



IN THE DISTRICT COURT OF CLEVELAND COUNTY  
STATE OF OKLAHOMA

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

Plaintiff,

v.

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

Defendants.

Case No. CJ-2017-816

Judge Thad Balkman

STATE OF OKLAHOMA } S.S.  
CLEVELAND COUNTY }

**FILED**

**JUL 17 2019**

In the office of the  
Court Clerk MARILYN WILLIAMS

CONFIDENTIAL  
FILED UNDER SEAL  
PURSUANT TO  
PROTECTIVE ORDER  
DATED APRIL 16, 2018

DEFENDANTS JANSSEN PHARMACEUTICALS, INC. AND JOHNSON AND  
JOHNSON'S OFFER OF PROOF FOR EVIDENCE RELATED TO NONPUBLIC  
ARCOS DATA IN THE EXAMINATION OF DR. LAURENTIUS MARAIS

**REDACTED VERSION**

THIS DOCUMENT WAS FILED IN ITS ENTIRETY JULY 12, 2019,  
UNDER SEAL PER COURT ORDER DATED APRIL 16, 2018

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ARCOS DATA IN THE EXAMINATION OF DR. LAURENTIUS MARAIS**

Janssen<sup>1</sup> hereby submits an offer of proof in response to the Court's exclusion of certain evidence and testimony during the examination of Dr. M. Laurentius Marais, Ph.D. The excluded evidence and testimony concerned an analysis performed by Dr. Marais of nonpublic data from the Drug Enforcement Administration's ("DEA") Automation of Reports and Consolidated Orders System ("ARCOS"). The Court expressly permitted Janssen to submit a written offer of proof.<sup>2</sup>

1. ARCOS is an automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at retail level dispensing facilities (such as

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<sup>1</sup> "Janssen" is Janssen Pharmaceuticals, Inc. and Johnson & Johnson, as well as Janssen's predecessors, Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc.

<sup>2</sup> July 10, 2019 Tr. 25:7-12.

hospitals and pharmacies).<sup>3</sup> ARCOS tracks all Schedule II and III narcotics and selected Schedule III and IV drugs.<sup>4</sup> The DEA reports certain ARCOS data publicly. However, as Dr. Marais explained during his July 11, 2019 examination, the public ARCOS data reports only the aggregate shipment of controlled substance compounds (e.g., all shipments of oxycodone or fentanyl) to specified states and other localities. It does not permit an analysis of any particular drug's share of the overall market. The nonpublic ARCOS data that Janssen sought to introduce with Dr. Marais is not aggregated, and permits an analysis of shipments of controlled substances by drug and drug manufacturer based on National Drug Code ("NDC") labeler and product codes.

The nonpublic ARCOS data was produced in federal multi-district litigation related to prescription opioids pursuant to a protective order that initially prohibited its use in other litigation. On April 12, 2019, the MDL court amended the protective order to allow limited disclosure, including to state attorneys general that agreed to be bound by the MDL protective order. Accordingly, Janssen provided the State with notice of its intent to introduce the analysis by listing the nonpublic ARCOS data on its amended exhibit list along with an exhibit identified as Dr. Marais's analysis of that data. Janssen also specifically identified the nonpublic ARCOS data and Dr. Marais's analysis of that data in the cover email transmitting the amended exhibit list to the State's counsel and offered to assist the State in accessing the data, if necessary.

On July 1, the State informed Defendants that the Attorney General had not elected to access the data. The same day, Janssen provided written notice to the State, the DEA, and all parties in the opioids multi-district litigation in the U.S. District Court for the Northern District of

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<sup>3</sup> See Automation of Reports and Consolidated Orders System (ARCOS), U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Division, *available at* <https://www.deadiversion.usdoj.gov/arcos/index.html> (last accessed: July 11, 2019).

<sup>4</sup> *Id.*

Ohio of its intent to produce nonpublic ARCOS data to the State in this case. No party objected by the time specified in the written notice. On July 4, Janssen then electronically produced the data to the State, which refused to access the data.

On July 10, 2019, the Court sustained the State's objection to Janssen's presentation of Dr. Marais's ARCOS analysis.

2. Had the Court overruled the State's objection, Janssen would have introduced Dr. Marais's analysis of the nonpublic ARCOS data, as reported in Trial Exhibit J3767, attached hereto as Exhibit A, and elicited testimony from Dr. Marais concerning that analysis. The analysis reports the percentage share of certain Janssen prescription opioids—specifically, Duragesic, Nucynta, Nucynta ER—in both morphine milligram equivalents (“MME”) and prescription-equivalents. Both measured were calculated by Dr. Marais using statistical methods for analyzing large databases.

3. The ARCOS market share analysis is relevant to rebut the State's criticism of Janssen's market share evidence based on Medicaid, HealthChoice, and BlueCross BlueShield data produced by the State. At trial, the State has repeatedly argued those data sets do not accurately reflect Janssen's market share in Oklahoma, purportedly because they only account for a portion of the total market.<sup>5</sup> The nonpublic ARCOS data analyzed by Dr. Marais—which the

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<sup>5</sup> See, e.g., June 3, 2019 (AM) Trial Tr. (Deem-Eshleman) at 36:18-37:1 (Questioning by the State: “Do you see there where in the drug company's opening statement they said that there was a small share of state-paid medicated opioid prescriptions and tried to show it was less than one percent? ... You understand that the state-paid or SoonerCare part of prescriptions in the State is a very low percentage of the overall paying sources?”); June 26, 2019 (PM) (White) at 98:18-99:6 (“Medicaid does not cover the entire population in the State of Oklahoma. And in fact, when you look at the actual data about sales of opioid products in the State of Oklahoma, certainly less than 30 percent and -- I actually think it's less than 20 percent. But certainly less than 30 percent of opioid sales in Oklahoma were paid for by Medicaid. The vast majority were paid for by other sources. This is just a sliver of the problem.”); July 8, 2019 (AM) Trial Tr. (Beckworth Arg.) at 68:12-22 (“What they've shown and will continue to show about market

State refused to access—would have allowed Janssen to demonstrate its share of the entire market in Oklahoma.

Janssen maintains that Dr. Marais's calculation of its share of Medicaid, HealthChoice, and BlueCross BlueShield prescriptions is a reasonable basis for apportionment. *See, e.g., Waller ex rel. Estate of Hunt v. Danville, VA*, 556 F.3d 171, 175 (4th Cir. 2009) (“Reasonableness in law is generally assessed in light of the totality of the circumstances.”). The State, however, contends otherwise. Dr. Marais's analysis of the nonpublic ARCOS data would have obviated the State's suggestion that the data sources Janssen used to calculate market share are not sufficiently representative.

Dated: July 12, 2019

Respectfully submitted,

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share is based on ... state payments, which is a very tiny fraction. They know that. ... The government payment accounts for about 15 percent of all prescriptions. What about their market share for third party in cash? ... You know, they don't like to talk about it. They just ignore it.”); *see also* June 26, 2019 (PM) Trial Tr. (White) at 26:16-27:18 (characterizing Medicaid as “only a sliver of the opioids sold in the State of Oklahoma”).

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**CERTIFICATE OF MAILING**

Pursuant to OKLA. STAT. tit. 12, § 2005(D), this is to certify on July 12, 2019, a true and correct copy of the above has been served via email to counsel. At the request of counsel for Plaintiffs, a copy of Exhibit A is not included as part of this service.

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**EXHIBIT A**

**REDACTED**

**Shares of Opioid Prescription-Equivalents Shipped to Dispensers in Oklahoma**  
**ARCOS, January 2006-2012**

Period	All Opioids Excluding Buprenorphine and Methadone				Janssen Duragesic				Janssen Nucynta and Nucynta ER				Janssen Duragesic, Nucynta, and Nucynta ER			
	Prescription-Equivalents		Percent		Prescription-Equivalents		Percent		Prescription-Equivalents		Percent		Prescription-Equivalents		Percent	
2006	3,865,791	100%			18,028	0.47%							18,028	0.47%		
2007	3,938,722	100%			14,587	0.37%							14,587	0.37%		
2008	3,943,068	100%			12,958	0.33%							12,958	0.33%		
2009	4,240,723	100%			11,839	0.28%			4,537	0.11%			16,376	0.39%		
2010	3,948,052	100%			15,078	0.38%			6,853	0.17%			21,931	0.56%		
2011	3,801,681	100%			10,895	0.29%			8,580	0.23%			19,475	0.51%		
2012	3,783,429	100%			13,605	0.36%			10,751	0.28%			24,356	0.64%		

**Shares of Opioid MME Shipped to Dispensers in Oklahoma**  
**ARCOS, January 2006-2012**

Period	All Opioids Excluding Buprenorphine and Methadone				Janssen Duragesic				Janssen Nucynta and Nucynta ER				Janssen Duragesic, Nucynta, and Nucynta ER			
	MME		Percent		MME		Percent		MME		Percent		MME		Percent	
2006	3,106,611,596	100%			86,645,800	2.79%							86,645,800	2.79%		
2007	3,421,165,326	100%			69,040,611	2.02%							69,040,486	2.02%		
2008	3,721,354,785	100%			60,855,262	1.64%							60,855,262	1.64%		
2009	3,872,894,921	100%			55,102,585	1.42%			8,773,290	0.23%			63,850,835	1.65%		
2010	4,003,527,432	100%			68,850,853	1.72%			15,707,440	0.39%			84,675,793	2.12%		
2011	3,958,766,312	100%			50,159,040	1.27%			19,037,128	0.48%			69,133,493	1.75%		
2012	4,102,848,703	100%			62,217,457	1.52%			27,256,059	0.66%			89,473,516	2.18%		

**Notes:**

- "Prescription-Equivalents" based on SoonerCare, BCBS, HealthChoice data ( $\Sigma$ MME/ $\Sigma$ Rx by drug).

**Sources:**

- Oklahoma ARCOS files: confidential\_arcos\_20060101-20120101\_all\_exclude\_6states\_20060101-20120101.txt, confidential\_arcos\_20060101-20120101\_all\_states\_20060101-20120101.txt, and confidential\_arcos\_20060101-20120101\_all\_states\_20060101-20120101.txt
- Oklahoma BCBS files: BCBSOK00000001.xlsx - BCBSOK000000024.xlsx
- Oklahoma HealthChoice file: EGID-00000141.txt
- Oklahoma SoonerCare file: OHCA-00000001.sav
- CDC MME conversion table: cdc\_mme\_table\_sept2018.sas7bdat (<https://www.cdc.gov/drugoverdose/resources/data.html>)

**J 3767**