what you're asking and what I think we might be able to agree on is that there is evidence that the vast majority of people who die from a prescription opioid or any opioid overdose, the vast

majority of those deaths appear to occur in people who were suffering from the disease of opioid addiction.

And while it's true some people develop the disease of opioid addiction because they misused opioids, maybe even took them because they liked the effect, and that's how they got addicted, other people became -- developed the disease of opioid addiction taking opioids exactly as prescribed by doctors.

And really important data that helps to answer this question from a state similar in its opioid stats to Oklahoma is Utah. What's happened in Utah is in some way similar to what's happened in Oklahoma. It certainly makes better sense to look at Utah than what's happening on the east coast where there's fentanyl.

In a study that was done by the health department in the state of Utah that looked at every single overdose death involving a prescription opioid in the 2008-2009 year, what the State did was they interviewed next of kin and obtained records on every single person who had died of a prescription opioid overdose in this two-year period.

What they found is that 92 percent of the

deaths occurred in people who were receiving prescriptions from doctors for chronic pain, not what I think you were referring to as so-called drug abusers or misusers.

Q (BY MR. LIFLAND) In fact, a lot of people are overdosing from opioid drugs that weren't prescribed to them, correct?

MR. PATE: Object to form.

A So as we just discussed, many of the people who are dying of opioid overdoses were suffering from the disease of opioid addiction, and some people who developed this disease developed it misusing opioids, taking them because they liked the effect, and some of them developed this disease taking opioids as prescribed by doctors, and that's how they got addicted, and they're dying from addiction.

Addiction is the disease that's killing them, and whether they developed their opioid addiction taking their opioids as prescribed by a doctor or taking them because they liked the effect, regardless, when you look at the source of the opioid even for the people taking it, misusing it, the source was from a doctor, was originally from a doctor, and it's a prescription that might not have

been written were it not for this multifaceted deceptive campaign that J&J engaged in, that Johnson & Johnson engaged in.

Q So what percentage is from abuse versus what percentage -- I'm talking Oklahoma -- versus what percentage is from use of legitimate prescriptions for chronic pain as directed?

MR. PATE: Object to form.

A So the people who are dying of an opioid overdose in the state of Oklahoma, if a study was done similar to the study that was done in Utah, I think the results would be similar because Utah has similar drug use patterns to Oklahoma.

And what they found in the state of Utah, when they looked at every single death involving a prescription opioid in the 2008-2009 year and interviewed next of kin, was that 92 percent of the people who had died of a prescription opioid overdose were receiving prescriptions from doctors for chronic pain.

When they interviewed the next of kin, the next of kin believed that their loved ones were also addicted. About 80 percent of the next of kin or of the opioid overdose decedents the next of kin believed were also suffering from addiction, but

these were people getting prescriptions from doctors for chronic pain.

That study has not been replicated in Oklahoma. If it was replicated in Oklahoma, I believe the findings would be similar.

Q (BY MR. LIFLAND) You don't have an Oklahoma study, correct?

MR. PATE: Object to form.

A That study has not been replicated in this state.

Q (BY MR. LIFLAND) And you're relying on a Utah study, correct?

A I'm explaining that I believe that if we replicated the Utah study, my opinion is that we would find that the findings would be similar.

[redacted]

Q My question for you is have you done a study that shows that's a causal relationship, not a correlation?

MR. PATE: Object to form; asked and answered.

A So I have not done a study to show that this line going up showing the increase in prescribing caused the deaths to go up.

But there are studies showing that the vast majority of the deaths, and I think you would agree, are occurring in people suffering from the disease of opioid addiction, and we know that one becomes addicted to opioids by taking them repeatedly.

And so we know that if you put a highly addictive drug, if you overexpose a population like the population of Oklahoma to this highly addictive drug, if you flood Oklahoma with this highly addictive drug, many people are going to get addicted to it.

And as you increase the number of people with this disease of opioid addiction within a population, overdose death which is an unfortunate

but common outcome in people with this disease is going to go up with the increase in the prevalence of this disease.

So have I done a study proving that A is causing B? I haven't done that study. But I also haven't done a study showing that parachutes are effective when you jump out of an airplane, but I think we have pretty good reason to believe they are.

Q (BY MR. LIFLAND) So you haven't done any regression analysis that evaluates other possible causes?

A Other possible causes for what?

Q For the parallel lines that you're pointing to between prescriptions and opioid overdose mortality and morbidity.

A I'm sorry. Can you ask me that question again?

Q You said you hadn't done a study to establish the causal relationship. So I'm just saying you have not done a regression analysis to explore the possibility of other causes.

A The other causes --

MR. PATE: Object to form.

A -- for an epidemic of opioid addiction?

Q (BY MR. LIFLAND) Yes. No. For increased morbidity and mortality.

A When we talk about morbidity, I think opioid-related morbidity we're mainly talking about addiction. When we talk about the mortality --

Q We're talking about overdoses. We're talking about abuse.

A The overdoses are mainly -- not everybody who dies from an opioid overdose was addicted.

There's some people, for example, a friend of mine who I know through advocacy, he lost his daughter. She was 18 years old. It was the night before starting college, and she made the mistake of experimenting for the first time with an 80 milligram OxyContin, and that one pill was enough to take her life. She was not addicted, and there are many deaths that occur in people who were not addicted.

But in the studies of opioid overdose decedents, they really show us that the overwhelming majority of people who died were, in fact, addicted.

And we know how addiction -- we know how addiction to opioids develops. You become addicted to opioids by taking opioids.

So as you make opioids more available,

about the opioid crisis, we're really talking about this increase in the number of people who are addicted which is why we've got the deaths.

And if we're talking about this increase in the number of people with opioid addiction, the vast majority of whom developed that disease taking prescription opioids, I don't know of other ways that someone can become addicted to opioids other than taking an opioid.

As we've just established, some people do develop the disease taking heroin, but that's very uncommon. Most have developed that disease taking prescription opioids, and the prescription opioids have been available to people because of this change in medical practice.

Q (BY MR. LIFLAND) I'm asking you if you think that promotion, over-promotion, whatever you want to call it, the brilliant, multifaceted whatever by pharmaceutical companies is the sole cause of the increase of morbidity and mortality --

MR. PATE: Object to form.

Q (BY MR. LIFLAND) -- from opioids?

MR. PATE: Object to the form; misrepresents the State's burden of proof in this case. Oklahoma law does not require us to prove the

sole cause.

MR. LIFLAND: I'm not asking -- that's irrelevant to my question.

Q (BY MR. LIFLAND) Can you answer the question, please?

MR. PATE: Then maybe your question is irrelevant. Go ahead. If you know, you can answer, Doctor.

MR. LIFLAND: That's your contention.

A I think there are other factors that have contributed aside from the marketing campaign. I think our health care system has played a role.

The fact that doctors don't have very much time to spend with patients, and if you've got a very busy practice and there's pressure from managed care companies to see as many patients per hour as possible, writing prescriptions can be the easiest way to get the patient out of your office quickly.

So there -- I think it's not just opioids. It's other -- relying on prescriptions I think is a factor.

So I think there are different factors that have contributed to overprescribing. I think the most significant factor by far is this campaign that deceived the medical community because without

that campaign, I don't think we'd be here today.

But I think there are other contributing factors.

Q (BY MR. LIFLAND) What about doctors operating pill mills to make money?

MR. PATE: Object to form.

A So I don't see doctors who operate pill mills as having played much of a role in causing the epidemic of opioid addiction. They've played a role in the mortality because the people they sell their prescriptions to, many of their customers die of overdoses. So they've contributed to the mortality.

But, in general, they're profiteering off of the epidemic that your client was a kingpin in creating because there were so many people who became opioid addicted and were desperate to maintain a supply of opioids, these pill mill doctors profiteered off of their desperation.

Q (BY MR. LIFLAND) What about distributors?

A What about the distributors?

Q Do you think they had a role in causing the crisis?

A I think that the distributors played an important role in pouring fuel on the fire, and I believe that the manufacturers and distributors

worked collaboratively in the Pain Care Forum to preserve a status quo of aggressive prescribing, to block interventions that might result in more cautious prescribing.

So I think they're a major contributor to opioid-related morbidity and mortality.

Q And what about illegal drug suppliers?

MR. PATE: Object to form.

A I see them as like very similar to the pill mill doctors. They are profiteering off of an epidemic that your client was a -- Johnson & Johnson was a kingpin in helping create.

Q (BY MR. LIFLAND) Do you think they contributed to the increase in morbidity and mortality?

A Maybe the mortality. So certainly cartels that are bringing in fentanyl into the United States on the east coast, not so much -- not really a problem fortunately here in Oklahoma, but certainly like the pill mill doctors, the cartels have played an important role in the mortality that we see.

But the opioid crisis I think is best understood as an epidemic of opioid addiction, a sharp increase in the number of people suffering from the condition of opioid addiction, and I don't

Q (BY MR. LIFLAND) That you don't know what the FDA believed, we do know what they wrote in their letter, correct?

MR. PATE: Object to form.

A That's correct. We don't -- I don't know what they were thinking. I know what they put in writing.

Q (BY MR. LIFLAND) And even on the change they did make to the label, they didn't fully agree with your position, did they?

A You mean on the severity of pain?

Q Yes.

A That's correct. You're correct. We wanted "moderate" removed, and we wanted the indication to be for severe pain.

Rather than just doing severe pain, what they did was pain severe enough to require around-the-clock opioids or pain severe enough rather than severe pain, and so that was different from what we had asked.

Q And they stated their reasoning for that was not that they thought the category of pain "moderate" was inappropriate, but that they thought it ought to be -- the decision ought to be made based on an individual evaluation of the individual

patient's pain as opposed to some kind of category, correct?

MR. PATE: Object --

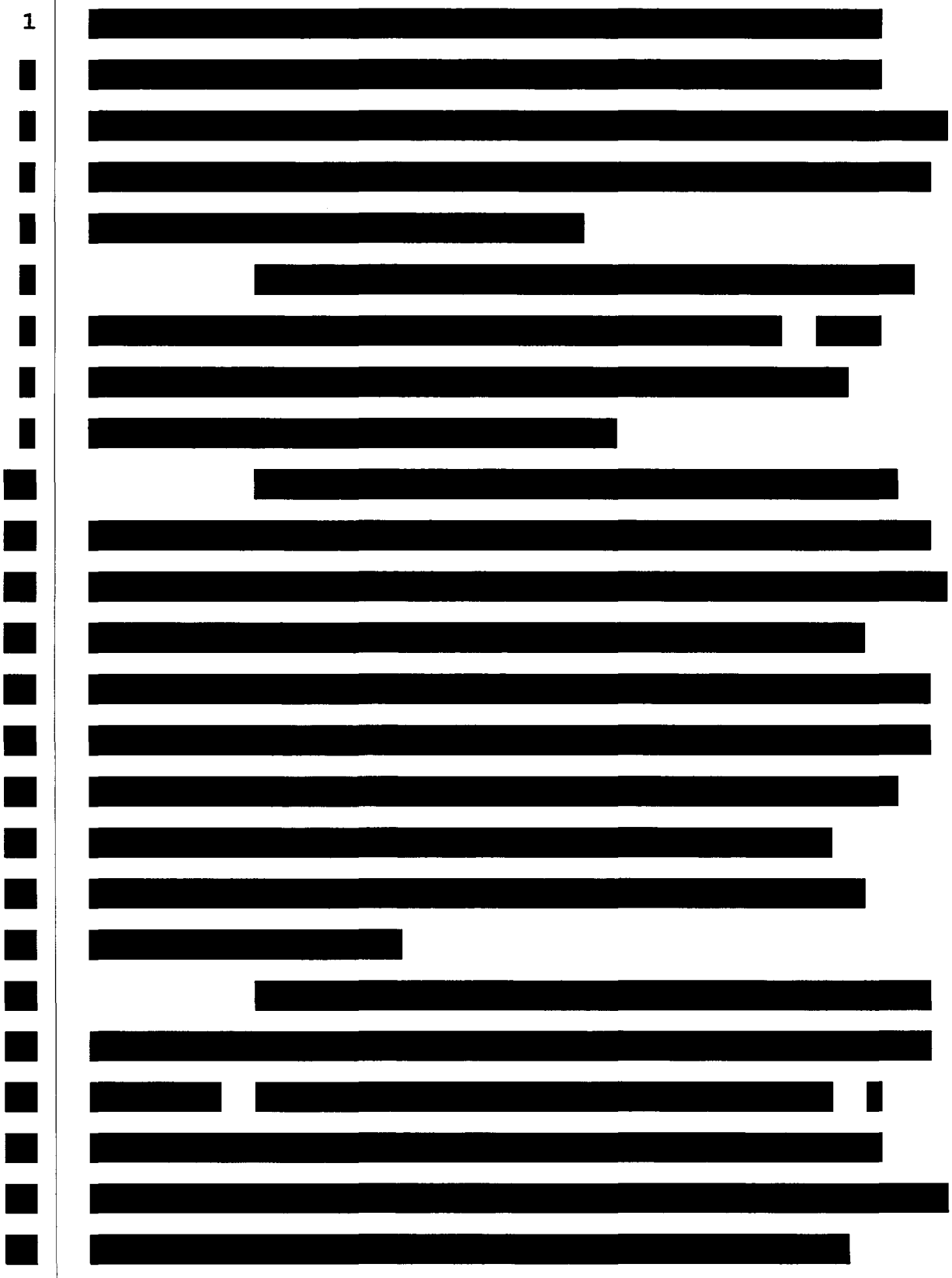
Q (BY MR. LIFLAND) That's what they said?

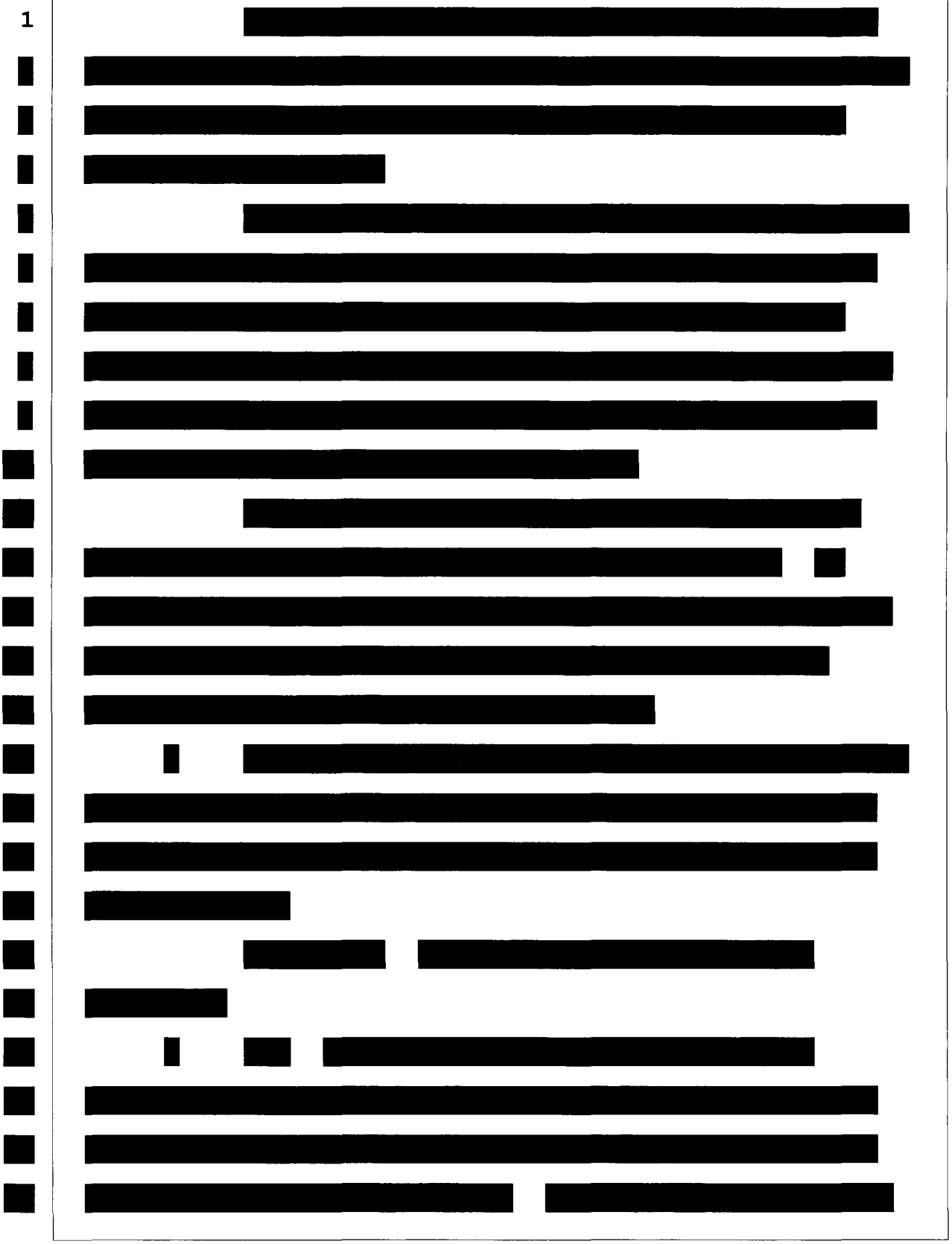
MR. PATE: Object to form.

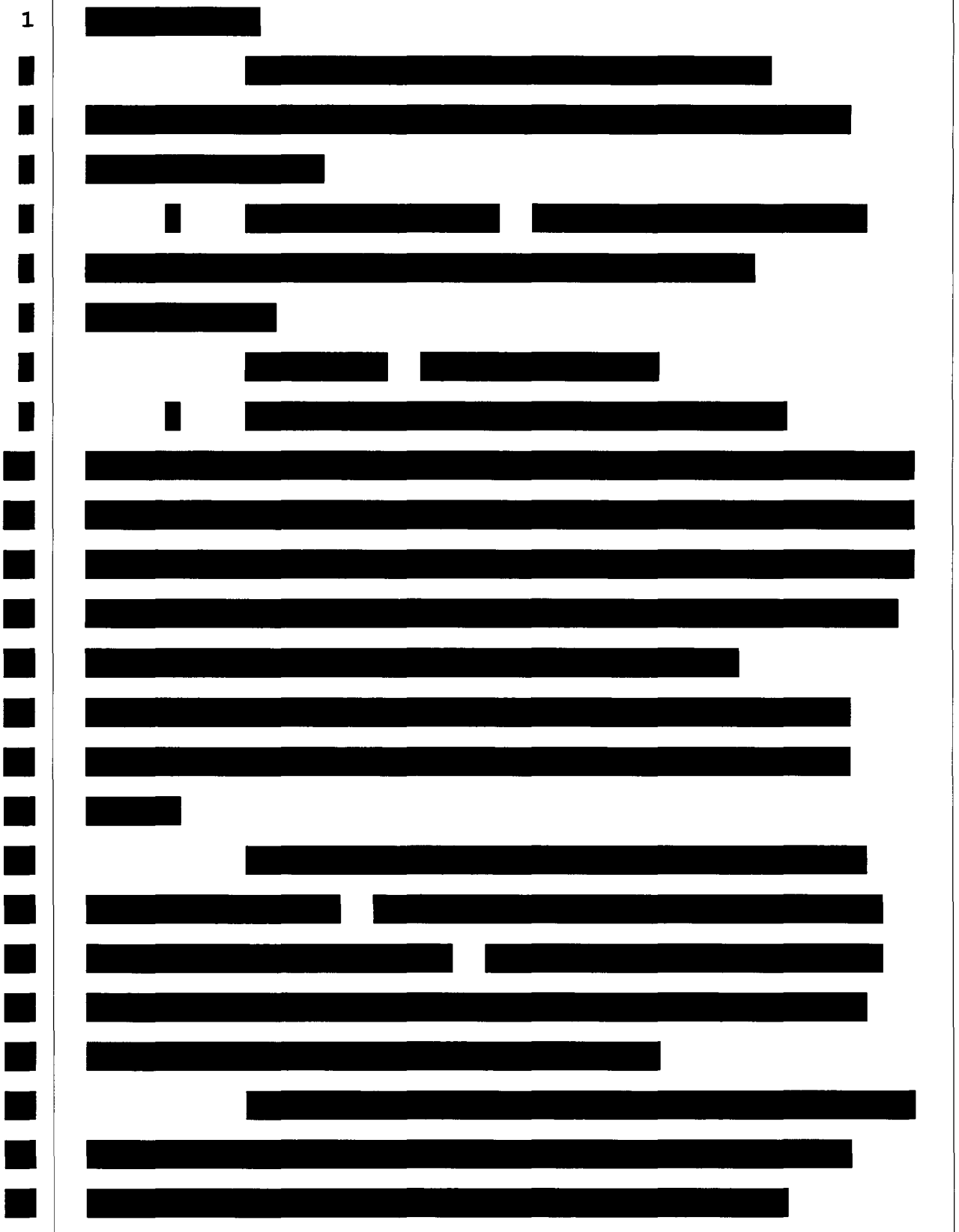
Do you want to show him the letter that you're reading from or quoting from?

A I don't remember exactly what they wrote in the letter.

[redacted]







[redacted]

Q (BY MR. LIFLAND) So since the beginning of this case -- hold on. Since the beginning of this case --

MR. LIFLAND: Let's take a five minute break.

VIDEOGRAPHER: We're off the record at 3:34 p.m.

(Break taken from 3:34 p.m. to 3:59 p.m.)

VIDEOGRAPHER: We're back on the record at 3:59 p.m.

Q (BY MR. LIFLAND) Doctor, you agreed that

chronic pain can have a substantial negative impact on a person's life?

A Yes.

Q It can interfere with the ability to work?

A Yes.

Q Cause someone to miss work?

A Chronic pain can result in missing work, yes.

Q Interfere with personal relationships?

A Yes.

Q Interfere with sexual relationships?

A Sure.

Q Lead to anxiety?

A That's a little harder to say, but it could lead to emotional distress.

Q It can lead to depression?

A Yes and vice versa. Depression can present as chronic pain.

Q And you understand that individuals with untreated chronic pain are at a higher risk for suicide?

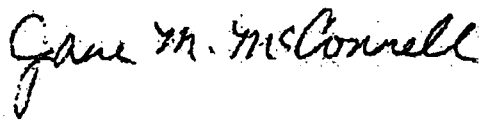
A I haven't seen evidence. I haven't seen a study with that statistic, but it could be true.

Q We hear from chronic pain patients that daily use of opioid medications improves their

C E R T I F I C A T E

I, Jane McConnell, Certified Shorthand Reporter, do hereby certify that the above-named ANDREW KOLODNY, M.D., was by me first duly sworn to testify the truth, the whole truth, and nothing but the truth, in the case aforesaid; that the above and foregoing deposition was by me taken in shorthand and thereafter transcribed; and that I am not an attorney for nor relative of any of said parties or otherwise interested in the event of said action.

IN WITNESS WHEREOF, I have hereunto set my hand and official seal this 29th day of March, 2019.



Jane McConnell, CSR RPR RMR CRR