



STATE OF OKLAHOMA } S.S.
CLEVELAND COUNTY }

IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

FILED

MAY 20 2019

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

Plaintiff,

v.

PURDUE PHARMA L.P., *et al.*,

Defendants.

In the office of the
Court Clerk MARILYN WILLIAMS

Case No. CJ-2017-816

Judge Thad Balkman

William C. Hetherington
Special Discovery Master

DEFENDANTS JANSSEN PHARMACEUTICALS, INC.
AND JOHNSON & JOHNSON'S SUPPLEMENTAL MOTION
TO EXCLUDE THE TESTIMONY OF
DR. JAMES GIBSON AND BRIEF IN SUPPORT

REDACTED VERSION

THIS DOCUMENT WAS FILED IN ITS ENTIRETY MAY 13, 2019,
UNDER SEAL
PER COURT ORDER DATED APRIL 16, 2018

Defendants Janssen Pharmaceuticals, Inc. (“Janssen”)¹ and Johnson & Johnson (“J&J”) (collectively, “Defendants”) move this Court for an order excluding the testimony of the State’s purported expert witness, Dr. James Gibson, pursuant to 12 O.S. §§ 2702–2705. The Court should bar Gibson’s testimony and disclosures concerning his erroneous statistical estimates of medically unnecessary opioid prescriptions reimbursed by Oklahoma Medicaid. Dr. Gibson’s biased methodology is fundamentally flawed and, therefore, unreliable. Defendants thus respectfully request that their Supplemental Motion to Exclude be granted, and for such other relief as the Court deems just and proper.

BRIEF IN SUPPORT

In support of this Motion, the Defendants show the following:

I. INTRODUCTION

The entire point of statistical sampling is to draw inferences about a larger population from a smaller sample. For those inferences to be reliable, however, the sample must be randomized and representative of the larger population. The State hopes to offer Dr. James Gibson to testify about his sampling of Medicaid data to calculate the number of allegedly unnecessary opioid prescriptions, as determined by Dr. Jason Beaman, written between 1996 and 2017. But Dr. Gibson’s sample is neither random nor representative because it ignores more than half the population it purports to represent.

Although his sample consists entirely of post-2008 data, Gibson simply assumes that there was the same rate of “medically unnecessary” opioid prescriptions between 1996 and 2007. He

¹ “Janssen” also refers to Janssen Pharmaceuticals, Inc.’s predecessors, Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc.

makes that assumption without accounting for relevant variables, such as changes in prescription marketing practices, the emergence of new opioid products, and legal and regulatory developments. And he makes that assumption even though every other variable he analyzed shifted dramatically between those two time periods. Indeed, Gibson himself opines that the opioid epidemic had not begun to manifest in Oklahoma until [REDACTED] and did not [REDACTED]. By projecting 2008-2017 levels backwards to 1996-2007, Gibson's calculation almost certainly inflated the total number of allegedly unnecessary opioid prescriptions. This design choice was not incidental; it was a results-driven decision calculated to inflate the State's recovery back when it was still seeking damages and civil penalties for allegedly unnecessary prescriptions. Although the State has abandoned those theories, Gibson's calculations remain fatally tainted as a result.

Beyond the flawed design, this Court should exclude Gibson's calculation on relevance grounds. Having sought only to estimate statutory penalties for Medicaid fraud, Gibson's medical necessity calculation has been mooted by the State's dismissal of all fraud claims. The calculation no longer has any bearing on any fact of consequence, including the amorphous and inapposite question of the opioid crisis's "severity."

Because his methodology is unsound and his calculation has nothing to do with whether any defendant created a public nuisance in Oklahoma, this Court should exclude Dr. Gibson's "medical necessity" calculation.

II. LEGAL STANDARD²

The Court has an obligation to “prevent improper testimony from an expert witness.” *Christian*, 2003 OK 10, ¶¶7, 9, 65 P.3d at 598. Thus, the Court may admit expert testimony only if it satisfies several prerequisites. *See, e.g., Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999); *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 595 (1993); *Twyman v. GHK Corp.*, 2004 OK CIV APP 53, ¶¶21–28, 93 P.3d 51, 56–58. First, expert 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.” 12 O.S. § 2702; *see also Nelson*, 2016 OK 69, ¶13, 376 P.3d at 217. Thus, an expert’s conclusions must “rest[] on a reliable foundation.” *Daubert*, 509 U.S. at 597.

On the other hand, opinions based on speculative assumptions or unsupported by reliable data are inadmissible. *See, e.g., Guidroz-Brault v. Mo. Pac. R.R. Co.*, 254 F.3d 825, 829 (9th Cir. 2001) (expert may not rely upon “unsupported speculation and subjective beliefs” (citing *Daubert*, 509 U.S. at 590–91)). The Court thus must closely inspect the means by which 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); *see also Shank v. Whiting-Turner Contracting Co.*, 2018 WL 6681223, at *2 (N.D. Okla. Dec. 19, 2018) (“analytical gap” in expert’s testimony requires exclusion under *Daubert*).

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 cases on the subject are instructive. *See, e.g., Nelson v. Enid Med. Assocs., Inc.*, 2016 OK 69, ¶¶10–62, 376 P.3d 212, 215–231; *Christian v. Gray*, 2003 OK 10, ¶¶6, 8–11, 65 P.3d 591, 597–99.

Second, expert testimony is admissible only if it is relevant—that is, it must “assist the trier of fact to understand the evidence or to determine a fact in issue.” 12 O.S. § 2702. The party offering the expert testimony—here, the State—has the burden of showing, by a preponderance of the evidence, that the testimony meets these preconditions. *Christian*, 2003 OK 10, ¶23, 65 P.3d at 603. Under these basic evidentiary principles, Gibson’s outcome-driven methodology for calculating allegedly medically unnecessary prescriptions, and the irrelevant calculation it yielded, are inadmissible and this Court should exclude them accordingly.

III. ARGUMENT

A. Gibson’s Medical Necessity Calculation Should Be Excluded Because It Is Not Reliable

The Court should bar Dr. Gibson’s calculation because it is not “based upon sufficient facts or data” and is not “the product of reliable principles and methods.” *See* 12 O.S. § 2702. Rather, his biased calculation is the product of outcome-oriented design choices and unwarranted assumptions.

1. *Gibson’s Exclusive Reliance on Post-2008 Data Violates Basic Statistical Principles*

First, Gibson’s methodology violates fundamental statistical norms because his sample was neither “randomly selected” nor “representative of the whole.” *United States v. Pena*, 532 F. App’x 517, 520 (5th Cir. 2013) (citing *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1019–20 (5th Cir. 1997)).³ A sample must have both characteristics “to fairly and reliably” support inferences

³ *See also* MANUAL FOR COMPLEX LITIGATION (FOURTH) § 11.493, at 102 (2015) (When “sampling to generate data about a population so the data will be verified or declared true,” “the reliability and validity of estimates about the population derived from sampling are critical.”)

about a larger population. *Id.*; see also *United Parcel Serv., Inc. v. U.S. Postal Serv.*, 184 F.3d 827, 840 n.14 (D.C. Cir. 1999) (“[R]esults [are] undermined if the sample is not representative of the population it purports to represent or is not selected in a sufficiently random manner.”). Yet, of the 9 million opioid prescriptions submitted to Oklahoma Medicaid from 1996 through 2017, Gibson’s sample of allegedly medically unnecessary claims consists *entirely* of claims submitted post-June 2008. Ex. A, Mar. 11–12, 2019 Deposition of James Gibson, Ph.D. (“Gibson Dep.”) 150:2–9, 233:25–234:8 [REDACTED]

[REDACTED] see also Ex. B, Supplemental Disclosures of James Gibson (“Gibson Disc.”) Ex. G-1 at 48–49, n.63.

Nothing required Gibson to rely exclusively on post-2008 data. Although Gibson justified this choice by noting that physicians’ identifications numbers changed in June 2008, *id.* at 156:23–157:18, he concedes that he could have used the physicians’ names to identify them in each data set, *id.* at 158:15–22 [REDACTED]

[REDACTED] He simply did not attempt to collect any medical records from January 1, 1996 to May 31, 2008, speculating that older records would be too difficult to procure and the response rate too low. *Id.* at 281:23–282:15, 283:9–19, 287:2–288:5 [REDACTED]

[REDACTED]

Because not one prescription in Gibson’s sample originated between January 1996 and June 2008—i.e., the entire first half of his data window, *see supra*, Gibson can establish neither that his sample was “randomly selected,” nor that it is “representative of the whole” population of

Medicaid prescriptions. *See e.g., Pena*, 532 F. App'x at 520. Simply put, Gibson cannot draw estimates for a 22-year period when he does not have one piece of data—not one prescription—from the period's first twelve years. This Court should reject his calculation and associated testimony, and exclude it from trial. *See, e.g., United States ex rel. Wall v. Vista Hospice Care, Inc.*, 2016 WL 3449833, at *14 (N.D. Tex. June 20, 2016) (excluding expert's testimony on number of fraudulent claims because, *inter alia*, the sample was not randomly selected from the whole population); *United States ex rel. Trim v. McKean*, 31 F. Supp. 2d 1308, 1314 (W.D. Okla. 1998) (refusing to extrapolate proposed statistical sample that failed to accurately represent the entire universe of claims); *Ellis v. Costco Wholesale Corp.*, 240 F.R.D. 627, 648 (N.D. Cal. 2007) (striking portion of expert declaration where expert failed to incorporate data for half of a year into his regression analysis), *vacated in part on other grounds*, 657 F.3d 970 (9th Cir. 2011); *cf. Wallace v. Countrywide Home Loans Inc.*, 2012 WL 11896333, at *4 (C.D. Cal. Aug. 31, 2012) (“A survey that begins with a random sample, but does not take measures to assure that nonresponses are random and provide analysis of the reasons of nonresponse, is not the product of reliable principles and methods.” (internal quotations and citation omitted)).

But there is more: The sample also fails to fairly depict the population it purports to represent because Gibson ignored important variables likely to skew his data, such as age, disease type, and geographic location. Ex. A, Gibson Dep. 186:18–188:2, 291:22–292:1. By failing to observe such variables, determine their frequencies and distributions, and control for any represented disproportionately, Gibson has further undermined any contention that the sample is representative. *See, e.g., Wall*, 2016 WL 3449833, at *13. For example, a representative sample of prescription opioid claims in Oklahoma from 1996 to 2017 would not disproportionately

represent younger patients (who are less likely to require cancer treatment)⁴ or rural regions like northwest Oklahoma (where industries with high incidences of physical injury dominate the labor market).⁵ Gibson concedes that samples are not representative unless such variables are uniformly distributed. Ex. A, Gibson Dep. 189:12–15 [REDACTED]

[REDACTED]. And he certainly *could* have controlled for these variables, as statisticians routinely do. *See, e.g., United States ex rel. Martin v. Life Care Centers of Am., Inc.*, 2014 WL 4816006, at *5–11 (E.D. Tenn. Sept. 29, 2014) (expert performed pre-sampling design tasks to determine “frequencies and distributions of certain variables” in order to identify variables that needed to be controlled). But Gibson did not so much as consider doing so. Ex. A, Gibson Dep. at 187:20–188:2. Gibson’s failure to control for relevant variables in the sample additionally warrants its exclusion. *See Wall*, 2016 WL 3449833, at *14.

2. *Gibson’s Assumption that Rates Did Not Change Over Time Is Illogical and Unsound*

Gibson’s use of post-2008 data to calculate a rate for the period between 1996 and 2007, *see supra*, rests on a transparently unsound assumption rendering his calculation of medically unnecessary prescriptions unreliable. Gibson simply assumes that the rate of allegedly unjustified prescriptions was the same between 1996 and 2007 as it was between 2008 and 2017.⁶ *See* Ex. B,

⁴ *See, e.g.,* Mary C. White et al., *Age and Cancer Risk: A Potentially Modifiable Relationship*, 46 AM. J. PREV. MED. 3(1), S7–15, (Mar. 2014) (“Cancer can be considered an age-related disease because the incidence of most cancers increases with age . . .”).

⁵ *See* OKLA. DEP’T OF COMMERCE, RESEARCH & ECONOMIC ANALYSIS DIV., GOVERNOR’S COUNCIL FOR WORKFORCE AND ECONOMIC DEV., NW. WORKFORCE INVESTMENT AREAS (2006), http://www.oesc.state.ok.us/lmi/employer/Regional%20Employment%20Analysis/Northwest_Regional_Layout.pdf.

⁶ Even Gibson acknowledged [REDACTED] that his assumption [REDACTED] [REDACTED] Ex. B, Gibson Disc. Ex. G-1 at 48–49, n.63. And in attempting to justify his

Gibson Disc. Ex. G-1 at 49 [REDACTED]

[REDACTED]. He makes this assumption despite strong reasons to suspect that earlier rates of medically unnecessary prescriptions would be much lower than in the period he actually examined: Gibson himself believed that Oklahoma's opioid crisis [REDACTED]

[REDACTED] Ex. B, Gibson Disc. Ex. G-1 at 42, [REDACTED]

[REDACTED] *see id.*, at 9, [REDACTED]

[REDACTED] *see id.*, at 3; *see also id.* at 4 [REDACTED]

[REDACTED] Yet, even while recognizing that every other variable was in flux, Gibson chose to assume that the rate of medically unnecessary prescriptions remained completely unchanged over a twenty-two year period. That assumption, which served only to inflate the State's attempted recovery and paper over Gibson's failure to consider pre-2007 data, renders Gibson's analysis unreliable.

"[E]xpert testimony based on assumptions lacking factual foundation in the record is properly excluded." *Meadows v. Anchor Longwall & Rebuild, Inc.*, 306 F. App'x 781, 790 (3d

design choice, Gibson notes that the distribution of prescription dosages and durations are comparable between 1996-2007 and 2008-2017. *See id.*; Ex. A, Gibson Dep. 264:1-9. He assumes that if these variables are equally represented across periods, so, too, is the proportion of medically unnecessary claims. Ex. A, Gibson Dep. 291:7-11 [REDACTED]

[REDACTED] Yet, Gibson supplies no basis for this assumption. Not to mention, Gibson cannot even get his story straight on whether the periods' varied to a statistical significant degree. *Compare id.* at 259:2-5 [REDACTED]

[REDACTED] *with Ex. B, Gibson Disc. Ex. G-1 at 48-49, n.63* [REDACTED]

Cir. 2009). Here, Gibson’s calculations are premised on unfounded assumptions—assumptions that have slanted the results in the State’s favor. Even if other components of Gibson’s design were sound, “any step that renders the analysis unreliable under the *Daubert* factors renders the expert’s testimony inadmissible.” *McClain v. Metabolife Int’l, Inc.*, 401 F.3d 1233, 1245 (11th Cir. 2005) (emphasis omitted).

Gibson could have simply looked at the complete set of data available to him and collect the relevant medical records, which would have included pre-2007 prescriptions. Failing that, he could have at least accounted for variables likely to differentiate the two time periods. *See, e.g., Martin*, 2014 WL 4816006, at *5–11. But aside from prescription dosage and duration, Gibson failed to consider *any* variables that might distinguish the datasets. Ex. A, Gibson Dep. 291:22–292:1 [REDACTED]

[REDACTED]. In neither period did he measure or control for changes in manufacturers’ marketing behaviors, the release of new opioid products, differences in product labeling, physicians’ prescribing behaviors, differing regulations, or any other variable likely to influence the number of medically unnecessary claims across time periods. *Id.* at 289:23–294:18.

Where, like here, a purported expert’s testimony is not “based upon a reliable method,” and his conclusions are not “analytically appropriate to that method,” the evidence should not be admitted. *See Christian*, 2003 OK 10, ¶36–38, 65 P.3d at 607. It is hard to imagine a less reliable statistical method than ignoring data covering half the relevant time period and then assuming data from the other half will do the trick. Because Gibson’s calculation is based neither “upon sufficient

facts or data” nor “reliable principles and methods,” this Court should exclude his analysis and all corresponding testimony. *See* 12 O.S. § 2702.

B. The Court Should Exclude Gibson’s Medical Necessity Calculation Because It Is Not Relevant

Gibson’s calculation, which he concedes was performed for the sole purpose of estimating penalties under the Oklahoma Medicaid False Claims Act, Ex. A, Gibson Dep. 146:25–147:1, 245:2–10, is also inadmissible because it has no bearing on any fact of consequence. Expert opinions are admissible only where they “assist the trier of fact to understand the evidence or to determine a fact in issue.” 12 O.S. § 2702. Gibson’s analysis does neither. It has nothing to do with Defendants’ conduct or products. *See* Ex. A, Gibson Dep. 244:5–245:1, 305:7–306:25 [REDACTED]. Simply put, the calculation is not relevant to the only question before this Court—whether any defendant created a public nuisance in Oklahoma. *See* 50 O.S. §§ 1, 2. Having pertained only to the State’s Medicaid fraud claims, Gibson’s calculation is now moot. *See* State’s Ntc. of Vol. Dismissal of Certain Claims (Apr. 4, 2019). Indeed, the State conceded this much—on the same day it dismissed those other claims, it vowed the sample was [REDACTED] such that the dismissal of its fraud claims meant [REDACTED]. *See* Ex. C, Apr. 4, 2019 Hearing Tr. at 13:19–14:9.

In its Opposition to Defendants’ initial motion to exclude Gibson’s testimony, the State, for the first time, suggested that this calculation is relevant to the “severity” of the opioid epidemic in Oklahoma. *See* State’s Opp. to Def.’s Mot. to Exclude Gibson at 37. But all Gibson’s sample estimates is how many of the prescriptions that Oklahoma Medicaid reimbursed between 1996 and 2017 did not meet Dr. Beaman’s medical necessity criteria. That backward-looking calculation


says nothing about the severity of the State's alleged injuries today, or as they will evolve over the thirty-year period covered by its proposed abatement plan.

To the extent the State believes it bears the burden of establishing the epidemic's severity, Defendants anticipate the State will present evidence on mortality rates, admissions to substance treatment for prescription opioid abuse, and so forth. But the estimated number of "medically unnecessary" opioid prescriptions years or even decades ago, as determined by a flawed and biased calculation, does not speak to that issue, and is not relevant to the State's request for prospective equitable relief.

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 any testimony by Gibson relating to his calculation of alleged medically unnecessary opioid prescriptions.

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 May 13, 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

[FILED UNDER SEAL]

EXHIBIT B

[FILED UNDER SEAL]

EXHIBIT C

[FILED UNDER SEAL]