IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA,	§	
Plaintiff,	§	
vs.	§	Case No. CJ-2017-816
	§	The Honorable Thad Balkman
(1) PURDUE PHARMA L.P.;	§	
(2) PURDUE PHARMA, INC.;	§	
(3) THE PURDUE FREDERICK COMPANY;	§	***Motion Submitted to***:
(4) TEVA PHARMACEUTICALS USA, INC.;	§	***The Honorable Thad Balkman***
(5) CEPHALON, INC.;	§	
(6) JOHNSON & JOHNSON;	§	
(7) JANSSEN PHARMACEUTICALS, INC.;	§	
(8) ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.;	§	
(9) JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.;	§	
(10) ALLERGAN, PLC, f/k/a ACTAVIS PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.;	§	
(11) WATSON LABORATORIES, INC.;	§	
(12) ACTAVIS LLC; and	§	
(13) ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.,	§	
Defendants.	§	

STATE'S RESPONSE TO JANSSEN'S OBJECTION TO THE SPECIAL DISCOVERY MASTER'S ORDER ON DEFENDANT JANSSEN'S MOTION TO COMPEL RESPONSES TO ITS THIRD SET OF INTERROGATORIES

Janssen's Objection to the Special Discovery Master's Order is a delay tactic. It is one of many that Janssen has deployed in this case. And it is part of an overarching strategy that was laid bare before this Court on March 8. As the Court is aware, Defendants' arguments for continuance misrepresented the extent of discovery that the State has provided and the nature of the discovery

orders entered in this case. Janssen's arguments in the instant Objection do the same. The Court denied Janssen's delay effort on March 8, and it should deny this one as well.

The State's allegations have always been that Defendants' misinformation regarding the safety and efficacy of opioids misled the public, policy makers, and medical community. Indeed, the State provided this answer in response to Janssen's very first interrogatory:

> Based on the unprecedented scope of the misinformation campaign at issue in this litigation and given the fact that the totality of information that was available was conflated with the misleading, false, and deceptive information disseminated by Defendants and their co-conspirators, neither medical providers nor patients had the benefit of all material information regarding Defendants' drugs. As such, it was not possible for providers or patients to discern whether any prescription was medically necessary or to informatively consider the "medical necessity" criteria set forth in Oklahoma regulations and truthfully certify the accuracy of such determinations.

Ex. 1 (Plaintiff's Responses and Objections to Defendant Janssen Pharmaceuticals, Inc.'s First Set of Interrogatories, Resp. to Rog No. 1 (Feb. 14, 2018)). Despite having this answer for over a year, Janssen has never attempted to depose an Oklahoma doctor.

Of course, the interrogatories that Janssen now seeks to compel the State to answer are not really about understanding the State's allegations. They are about dictating the way the State seeks to prove its case. Janssen's interrogatories do not simply ask, as Janssen would have the Court believe, who the State contends was misled by Janssen's conduct. Rather, they attempt to force the State to prove individualized physician reliance on false and/or misleading promotion[1] and individualized doctor and patient interaction.[2] The Special Discovery Master and the Court have repeatedly and expressly prohibited this *exact* type of discovery:

[1] "Identify all Oklahoma Doctors who were misled, and for each, the specific Janssen Communication (s) that misled the Doctor." Interrogatory No. 20 (Ex. C to Janssen's Obj. at 5).
[2] "Identify all Oklahoma Doctors who were unable to accurately counsel their patients about the risks or benefits of prescription Opioid medications as a result of any Communication made, sponsored, or supported by Janssen." Interrogatory No. 21 (Ex. C to Janssen's Obj. at 5).

> As argued, ***State's proof approach does not require proof of individualized doctor and patient interaction as a global population of individualized proof of each physician's reliance on false and/or misleading promotion and marketing*** resulting in individual excessive or unnecessary prescriptions.
>
> ...
>
> The State of Oklahoma is the plaintiff, not individual patients. As such, it is not an individualized proof process which State argues to be unnecessary and in fact would likely result in an unreasonably lengthy and highly burdensome discovery process as Defendants have stated intentions to depose all patients with claims.

Order of Special Discovery Master (2018.10.10) (emphasis added), *affirmed* 2018.12.04.

> ***State is only compelled to admit or deny the requests made without identifying any doctors or patient personal information*** . . . As indicated in previous Orders, the allegations pled and proof model elected by State raise allegations that all Defendants misled all physicians in a joint marketing and promotion effort.

Order of Special Discovery Master (2019.02.14) (emphasis added).

Janssen first argued it was entitled to individualized discovery regarding doctors and patients in Defendants' Motion to Compel Discovery Regarding Claims Data filed on September 7, 2018. The basis for that Motion was the same as Janssen's current Objection: Defendants claimed they needed the identities of prescribers and patients in order to test the State's allegations. Def.'s Mtn. to Compel Claims Data at 1. The Special Discovery Master denied that Motion and the Court affirmed his Order.

The reasons why the State is not required to respond to this type of discovery are clear—and clearly set forth in the Court's prior Orders. First, Janssen's requests are unduly burdensome in violation of 12 O.S. § 3226(B)(1)(a). "In the context of this case, proportionality would prohibit individualized discovery as it would not be feasible to allow discovery into approximately 9 million claims, 950,000 patients and 42,000 doctor/prescribers contained in the State data bases." Order of Special Discovery Master (2018.10.10), *affirmed* 2018.12.04. Second, Janssen can fairly defend itself and "obtain evidence necessary to rebut the State's contentions" without forcing the

State to respond to impermissibly burdensome discovery requests: "Defendants' have a fair and proportional way to defend this case and can bring in their own experts, doctors/providers and patients as they choose to defend and test the State's theory." *Id.* Janssen's interrogatories are not permissible under the discovery statute and they are not necessary for Janssen to defend itself. The fact that Janssen has chosen not to pursue proper forms of discovery in this case is on Janssen. Janssen's improper interrogatories should be denied. Again.

While it is unclear whether Janssen's motion even encompasses Interrogatory No. 22,[3] which is not specifically addressed, that Interrogatory is likewise foreclosed by multiple prior orders of the Special Discovery Master and this Court. Interrogatory 22 requests identification of specific claims denied during State investigations and proceedings regarding doctor prescribing behaviors. Such information would reveal confidential and protected mental impressions regarding specific investigations and could have a chilling effect on the State's ability to effectively conduct investigations in the future. This cannot be permitted. As previously held, "[a]ny production of criminal investigatory files is likely going to place ongoing criminal prosecutions or disciplinary actions in jeopardy. Investigative notes, reports, witness interviews, interview notes, contact information or transcripts are work product and protected." Order of Special Discovery Master (2019.10.22).[4] Accordingly, the State is not required to identify "ongoing, past or present investigatory information or confidential investigative file content" such as individualized

[3] "Identify all Claims for reimbursement of Opioid prescriptions, if any, that were denied by You after they were written by a Doctor who was subject to a civil, criminal, or administrative proceeding or subject to investigation, the existence of which is public record or not privileged or confidential, for their Prescribing Behaviors." (Ex. E to Janssen's Obj.).

[4]This Court upheld Special Master Hetherington's Order with respect to production of investigative files but ordered the State to produce non-sealed pleadings and other documents filed with a tribunal, documents produced to the attorney for the defendant in those proceedings, and an *in camera* list of investigations—all of which the State has done. *See* Dec. 20, 2018 Order.

decisions to deny specific claims during those investigations and proceedings. Order of Special Discovery Master (2019.02.14). The Court should affirm that finding.

Janssen's Third Set of Interrogatories are improper under the Oklahoma Rules, and the Special Discovery Master and this Court have repeatedly denied discovery into the information they seek. The State respectfully requests that the Court do so once again and deny Janssen's Objection to the Special Discovery Master's Order.

DATED: March 11, 2019

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EXHIBIT

1

IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA,	§	
Plaintiff,	§	
vs.	§	
(1) PURDUE PHARMA L.P.; (2) PURDUE PHARMA, INC.; (3) THE PURDUE FREDERICK COMPANY; (4) TEVA PHARMACEUTICALS USA, INC.; (5) CEPHALON, INC.; (6) JOHNSON & JOHNSON; (7) JANSSEN PHARMACEUTICALS, INC.; (8) ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.; (9) JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.; (10) ALLERGAN, PLC, f/k/a ACTAVIS PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.; (11) WATSON LABORATORIES, INC.; (12) ACTAVIS LLC; and (13) ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.,	§	Case No. CJ-2017-816 The Honorable Thad Balkman JURY TRIAL DEMANDED
Defendants.	§	

PLAINTIFF'S RESPONSES AND OBJECTIONS TO DEFENDANT JANSSEN PHARMACEUTICALS, INC.'S FIRST SET OF INTERROGATORIES

Pursuant to 12 OKLA. STAT. §3233, Plaintiff, the State of Oklahoma (the "State" or "Plaintiff"), hereby submits its Responses and Objections to Defendant Janssen Pharmaceuticals, Inc.'s ("Defendant") First Set of Interrogatories to Plaintiff. The State specifically reserves the right to supplement, amend and/or revise these Responses and Objections in accordance with 12 OKLA. STAT. §3226.

GENERAL OBJECTIONS

1. By responding to Defendant's interrogatories, the State concedes neither the relevance nor admissibility of any information provided or documents or other materials produced in response to such requests. The production of information or documents or other materials in response to any specific interrogatory does not constitute an admission that such information is probative of any particular issue in this case. Such production or response means only that, subject to all conditions and objections set forth herein and following a reasonably diligent investigation of reasonably accessible and non-privileged information, the State believes the information provided is responsive to the request.

2. The State objects that much of the requests sought are premature and, as such, provides the responses set forth herein solely based upon information presently known to and within the possession, custody or control of the State. Discovery has only just begun in this action. Subsequent discovery, information produced by Defendant or the other named Defendants in this litigation, investigation, expert discovery, third-party discovery, depositions and further analysis may result in additions to, changes or modifications in, and/or variations from the responses and objections set forth herein. Accordingly, the State specifically and expressly reserves the right to supplement, amend and/or revise the responses and objections set forth herein in due course and in accordance with 12 OKLA. STAT. §3226.

3. The State objects to the inappropriate manner by which Defendants attempt or may attempt in the future to increase the number of interrogatories to which the State must respond, as Defendants have purported to serve separate interrogatories from subsidiaries and affiliates of related entities. The Oklahoma Code of Civil Procedure states, "[t]he number of interrogatories to a party shall not exceed thirty in number." 12 O.S. 3233(A). As such, absent an order to the

contrary modifying these limitations, each party to this litigation, including the State, is only required to respond to a sum total of 30 interrogatories, regardless of the number of parties purporting to serve such interrogatories. This is especially true, where here, the Defendants are defending this litigation and conducting discovery pursuant to a joint defense agreement and, as such, the State believes the Defendants coordinated to submit their discovery requests in a targeted manner to get around these discovery limitations when, because they are working in concert, the State should not be required to respond to more than a total of 30 separate Interrogatories. The State further objects to the compound nature of Defendant's Interrogatories and will appropriately construe any compound Interrogatories as consisting of separate Interrogatories that count towards the total of 30 interrogatories to which the State must respond. However, any response to a compound Interrogatory herein shall not constitute a waiver of the State's objection to the Interrogatories' compound nature or the State's right to refuse to respond to any Interrogatories that exceed the number of interrogatories to which the State must respond under Section 3233(A).

OBJECTIONS TO INSTRUCTIONS

1. The State objects to Defendant's Instruction Number 1 as vague, ambiguous, overly broad, disproportionate to the needs of the case, seeking to impose a burden on the State that exceeds what is permissible under Oklahoma law, seeking information protected from disclosure by privilege and/or the work product doctrine, and calling for information that is not in the possession, custody or control of and is not reasonably accessible to the State. To the extent the State can and does provide a response to any interrogatory, the State's response is based on the information known to and within the possession, custody and control of the State following a reasonably diligent investigation. The State further objects to Defendant's Instruction Number 1 to the extent that it attempts to require the State to describe or identify sources of information

outside the State's possession, custody or control. The State will object and/or respond to each interrogatory in accordance with 12 OKLA. STAT. §3233.

2. The State objects to Defendant's Instruction Number 2, which states that Defendant's requests are "continuing," as seeking to impose a burden upon the State that is beyond what is permissible under Oklahoma law. The State will respond to Defendant's interrogatories based on a reasonably diligent investigation of the information currently known to and within the possession, custody and control of the State, and the State will amend or supplement its responses, if necessary, in accordance with 12 OKLA. STAT. §3226.

3. The State objects to Defendant's Instruction Number 3 as ambiguous, vague, unreasonable, overbroad, unduly burdensome and an impermissible attempt to impose a burden upon the State beyond what is allowable under Oklahoma law. To the extent the State withholds otherwise discoverable information on the basis of any claim of privilege or work-product trial preparation material, the State will supply Defendant with the information required under Oklahoma law related to such information at the appropriate time and/or in accordance with the orders of the Court. *See* 12 OKLA. STAT. §3226(B)(5)(a). To the extent the State withholds any information for any other reasons, the State will comply with its obligations under Oklahoma law.

4. The State objects to Defendant's Instruction Number 5 because it seeks to impose a burden on the State beyond those permitted or contemplated under Oklahoma law. The State will respond to Defendant's requests according to how they are written. To the extent Defendant chose to use vague or indecipherable terms, the State will reasonably construe such term based upon their plain and ordinary meaning.

5. The State objects to Defendant's Instruction Number 6 because it seeks to impose a burden on the State beyond what is permitted under Oklahoma law. If the State answers an

interrogatory by reference to its business records, the State will do so in the manner permitted under 12 OKLA. STAT. §3233(C) and provide the information called for by that statute.

OBJECTIONS TO DEFINITIONS

1. The State objects to Defendant's Definition Number 1 of the term "claim" as vague, overbroad, ambiguous, unduly burdensome, disproportionate to the needs of the case, unreasonable, irrelevant and unworkable. "[A]ny request for payment or reimbursement" encompasses an infinitely unlimited amount of information that has no bearing whatsoever on the parties to this action or the claims or defenses asserted in this action. Based on the claims and defenses at issue in this case, the State will reasonably interpret the term "claim" to mean a request for payment or reimbursement submitted to the Oklahoma Health Care Authority pursuant to Oklahoma's Medicaid Program as related to the claims and defenses at issue in this litigation.

2. The State objects to Defendant's Definition Number 3 of the term "communication(s)" as vague, ambiguous, unduly burdensome, disproportionate to the needs of the case, unreasonable, unworkable and seeking to impose a burden upon the State beyond what is permissible under Oklahoma law. Specifically, the State objects to the terms "conduct" and "omissions" in Defendant's purported Definition Number 3. The State will reasonably interpret the term "communication(s)" to mean the transmittal of information between two or more persons, whether spoken or written.

3. The State objects to Defendant's Definition Number 7—Defendant's second purported definition of the term "document(s)"—as overly broad, unduly burdensome, disproportionate to the needs of the case, irrelevant and attempting to impose a burden on the State beyond what is permissible under Oklahoma law. The State will not create "instructions" or "other materials" that do not otherwise exist. Nor will the State produce: (i) "file-folder[s], labeled-

box[es], or notebook[s]"; and (ii) "ind[ices], table[s] of contents, list[s], or summaries that serve to organize, identify, or reference" a document simply because a responsive document is related to or contained within such information. Pursuant to 12 OKLA. STAT. §§3233-3234, following a reasonably diligent investigation, the State will permit inspection of the reasonably accessible, responsive, non-privileged documents, as that term is defined in 12 OKLA. STAT. §3234(A)(1), within the State's possession, custody or control that the State is reasonably able to locate at a time and place mutually agreeable to the parties. To the extent a folder, label, container, index, table of contents, list or summary is otherwise responsive to a request and satisfies these conditions, it will be made available for inspection or produced.

4. The State objects to Defendant's Definition Number 9 of "Electronically Stored Information" as overly broad, unduly burdensome, disproportionate to the needs of the case, irrelevant to the claims and defenses at issue, and seeking to impose a burden upon the State beyond what is permissible under Oklahoma law. The State will not produce ESI from sources that are not reasonably accessible or over which the State does not have sufficient custody and/or control. The State will produce or permit the inspection of ESI in the manner set forth in the State's Responses and Objections to Defendant's First Set of Requests for Production of Documents to Plaintiff.

5. The State objects to Defendant's Definition Number 10 of the term "employee" as overly broad, unduly burdensome, disproportionate to the needs of the case, irrelevant to the claims and defenses at issue, calling for information beyond what is within the State's possession, custody and control, and seeking to impose a burden upon the State beyond what is permissible under Oklahoma law. The State will reasonably construe the term "employee" to mean an individual employed by the State during the inquired-about time period over whom the State maintains

sufficient custody and control to enable the State to possess or access responsive records or information pertaining to the individual.

6. The State objects to Defendant's Definition Number 11 of the terms "Healthcare Professional(s)," "Health Care Provider(s)" or "HCP(s)." Defendant's proposed definition is overly broad, irrelevant to the claims and defenses at issue, unduly burdensome and disproportionate to the needs of the case in that the definition is not limited in any way to the State of Oklahoma or any particular time period. The State will reasonably construe the use of these terms to mean healthcare professionals or providers who provided medical or health care services in the State of Oklahoma to citizens—not "animals"—in the State of Oklahoma from January 1, 2007 to the date Defendant's requests were served. The State further incorporates each of its objections to Definition Numbers 13 (the term "Medical Assisted Treatment") and 21 (the term "Relevant Medication") as if fully set forth in this objection to Definition Number 11.

7. The State objects to Defendant's Definition Number 13 of the term "Medication Assisted Treatment." Defendant's purported definition is overly broad, unduly burdensome, irrelevant to the claims and defenses in this action, and disproportionate to the needs of this case, because it attempts to encompass treatment related to any "substance abuse disorder[]" and any effort to "prevent Opioid overdose." The State incorporates its objections to Defendant's Definition Number 16 of the term "Opioid(s)" as if fully set forth in this objection to Definition Number 13. The State will reasonably construe the term "Medication Assisted Treatment" to mean substance abuse treatment related to the claims and defenses at issue in this litigation.

8. The State objects to Defendant's Definition Number 15 of the terms "Oklahoma Agency" or "Oklahoma Agencies" as overly broad, unduly burdensome, irrelevant to the claims and defenses in this action, disproportionate to the needs of the case, and improperly calling for

information that is not in the possession, custody or control of the State. The State will reasonably construe the terms "Oklahoma Agency" or "Oklahoma Agencies" to mean agencies of the State of Oklahoma represented in this action and over whom the State of Oklahoma, through the Office of the Attorney General, maintains sufficient control to allow the State to have reasonable access to and possession of responsive information maintained by the agency.

9. The State objects to Defendant's Definition Number 16 of the term "Opioid(s)" as misleading because of its use of the terms "FDA-approved" and "pain-reducing" and because it is defined without regard to any of the pharmaceutical products or drugs at issue in this case. The State will reasonably construe the terms "Opioid(s)" to mean the opioid medications or drugs related to the claims and defenses at issue in this litigation.

10. The State objects to Defendant's Definition Number 17 of the term "Patient(s)." This definition—"any human being to whom an Opioid is prescribed or dispensed"—is overly broad, unduly burdensome, irrelevant to the claims and defenses at issue in this action and disproportionate to the needs of the case on its face because it lacks any geographical or temporal limitation that has any bearing on this case, and could be construed to seek information outside the State's possession, custody, or control. The State will reasonably construe the term "patient" to mean an individual who was prescribed an Opioid in the State of Oklahoma from January 1, 2007 through the date these requests were served.

11. The State objects to Defendant's Definition Number 19 of the term "Program" and incorporates its objections to Definition Numbers 15 ("Oklahoma Agency") and 16 ("Opioids") as if fully set forth herein. Defendant's purported definition of "Program" is similarly overly broad, irrelevant to the claims and defenses at issue in this action, unduly burdensome and disproportionate to the needs of the case, because it includes no temporal limitations and is entirely

untethered to the issues involved in this litigation. The State will reasonably construe the term "Program" to mean a program administered by the State of Oklahoma that reviews, authorizes, and/or determines the conditions for payment or reimbursement for the opioid medications or drugs and related treatment relevant to the claims and defenses at issue in this litigation and over which the State possesses control.

12. The State objects to Defendant's Definition Number 21 of the term "Relevant Medication(s)" as misleading to the extent it suggests each listed drug is relevant to the claims or defenses at issue in this action. Therefore, the State will reasonably construe the term "Relevant Medication(s)" to mean opioid medications or drugs related to the claims and defenses at issue in this litigation.

13. The State objects to Defendant's Definition Number 23 of the term "Vendor" as overly broad, unduly burdensome, disproportionate to the needs of the case, seeking to impose a burden upon the State that exceeds what is permitted under Oklahoma law, and calling for information that is not within the State's possession, custody or control. The State further incorporates its objections to and reasonable constructions of the terms defined in Definition Numbers 11 ("HCP") and 19 ("Program") as if fully set forth herein.

14. The State objects to Defendant's Definition Number 24 of the terms "You," "Your," "State," "Oklahoma," and "Plaintiff" as overly broad, unduly burdensome, disproportionate to the needs of the case, seeking to impose a burden upon the State that exceeds what is permitted under Oklahoma law, and calling for information that is not within the State's possession, custody or control because the definition attempts to require the State to not simply respond on its own behalf, but also on behalf of "all its departments, agencies, and instrumentalities" without regard for whether the State represents such entities in this litigation

and maintains sufficient control over such entities to enable the State to have reasonable access to or possession, custody or control of such entities' records. The State will respond on behalf of the State and those State agencies represented in this litigation and over which the State, through the Office of the Attorney General, maintains sufficient control to allow the State to have reasonable access to and possession of responsive information maintained by the agency.

RESPONSES AND OBJECTIONS TO INTERROGATORIES

INTERROGATORY NO. 1: Identify every Opioid prescription, whether manufactured by Defendants or not, that the State contends was false, fraudulent, or otherwise reimbursed in violation of the Oklahoma Medicaid False Claims Act, specifically identifying the HCP who recommended, drafted, wrote, administered, and/or dispensed each prescription.

RESPONSE TO INTERROGATORY NO. 1:

The State incorporates its general objections and objections to Defendant's instructions and definitions above, including the State's objections to Defendant's definitions of the terms "HCP," "State," and "Opioid," as if fully set forth herein.

The State further objects to this Interrogatory because it is a premature contention interrogatory that attempts to force the State to marshal all of its evidence, including expert evidence, before any meaningful discovery has taken place in this action. *See* 12 OKLA. STAT. §3233(B). To the extent the State can respond to this Interrogatory at this preliminary stage, the State will do so based on the information currently known to and within the possession, custody and control of the State following a reasonably diligent investigation and will supplement and/or amend its response in due course according to 12 OKLA. STAT. §3226. Moreover, because this Interrogatory implicates the identity of documents and materials at this preliminary stage of discovery while the State is reasonably collecting, gathering, investigating, reviewing and

searching for such responsive documents, the State will supplement and/or amend its response to this Interrogatory in accordance with 12 OKLA. STAT. §3226 and 12 OKLA. STAT. §3233(C). Further, the State will produce and disclose expert information called for by this Interrogatory in accordance with the scheduling Order entered by the Court.

The State further objects to this interrogatory as impermissibly compound because it indiscriminately groups multiple separate topics, subjects, questions and tasks under the guise of a single interrogatory. In reality, this Interrogatory is actually at least two (2) separate interrogatories improperly disguised as one. *See* 12 OKLA. STAT. §3233(A). The State will reasonably and conservatively construe the Interrogatory as requesting the State to: (i) identify every Opioid prescription that the State contends was false, fraudulent, or otherwise reimbursed in violation of the Oklahoma Medicaid False Claims Act; and (ii) identify the HCP who recommended, drafted, wrote, administered, and/or dispensed each prescription

Subject to and without waiving the foregoing objections (including those incorporated into this response), the State responds as follows:

The State's principal processes, practices and procedures for ensuring that claims for reimbursement are reimbursable and relate to medically necessary treatment are primarily based on the relationship between State-imposed safeguards, implemented through regulations, and the State's trust in and reliance upon certifying parties to be fully and accurately informed and capable of accurately assessing that claims submitted for reimbursement are for medically necessary services, treatments and prescriptions. This trust is predicated on the State's reasonable reliance on the presumption that any pharmaceutical marketing activity that takes place in the State, or otherwise reaches certifying parties and patients in the State, is lawful and truthfully characterizes the risks and efficacy of the marketed pharmaceuticals in a manner that does not unduly or

improperly influence or hinder the appropriate analysis of the medical necessity of prescribing any marketed pharmaceuticals.

Based on the unprecedented scope of the misinformation campaign at issue in this litigation and given the fact that the totality of information that was available was conflated with the misleading, false, and deceptive information disseminated by Defendants and their co-conspirators, neither medical providers nor patients had the benefit of all material information regarding Defendants' drugs. As such, it was not possible for providers or patients to discern whether any prescription was medically necessary or to informatively consider the "medical necessity" criteria set forth in Oklahoma regulations and certify the accuracy of such determinations. Defendants flooded the medical community with false and misleading information—and omitted material information—as part of a scheme and conspiracy designed to make the public believe that opioids were more effective and less addictive than they actually were. Without the benefit of all material information, and given the fact that the totality of information that was available was conflated with the misleading, false, and deceptive information disseminated by Defendants and their co-conspirators, it was not possible for providers or patients to discern whether any prescription was medically necessary.

The Medical Assistance Program ("Medicaid") is a cooperative program of the state and federal governments that provides medical assistance for the poor. *See* Title XIX of the Social Security Act of 1935, 42 U.S.C. §1396 *et seq.* While a state is not obligated to participate in a Medicaid program, if it chooses to participate, the state administers its Medicaid program, but it must operate its program in compliance with the federal Medicaid statues and regulations. *See id.* at §1396a. The State participates in Medicaid, and the Oklahoma Health Care Authority ("OHCA") administers the Oklahoma Medicaid Program ("SoonerCare"). The State further

provides prescription drug coverage under its SoonerCare program. *See* Okla. Admin. Code §317:30-5-72. Accordingly, under the federal Medicaid Act, the State is required to provide coverage for all drugs approved by the U.S. Food and Drug Administration ("FDA") that are offered by any manufacturer that enters into a basic rebate agreement in order to participate in Medicaid under the Medicaid rebate program. *See, e.g.*, 42 U.S.C. §1396r-8.

By regulation, the State cannot legally reimburse claims for reimbursement for treatment that is not medically necessary. *See, e.g.*, Okla. Admin. Code §317:30-3-1(d). However, for the Medicaid system to work and for Medicaid beneficiaries to receive the benefit of timely and efficient medical treatment and coverage, the State cannot review in real time each individual claim submitted for reimbursement to ensure the claim relates to treatment that was medically necessary. Medical providers seeking reimbursement from SoonerCare for medical services or prescriptions submit their claims for reimbursement to the OHCA in the form of Current Procedural Terminology ("CPT") codes—accepted numeric codes which indicate the treatment, medical decision-making, and services or prescriptions for which the provider seeks reimbursement.

Claims for reimbursement for covered prescriptions are submitted separately by the dispensing pharmacy, such that SoonerCare typically receives two claims for reimbursement related to a single patient visit: one from the medical provider for his or her services (which are identified by CPT codes and based on the medical providers' decision-making and analysis, including any relevant diagnoses identified by ICD-9/10 codes) and one from the pharmacy for any resulting prescription (which is not accompanied by the medical provider's records or any ICD-9/10 codes). Due to the real-time nature of pharmacy claims, the pharmacy claim is submitted days to weeks ahead of the medical claim. As a result, OHCA maintains separate claims databases

for (1) claims and reimbursement for medical providers' services and (2) claims and reimbursement for prescriptions.

The State's ability to audit medical providers' documentation and other information that forms the basis for any claim for reimbursement is limited to the retrospective ability to determine whether a claim submitted should have been reimbursed on the back-end of the Medicaid process. On the front-end, when a claim for reimbursement is submitted, the State must and does rely upon the certification of medical necessity, which certifies that the services, treatment, products or prescriptions for which reimbursement is sought were medically necessary with each claim for reimbursement. This in turn is based, at least in part, on the State's trust and reliance upon the reasonable presumption that the totality of information available to the certifying party is not deceptive, incomplete, false and/or misleading and is not the product of fraudulent marketing activity that obscured or mischaracterized the risks and efficacy of any marketed pharmaceuticals.

Therefore, in order to allow the Medicaid system to work correctly and enable Medicaid beneficiaries to receive timely and effective medical treatment, the State has defined the standards that must be considered in determining whether medical treatment is medically necessary and requires certification that each claim submitted for reimbursement is for medically necessary treatment. The State requires entry of a standard form Provider Agreement in order to be eligible for reimbursement from SoonerCare. *See* OKLA. ADMIN. CODE §317:30-3-2. Under this Provider Agreement, it is expressly certified with each claim for payment that, amongst other things, the services or products for which payment is billed by or on behalf of the provider were medically necessary, as the State, through OHCA, has defined that term. Essential to the proper functioning of SoonerCare is the reasonable presumption that any pharmaceutical marketing that may influence the certifying party's decision-making is proper and lawful and that such medical-

decision making was not unduly influenced or hindered by predatory, false, misleading, coercive, negligent or fraudulent marketing tactics, such as those at issue here.

The State has defined "[m]edical necessity" as an assessment and consideration of the following standards and conditions:

> **(1)** Services must be medical in nature and must be consistent with accepted health care practice standards and guidelines for the prevention, diagnosis or treatment of symptoms of illness, disease or disability;
> **(2)** Documentation submitted in order to request services or substantiate previously provided services must demonstrate through adequate objective medical records, evidence sufficient to justify the client's need for the service;
> **(3)** Treatment of the client's condition, disease or injury must be based on reasonable and predictable health outcomes;
> **(4)** Services must be necessary to alleviate a medical condition and must be required for reasons other than convenience for the client, family, or medical provider;
> **(5)** Services must be delivered in the most cost-effective manner and most appropriate setting; and
> **(6)** Services must be appropriate for the client's age and health status and developed for the client to achieve, maintain or promote functional capacity.

OKLA. ADMIN. CODE §317:30-3-1(f). However, when parties engage in and conspire to engage in a widespread misinformation campaign, such as Defendants did here, such conduct corrupts the informed consideration of these criteria and, thus, the certification of these determinations.

The State notes that Defendant has pled the learned intermediary doctrine in an attempt to blame physicians for the fallout of the opioid epidemic. The State disagrees that such a defense is legally or factually applicable to this case. In Oklahoma, the learned intermediary defense is only available in products liability cases. *See McKee v. Moore*, 1982 OK 71, ¶¶6–8, 648 P.2d 21; *Brown v. Am. Home Prods. Corp.*, No. 1203, 2009 U.S. Dist. LEXIS 30298, at *24 (E.D. Pa. Apr. 2, 2009). This case is not a products liability case. Therefore, the learned intermediary doctrine is not applicable. Moreover, even if it were applicable, the doctrine only shields manufacturers of prescription drugs from liability "if the manufacturer adequately warns the prescribing physicians

of the dangers of the drug." Edwards, 1997 OK 22, ¶8. "To invoke a defense to liability under the learned intermediary doctrine, a manufacturer seeking its protection must provide sufficient information to the learned intermediary of the risk subsequently shown to be the proximate cause of a plaintiff's injury." *Tortorelli v. Mercy Health Ctr., Inc.*, 2010 OK CIV APP 105, ¶27, 242 P.3d 549. Here, Defendants intentionally *misrepresented* the risks of opioid addiction—often contradicting their own labeling—in a sprawling and coordinated marketing campaign targeting doctors and others throughout Oklahoma and the country. Defendants initiated a scheme to change the way physicians think about opioids. Defendants cannot falsely market their drugs to physicians and, at the same time, claim physicians should have known better. As such, even if the learned intermediary doctrine were applicable here (which it is not), Defendants cannot take advantage of the doctrine because they failed to adequately warn of the true risks of opioids, which risks caused the opioid epidemic in Oklahoma.

Based on the foregoing and by operation of law, every claim for reimbursement for an opioid prescription submitted to Oklahoma Medicaid (including, but not limited to, each of the more than 99,000 identified in the Petition) necessarily was based on certifications that the "services or products" provided (*i.e.*, prescription opioids) met the OHCA's definition of "medical necessity." *See, e.g.*, Provider Agreement at ¶4.3(g); *see also* OAC §317:30-3-2. However, the false representations Defendants and their co-conspirators imbedded in the Oklahoma medical community prevented an accurate and complete assessment of the "medical necessity" of Defendants' drugs for any patient in the first place.

Had Defendants not engaged in the conspiratorial and widespread, unlawful and fraudulent marketing of opioids, which reached every corner of the State, and had medical providers instead been equipped with the full and un-tainted truth regarding the efficacy and addictiveness of the

opioids at issue, such medical providers may never have prescribed opioids at all or would have prescribed exponentially fewer, as was the case prior to 1996, when Defendants' conspiratorial and fraudulent marketing campaign first began. Accordingly, at this time and based on the information reviewed to date, and subject to ongoing discovery and expert disclosures, the State's position is that it is more likely than not that (1) opioid prescriptions written in the State of Oklahoma since 1996 and reimbursed by the SoonerCare, other than those written for end-of-life palliative care or for a three-day supply to treat acute pain, were "false, fraudulent, or otherwise reimbursed in violation of the Oklahoma Medicaid False Claims Act," and (2) opioids prescriptions written in the State of Oklahoma since 1996 and reimbursed by the SoonerCare for end-of-life palliative care or for a three-day supply to treat acute pain were not "false, fraudulent, or otherwise reimbursed in violation of the Oklahoma Medicaid False Claims Act." The State will continue to supplement this response as expert review continues for these claims.

Further, the State intends to produce (but cannot guarantee production of) de-identified claims data related to both medical provider services and pharmacy claims, from which Defendants can identify those claims related to opioids which are relevant to this lawsuit. For context, medical providers seeking reimbursement from SoonerCare for medical services submit their claims for reimbursement to the OHCA in the form of CPT codes—accepted numeric codes which indicate the treatment, medical decision-making, and services for which the provider seeks reimbursement. Claims for reimbursement for covered prescriptions are submitted separately by the dispensing pharmacy, such that SoonerCare typically receives two claims for reimbursement related to a single patient visit: one from the medical provider for his or her services (which are identified by CPT codes and based on the medical providers' decision-making and analysis, including any relevant diagnoses identified by ICD-9/10 codes) and one from the pharmacy for any resulting

prescription (which is not accompanied by the medical provider's records or any ICD-9/10 codes). Due to the real-time nature of pharmacy claims, the pharmacy claim is submitted days to weeks ahead of the medical claim. As a result, OHCA maintains separate claims databases for (1) claims and reimbursement for medical providers' services and (2) claims and reimbursement for prescriptions. The State is currently in the process of collecting this claims data in a manner that complies with applicable state and federal regulations and hope to produce such claims data in a de-identified format.

The State will supplement its Response to this Interrogatory No. 1 as additional information is gathered, reviewed and produced as a part of the State's ongoing investigation and reasonably diligent search for information responsive to Defendants' Interrogatories and Requests for Production of Documents.

INTERROGATORY NO. 2: Identify every Opioid prescription, whether manufactured by Defendants or not, that the State contends was not a Medical Necessity, was "unnecessary or excessive" as described in the Complaint, or that You otherwise contend should not have been written, specifically identifying the HCP who recommended, drafted, wrote, administered, and/or dispensed each prescription.

RESPONSE TO INTERROGATORY NO. 2:

The State incorporates its general objections and objections to Defendant's instructions and definitions above, including the State's objections to Defendant's definitions of the terms "HCP," "You," "State," and "Opioid," as if fully set forth herein.

The State further objects to this Interrogatory because it is a premature contention interrogatory that attempts to force the State to marshal all of its evidence, including expert evidence, before any meaningful discovery has taken place in this action. *See* 12 OKLA. STAT.

§3233(B). To the extent the State can respond to this Interrogatory at this preliminary stage, the State will do so based on the information currently known to and within the possession, custody and control of the State following a reasonably diligent investigation and will supplement and/or amend its response in due course according to 12 OKLA. STAT. §3226. Moreover, because this Interrogatory implicates the identity of documents and materials at this preliminary stage of discovery while the State is reasonably collecting, gathering, investigating, reviewing and searching for such responsive documents, the State will supplement and/or amend its response to this Interrogatory in accordance with 12 OKLA. STAT. §3226 and 12 OKLA. STAT. §3233(C). Further, the State will produce and disclose expert information called for by this Interrogatory in accordance with the scheduling Order entered by the Court.

The State further objects to this interrogatory as impermissibly compound because it indiscriminately groups multiple separate topics, subjects, questions and tasks under the guise of a single interrogatory. In reality, this Interrogatory is actually at least two (2) separate interrogatories improperly disguised as one. *See* 12 OKLA. STAT. §3233(A). The State will reasonably and conservatively construe the Interrogatory as requesting the State to: (i) identify every Opioid prescription that the State contends was not a Medical Necessity, was "unnecessary or excessive" as described in the Complaint, or that You otherwise contend should not have been written; and (ii) identify the HCP who recommended, drafted, wrote, administered, and/or dispensed each prescription. Further, this Interrogatory, as written, improperly attempts to ask the same question about at least thirteen entities under the guise of a single interrogatory by requesting the "[i]dentify [of] every Opioid prescription, whether manufactured by Defendants or not." Accordingly, the State will limit its response to Defendant.

Subject to and without waiving the foregoing objections (including those incorporated into this response), the State responds as follows:

See the State's response to Interrogatory No. 1, which is incorporated as if fully set forth herein. The State's principal processes, practices and procedures for ensuring that claims for reimbursement are reimbursable and relate to medically necessary treatment are primarily based on the relationship between State-imposed safeguards, implemented through regulations, and the State's trust in and reliance upon certifying parties to be fully and accurately informed and capable of accurately assessing that claims submitted for reimbursement are for medically necessary services, treatments and prescriptions. This trust is predicated on the State's reasonable reliance on the presumption that any pharmaceutical marketing activity that takes place in the State, or otherwise reaches certifying parties and patients in the State, is lawful and truthfully characterizes the risks and efficacy of the marketed pharmaceuticals in a manner that does not unduly or improperly influence or hinder the appropriate analysis of the medical necessity of prescribing any marketed pharmaceuticals.

Based on the unprecedented scope of the misinformation campaign at issue in this litigation and given the fact that the totality of information that was available was conflated with the misleading, false, and deceptive information disseminated by Defendants and their co-conspirators, neither medical providers nor patients had the benefit of all material information regarding Defendants' drugs. As such, it was not possible for providers or patients to discern whether any prescription was medically necessary or to informatively consider the "medical necessity" criteria set forth in Oklahoma regulations and certify the accuracy of such determinations. Defendants flooded the medical community with false and misleading information—and omitted material information—as part of a scheme and conspiracy designed to

make the public believe that opioids were more effective and less addictive than they actually were. Without the benefit of all material information, and given the fact that the totality of information that was available was conflated with the misleading, false, and deceptive information disseminated by Defendants and their co-conspirators, it was not possible for providers or patients to discern whether any prescription was medically necessary.

The Medical Assistance Program ("Medicaid") is a cooperative program of the state and federal governments that provides medical assistance for the poor. *See* Title XIX of the Social Security Act of 1935, 42 U.S.C. §1396 *et seq.* While a state is not obligated to participate in a Medicaid program, if it chooses to participate, the state administers its Medicaid program, but it must operate its program in compliance with the federal Medicaid statues and regulations. *See id.* at §1396a. The State participates in Medicaid, and the Oklahoma Health Care Authority ("OHCA") administers the Oklahoma Medicaid Program ("SoonerCare"). The State further provides prescription drug coverage under its SoonerCare program. *See* Okla. Admin. Code §317:30-5-72. Accordingly, under the federal Medicaid Act, the State is required to provide coverage for all drugs approved by the U.S. Food and Drug Administration ("FDA") that are offered by any manufacturer that enters into a basic rebate agreement in order to participate in Medicaid under the Medicaid rebate program. *See, e.g.*, 42 U.S.C. §1396r-8.

By regulation, the State cannot legally reimburse claims for reimbursement for treatment that is not medically necessary. *See, e.g.*, Okla. Admin. Code §317:30-3-1(d). However, for the Medicaid system to work and for Medicaid beneficiaries to receive the benefit of timely and efficient medical treatment and coverage, the State cannot review in real time each individual claim submitted for reimbursement to ensure the claim relates to treatment that was medically necessary. Medical providers seeking reimbursement from SoonerCare for medical services or prescriptions

submit their claims for reimbursement to the OHCA in the form of Current Procedural Terminology ("CPT") codes—accepted numeric codes which indicate the treatment, medical decision-making, and services or prescriptions for which the provider seeks reimbursement.

Claims for reimbursement for covered prescriptions are submitted separately by the dispensing pharmacy, such that SoonerCare typically receives two claims for reimbursement related to a single patient visit: one from the medical provider for his or her services (which are identified by CPT codes and based on the medical providers' decision-making and analysis, including any relevant diagnoses identified by ICD-9/10 codes) and one from the pharmacy for any resulting prescription (which is not accompanied by the medical provider's records or any ICD-9/10 codes). Due to the real-time nature of pharmacy claims, the pharmacy claim is submitted days to weeks ahead of the medical claim. As a result, OHCA maintains separate claims databases for (1) claims and reimbursement for medical providers' services and (2) claims and reimbursement for prescriptions.

The State's ability to audit medical providers' documentation and other information that forms the basis for any claim for reimbursement is limited to the retrospective ability to determine whether a claim submitted should have been reimbursed on the back-end of the Medicaid process. On the front-end, when a claim for reimbursement is submitted, the State must and does rely upon the certification of medical necessity, which certifies that the services, treatment, products or prescriptions for which reimbursement is sought were medically necessary with each claim for reimbursement. This in turn is based, at least in part, on the State's trust and reliance upon the reasonable presumption that the totality of information available to the certifying party is not deceptive, incomplete, false and/or misleading and is not the product of fraudulent marketing activity that obscured or mischaracterized the risks and efficacy of any marketed pharmaceuticals.

Therefore, in order to allow the Medicaid system to work correctly and enable Medicaid beneficiaries to receive timely and effective medical treatment, the State has defined the standards that must be considered in determining whether medical treatment is medically necessary and requires certification that each claim submitted for reimbursement is for medically necessary treatment. The State requires entry of a standard form Provider Agreement in order to be eligible for reimbursement from SoonerCare. *See* OKLA. ADMIN. CODE §317:30-3-2. Under this Provider Agreement, it is expressly certified with each claim for payment that, amongst other things, the services or products for which payment is billed by or on behalf of the provider were medically necessary, as the State, through OHCA, has defined that term. Essential to the proper functioning of SoonerCare is the reasonable presumption that any pharmaceutical marketing that may influence the certifying party's decision-making is proper and lawful and that such medical-decision making was not unduly influenced or hindered by predatory, false, misleading, coercive, negligent or fraudulent marketing tactics, such as those at issue here.

The State has defined "[m]edical necessity" as an assessment and consideration of the following standards and conditions:

> **(1)** Services must be medical in nature and must be consistent with accepted health care practice standards and guidelines for the prevention, diagnosis or treatment of symptoms of illness, disease or disability;
> **(2)** Documentation submitted in order to request services or substantiate previously provided services must demonstrate through adequate objective medical records, evidence sufficient to justify the client's need for the service;
> **(3)** Treatment of the client's condition, disease or injury must be based on reasonable and predictable health outcomes;
> **(4)** Services must be necessary to alleviate a medical condition and must be required for reasons other than convenience for the client, family, or medical provider;
> **(5)** Services must be delivered in the most cost-effective manner and most appropriate setting; and
> **(6)** Services must be appropriate for the client's age and health status and developed for the client to achieve, maintain or promote functional capacity.

OKLA. ADMIN. CODE §317:30-3-1(f). However, when parties engage in and conspire to engage in a widespread misinformation campaign, such as Defendants did here, such conduct corrupts the informed consideration of these criteria and, thus, the certification of these determinations.

The State notes that Defendant has pled the learned intermediary doctrine in an attempt to blame physicians for the fallout of the opioid epidemic. The State disagrees that such a defense is legally or factually applicable to this case. In Oklahoma, the learned intermediary defense is only available in products liability cases. *See McKee v. Moore*, 1982 OK 71, ¶¶6–8, 648 P.2d 21; *Brown v. Am. Home Prods. Corp.*, No. 1203, 2009 U.S. Dist. LEXIS 30298, at *24 (E.D. Pa. Apr. 2, 2009). This case is not a products liability case. Therefore, the learned intermediary doctrine is not applicable. Moreover, even if it were applicable, the doctrine only shields manufacturers of prescription drugs from liability "if the manufacturer adequately warns the prescribing physicians of the dangers of the drug." Edwards, 1997 OK 22, ¶8. "To invoke a defense to liability under the learned intermediary doctrine, a manufacturer seeking its protection must provide sufficient information to the learned intermediary of the risk subsequently shown to be the proximate cause of a plaintiff's injury." *Tortorelli v. Mercy Health Ctr., Inc.*, 2010 OK CIV APP 105, ¶27, 242 P.3d 549. Here, Defendants intentionally *misrepresented* the risks of opioid addiction—often contradicting their own labeling—in a sprawling and coordinated marketing campaign targeting doctors and others throughout Oklahoma and the country. Defendants initiated a scheme to change the way physicians think about opioids. Defendants cannot falsely market their drugs to physicians and, at the same time, claim physicians should have known better. As such, even if the learned intermediary doctrine were applicable here (which it is not), Defendants cannot take advantage of the doctrine because they failed to adequately warn of the true risks of opioids, which risks caused the opioid epidemic in Oklahoma.

Based on the foregoing and by operation of law, every claim for reimbursement for an opioid prescription submitted to Oklahoma Medicaid (including, but not limited to, each of the more than 99,000 identified in the Petition) necessarily was based on certifications that the "services or products" provided (*i.e.*, prescription opioids) met the OHCA's definition of "medical necessity." *See, e.g.*, Provider Agreement at ¶4.3(g); *see also* OAC §317:30-3-2. However, the false representations regarding the risks and efficacy of opioids, which Defendants and their co-conspirators imbedded in the Oklahoma medical community, prevented an accurate and complete assessment of the "medical necessity" of Defendants' drugs for any patient. Accordingly, at this time and based on the information reviewed to date, and subject to ongoing discovery and expert disclosures, the State's position is that it is more likely than not that (1) opioid prescriptions written in the State of Oklahoma since 1996, other than those written for end-of-life palliative care or for a three-day supply to treat acute pain, were "not a Medical Necessity" and were "unnecessary or excessive," and (2) opioids prescriptions written in the State of Oklahoma since 1996 for end-of-life palliative care or for a three-day supply to treat acute pain were "a Medical Necessity" and were not "unnecessary or excessive." The State will continue to supplement this response as expert review continues for these claims.

In addition, the State intends to produce (but cannot guarantee production of) de-identified claims data related to both medical provider services and pharmacy claims, from which Defendants can identify those claims related to opioids which are relevant to this lawsuit, including those that, according to the State's allegations and to-be disclosed expert testimony, were "unnecessary or excessive." The State does not possess or control, and therefore cannot produce, similar claims data belonging to any private health insurers or self-insured private entities related to opioid prescriptions written or filled in the State of Oklahoma.

The State will supplement its Response to this Interrogatory No. 2 as additional information is gathered, reviewed and produced as a part of the State's ongoing investigation and reasonably diligent search for information responsive to Defendants' Interrogatories and Requests for Production of Documents.

INTERROGATORY NO. 3: Identify every Communication (1) that caused or contributed to Your payment or reimbursement of any prescription for one of Defendants' Opioids pursuant to the Oklahoma Medicaid Program, or (2) which states income or expense and was used to determine a rate of payment pursuant to the Oklahoma Medicaid Program for a prescription for one of Defendants' Opioids, or (3) made as part of an application for payment for one of Defendants' Opioids under any Program that You allege was false in violation of the Oklahoma Medicaid Program Integrity Act. In Your answer, specify the information in the Communication that you contend was false and identify the HCP or other Person who drafted, wrote, administered, or submitted each Communication.

RESPONSE TO INTERROGATORY NO. 3:

The State incorporates its general objections and objections to Defendant's instructions and definitions above, including the State's objections to Defendant's definitions of the terms "Communication," "HCP," "You," "State," "Program," "Person," and "Opioid," as if fully set forth herein.

The State further objects to this Interrogatory because it is a premature contention interrogatory that attempts to force the State to marshal all of its evidence, including expert evidence, before any meaningful discovery has taken place in this action. *See* 12 OKLA. STAT. §3233(B). To the extent the State can respond to this Interrogatory at this preliminary stage, the State will do so based on the information currently known to and within the possession, custody

and control of the State following a reasonably diligent investigation and will supplement and/or amend its response in due course according to 12 OKLA. STAT. §3226. Moreover, because this Interrogatory implicates the identity of documents and materials at this preliminary stage of discovery while the State is reasonably collecting, gathering, investigating, reviewing and searching for such responsive documents, the State will supplement and/or amend its response to this Interrogatory in accordance with 12 OKLA. STAT. §3226 and 12 OKLA. STAT. §3233(C). Further, the State will produce and disclose expert information called for by this Interrogatory in accordance with the scheduling Order entered by the Court.

The State further objects to this interrogatory as overbroad, unduly burdensome, vague, ambiguous, and seeking information that is irrelevant to the claims and defenses at issue in this case. Specifically, by asking the State to "[i]dentify every Communication . . . which states income or expense and was used to determine a rate of payment pursuant to the Oklahoma Medicaid Program for a prescription for one of Defendants' Opioids," this Interrogatory seeks information that is irrelevant to the claims and defenses at issue in this case or, to the extent such information has any marginal or limited relevance whatsoever, it is substantially outweighed by the incredible time and expense burden the State would have to endure. Likewise, Defendant's request for identification of "every Communication . . . made as part of an application for payment for one of Defendants' Opioids under any program" is vague and ambiguous and appears to seek information that is irrelevant to the claims and defenses at issue in this case.

The State further objects to this Interrogatory as seeking protected health information prohibited from disclosure under the Health Insurance Portability and Accountability Act ("HIPAA"). The State has provided Defendants with an acceptable version of a protective order covering HIPAA-protected documents and information. Defendants have not executed a proposed

protective order regarding HIPAA-protected documents and information. The State will not produce or otherwise disclose any protected health information until that protective order, or a substantially similar protective order, is agreed to by Defendants and/or entered by the Court.

The State further objects to this interrogatory as impermissibly compound because it indiscriminately groups multiple separate topics, subjects, questions and tasks under the guise of a single interrogatory. In reality, this Interrogatory is actually at least five (5) separate interrogatories improperly disguised as one. *See* 12 OKLA. STAT. §3233(A). The State will reasonably and conservatively construe the Interrogatory as requesting the State to: (i) identify every communication that caused or contributed to Your payment or reimbursement of any prescription for one of Defendants' Opioids pursuant to the Oklahoma Medicaid Program; (ii) identify every communication which states income or expense and was used to determine a rate of payment pursuant to the Oklahoma Medicaid Program for a prescription for one of Defendants' Opioids; (iii) identify every communication made as part of an application for payment for one of Defendants' Opioids under any Program that You allege was false in violation of the Oklahoma Medicaid Program Integrity Act; (iv) specify the information in each communication that you contend was false; and (v) identify the HCP or other Person who drafted, wrote, administered, or submitted each Communication. Further, this Interrogatory, as written, improperly attempts to ask the same question about at least thirteen entities under the guise of a single interrogatory by requesting information related to "Defendants' Opioids." Accordingly, the State will limit its response to Defendant.

Subject to and without waiving the foregoing objections (including those incorporated into this response), the State responds as follows:

The State's principal processes, practices and procedures for ensuring that claims for reimbursement are reimbursable and relate to medically necessary treatment are primarily based on the relationship between State-imposed safeguards, implemented through regulations, and the State's trust in and reliance upon certifying parties to be fully and accurately informed and capable of accurately assessing that claims submitted for reimbursement are for medically necessary services, treatments and prescriptions. This trust is based in part on the State's reasonable reliance on the presumption that any pharmaceutical marketing activity that takes place in the State, or otherwise reaches certifying parties and patients in the State, is lawful and truthfully characterizes the risks and efficacy of the marketed pharmaceuticals in a manner that does not unduly or improperly influence or hinder the appropriate analysis of the medical necessity of prescribing any marketed pharmaceuticals.

Based on the unprecedented scope of the misinformation campaign at issue in this litigation and given the fact that the totality of information that was available was conflated with the misleading, false, and deceptive information disseminated by Defendants and their co-conspirators, neither medical providers nor patients had the benefit of all material information regarding Defendants' drugs. As such, it was not possible for providers or patients to discern whether any prescription was medically necessary or to informatively consider the "medical necessity" criteria set forth in Oklahoma regulations and truthfully certify the accuracy of such determinations. Defendants flooded the medical community with false and misleading information—and omitted material information—as part of a scheme and conspiracy designed to make the public believe that opioids were more effective and less addictive than they actually were. Without the benefit of all material information, and given the fact that the totality of information that was available was conflated with the misleading, false, and deceptive information

disseminated by Defendants and their co-conspirators, it was not possible for providers or patients to discern whether any prescription was medically necessary.

The Medical Assistance Program ("Medicaid") is a cooperative program of the state and federal governments that provides medical assistance for the poor. *See* Title XIX of the Social Security Act of 1935, 42 U.S.C. §1396 *et seq*. While a state is not obligated to participate in a Medicaid program, if it chooses to participate, the state administers its Medicaid program, but it must operate its program in compliance with the federal Medicaid statues and regulations. *See id.* at §1396a. The State participates in Medicaid, and the Oklahoma Health Care Authority ("OHCA") administers the Oklahoma Medicaid Program ("SoonerCare"). The State further provides prescription drug coverage under its SoonerCare program. *See* Okla. Admin. Code §317:30-5-72. Accordingly, under the federal Medicaid Act, the State is required to provide coverage for all drugs approved by the U.S. Food and Drug Administration ("FDA") that are offered by any manufacturer that enters into a basic rebate agreement in order to participate in Medicaid under the Medicaid rebate program. *See, e.g.*, 42 U.S.C. §1396r-8.

By regulation, the State cannot legally reimburse claims for reimbursement for treatment that is not medically necessary. *See, e.g.*, Okla. Admin. Code §317:30-3-1(d). However, for the Medicaid system to work and for Medicaid beneficiaries to receive the benefit of timely and efficient medical treatment and coverage, the State cannot review in real time each individual claim submitted for reimbursement to ensure the claim relates to treatment that was medically necessary. Medical providers seeking reimbursement from SoonerCare for medical services or prescriptions submit their claims for reimbursement to the OHCA in the form of Current Procedural Terminology ("CPT") codes—accepted numeric codes which indicate the treatment, medical decision-making, and services or prescriptions for which the provider seeks reimbursement.

Claims for reimbursement for covered prescriptions are submitted separately by the dispensing pharmacy, such that SoonerCare typically receives two claims for reimbursement related to a single patient visit: one from the medical provider for his or her services (which are identified by CPT codes and based on the medical providers' decision-making and analysis, including any relevant diagnoses identified by ICD-9/10 codes) and one from the pharmacy for any resulting prescription (which is not accompanied by the medical provider's records or any ICD-9/10 codes). Due to the real-time nature of pharmacy claims, the pharmacy claim is submitted days to weeks ahead of the medical claim. As a result, OHCA maintains separate claims databases for (1) claims and reimbursement for medical providers' services and (2) claims and reimbursement for prescriptions.

The State's ability to audit medical providers' documentation and other information that forms the basis for any claim for reimbursement is limited to the retrospective ability to determine whether a claim submitted should have been reimbursed on the back-end of the Medicaid process. On the front-end, when a claim for reimbursement is submitted, the State must and does rely upon the certification of medical necessity, which certifies that the services, treatment, products or prescriptions for which reimbursement is sought were medically necessary with each claim for reimbursement. This in turn is based, at least in part, on the State's trust and reliance upon the reasonable presumption that the totality of information available to the certifying party is not deceptive, incomplete, false and/or misleading and is not the product of fraudulent marketing activity that obscured or mischaracterized the risks and efficacy of any marketed pharmaceuticals.

Therefore, in order to allow the Medicaid system to work correctly and enable Medicaid beneficiaries to receive timely and effective medical treatment, the State has defined the standards that must be considered in determining whether medical treatment is medically necessary and

requires certification that each claim submitted for reimbursement is for medically necessary treatment. The State requires entry of a standard form Provider Agreement in order to be eligible for reimbursement from SoonerCare. *See* OKLA. ADMIN. CODE §317:30-3-2. Under this Provider Agreement, it is expressly certified with each claim for payment that, amongst other things, the services or products for which payment is billed by or on behalf of the provider were medically necessary, as the State, through OHCA, has defined that term. Essential to the proper functioning of SoonerCare is the reasonable presumption that any pharmaceutical marketing that may influence the certifying party's decision-making is proper and lawful and that such medical-decision making was not unduly influenced or hindered by predatory, false, misleading, coercive, negligent or fraudulent marketing tactics, such as those at issue here.

The State has defined "[m]edical necessity" as an assessment and consideration of the following standards and conditions:

> **(1)** Services must be medical in nature and must be consistent with accepted health care practice standards and guidelines for the prevention, diagnosis or treatment of symptoms of illness, disease or disability;
> **(2)** Documentation submitted in order to request services or substantiate previously provided services must demonstrate through adequate objective medical records, evidence sufficient to justify the client's need for the service;
> **(3)** Treatment of the client's condition, disease or injury must be based on reasonable and predictable health outcomes;
> **(4)** Services must be necessary to alleviate a medical condition and must be required for reasons other than convenience for the client, family, or medical provider;
> **(5)** Services must be delivered in the most cost-effective manner and most appropriate setting; and
> **(6)** Services must be appropriate for the client's age and health status and developed for the client to achieve, maintain or promote functional capacity.

OKLA. ADMIN. CODE §317:30-3-1(f). However, when parties engage in and conspire to engage in a widespread misinformation campaign, such as Defendants did here, such conduct corrupts the informed consideration of these criteria and, thus, the certification of these determinations.

The State notes that Defendant has pled the learned intermediary doctrine in an attempt to blame physicians for the fallout of the opioid epidemic. The State disagrees that such a defense is legally or factually applicable to this case. In Oklahoma, the learned intermediary defense is only available in products liability cases. *See McKee v. Moore*, 1982 OK 71, ¶¶6–8, 648 P.2d 21; *Brown v. Am. Home Prods. Corp.*, No. 1203, 2009 U.S. Dist. LEXIS 30298, at *24 (E.D. Pa. Apr. 2, 2009). This case is not a products liability case. Therefore, the learned intermediary doctrine is not applicable. Moreover, even if it were applicable, the doctrine only shields manufacturers of prescription drugs from liability "if the manufacturer adequately warns the prescribing physicians of the dangers of the drug." Edwards, 1997 OK 22, ¶8. "To invoke a defense to liability under the learned intermediary doctrine, a manufacturer seeking its protection must provide sufficient information to the learned intermediary of the risk subsequently shown to be the proximate cause of a plaintiff's injury." *Tortorelli v. Mercy Health Ctr., Inc.*, 2010 OK CIV APP 105, ¶27, 242 P.3d 549. Here, Defendants intentionally *misrepresented* the risks of opioid addiction—often contradicting their own labeling—in a sprawling and coordinated marketing campaign targeting doctors and others throughout Oklahoma and the country. Defendants initiated a scheme to change the way physicians think about opioids. Defendants cannot falsely market their drugs to physicians and, at the same time, claim physicians should have known better. As such, even if the learned intermediary doctrine were applicable here (which it is not), Defendants cannot take advantage of the doctrine because they failed to adequately warn of the true risks of opioids, which risks caused the opioid epidemic in Oklahoma.

Further, the States intends to produce (but cannot guarantee production of) de-identified claims data related to both medical provider services and pharmacy claims, from which Defendants can identify those claims related to opioids which are relevant to this lawsuit.

As to the second sub-part of this Interrogatory, financial information related to individual Medicaid recipients is irrelevant to the claims and defenses at issue in this case and otherwise objectionable for the reasons stated herein. Accordingly, based on its understanding of this request, the State will stand on its objections and not respond to this sub-part of the Interrogatory.

The third sub-part of this Interrogatory, as written, is vague and ambiguous as to the information Defendant seeks and calls for all communications made as part of an application for payment for one of Defendants' opioids without regard to their relevance to the claims and defenses at issue in this case. Further, the State is currently in the process of collecting and producing claims data in a manner that complies with applicable state and federal regulations.

In regard to the remaining sub-parts of this Interrogatory, *see* the State's above responses to the preceding sub-parts of this Interrogatory.

The State will supplement its Response to this Interrogatory No. 3 as additional documents, information, reports, studies and research is gathered, reviewed and produced as a part of the State's ongoing investigation and reasonably diligent search for information responsive to Defendants' Interrogatories and Requests for Production of Documents.

INTERROGATORY NO. 4: For each prescription identified or subject to a Communication identified in response to Interrogatory No.1, Interrogatory No.2, or Interrogatory No.3, identify the Patient who received the prescription.

RESPONSE TO INTERROGATORY NO. 4:

The State incorporates its general objections and objections to Defendant's instructions and definitions above, including the State's objections to Defendant's definitions of the terms "Communication," and "Patient," as if fully set forth herein. Because this interrogatory depends

on Interrogatories 1–3, the State further incorporates its objections to those Interrogatories as if fully set forth herein.

The State further objects to this interrogatory as seeking information that is irrelevant to the claims and defenses at issue in this case. Specifically, the identity of persons receiving prescriptions is irrelevant to the claims and defenses at issue in this case or, to the extent such information has any marginal or limited relevance whatsoever, it is substantially outweighed by the incredible time and expense burden the State would have to endure.

The State further objects to this Interrogatory as seeking protected health information prohibited from disclosure under the Health Insurance Portability and Accountability Act ("HIPAA"). The State has provided Defendants with an acceptable version of a protective order covering HIPAA-protected documents and information. Defendants have not executed a proposed protective order regarding HIPAA-protected documents and information. The State will not produce or otherwise disclose any protected health information until that protective order, or a substantially similar protective order, is agreed to by Defendants and/or entered by the Court.

The State further objects to this interrogatory as impermissibly compound because it indiscriminately groups multiple separate topics, subjects, questions and tasks under the guise of a single interrogatory. In reality, this Interrogatory is actually at least five (5) separate interrogatories improperly disguised as one. *See* 12 OKLA. STAT. §3233(A). The State will reasonably and conservatively construe the Interrogatory as requesting the State to: (i) identify the Patient who received the prescription for each prescription identified or subject to a Communication identified in response to Interrogatory No.1; (ii) identify the Patient who received the prescription for each prescription identified or subject to a Communication identified in

response to Interrogatory No.2; and (iii) identify the Patient who received the prescription for each prescription identified or subject to a Communication identified in response to Interrogatory No.3.

Subject to and without waiving the foregoing objections (including those incorporated into this response), the State responds as follows:

In response to sub-parts one, two, and three, the State intends to produce de-identified claims data that contains a unique identifier for each patient. The State is currently in the process of collecting and producing claims data in a manner that complies with applicable state and federal regulations. Once that production is made, the State will supplement its response to identify those records in accordance with 12 OKLA. STAT. §3233(C). Under federal and state law, the State cannot and will not produce or identify the names of Medicaid patients and beneficiaries.

The State will supplement its Response to this Interrogatory No. 4 as additional documents, information, reports, studies and research is gathered, reviewed and produced as a part of the State's ongoing investigation and reasonably diligent search for information responsive to Defendants' Interrogatories and Requests for Production of Documents.

INTERROGATORY NO. 5: For each Patient identified in response to Interrogatory No.4, describe the alternative course of treatment that should have been implemented or prescribed instead of the Patient's receipt of an Opioid prescription.

RESPONSE TO INTERROGATORY NO. 5:

The State incorporates its general objections and objections to Defendant's instructions and definitions above, including the State's objections to Defendant's definitions of the term "Patient," as if fully set forth herein. Because this interrogatory depends on Interrogatories 1–4, the State further incorporates its objections to those Interrogatories as if fully set forth herein.

The State further objects to this interrogatory as seeking information that is irrelevant to the claims and defenses at issue in this case. Specifically, the identity of persons receiving prescriptions is irrelevant to the claims and defenses at issue in this case or, to the extent such information has any marginal or limited relevance whatsoever, it is substantially outweighed by the incredible time and expense burden the State would have to endure.

The State further objects to this Interrogatory because it is a premature contention interrogatory that attempts to force the State to marshal all of its evidence, including expert evidence, before any meaningful discovery has taken place in this action. *See* 12 OKLA. STAT. §3233(B). To the extent the State can respond to this Interrogatory at this preliminary stage, the State will do so based on the information currently known to and within the possession, custody and control of the State following a reasonably diligent investigation and will supplement and/or amend its response in due course according to 12 OKLA. STAT. §3226. Moreover, because this Interrogatory implicates the identity of documents and materials at this preliminary stage of discovery while the State is reasonably gathering, reviewing and producing such responsive documents, the State will supplement and/or amend its response to this Interrogatory in accordance with 12 OKLA. STAT. §3226 and 12 OKLA. STAT. §3233(C). Further, the State will produce and disclose expert information called for by this Interrogatory in accordance with the scheduling Order entered by the Court.

The State also objects to the Interrogatory as incorporating an unsubstantiated and unsupported predicate assumption with which the State disagrees. Specifically, this Interrogatory assumes that in all circumstances in which an opioid was prescribed there must have been an "alternative course of treatment" involving a prescription drug(s). There are a number of problems and inaccuracies with this assumption, including that in some instances there may be no alternate

course of treatment at all. Accordingly, the State cannot fully answer this Interrogatory due to the presence of this assumption.

The State further objects to this Interrogatory as seeking protected health information prohibited from disclosure under the Health Insurance Portability and Accountability Act ("HIPAA"). The State has provided Defendants with an acceptable version of a protective order covering HIPAA-protected documents and information. Defendants have not executed a proposed protective order regarding HIPAA-protected documents and information. The State will not produce or otherwise disclose any protected health information until that protective order, or a substantially similar protective order, is agreed to by Defendants and/or entered by the Court.

Subject to and without waiving the foregoing objections (including those incorporated into this response), the State responds as follows:

Based the information reviewed in the State's possession to date, and subject to ongoing discovery and expert disclosure, the alternative course of treatment that should have been implemented for persons receiving opioid prescriptions is one uninfected by Defendants' deceptive marketing scheme and consistent with regulations governing medical necessity. *See* OKLA. ADMIN. CODE §317:30-3-1(f) Subject to the foregoing, this may include no course of pain treatment at all.

The State notes that Defendant has pled the learned intermediary doctrine in an attempt to blame physicians for the fallout of the opioid epidemic. The State disagrees that such a defense is legally or factually applicable to this case. In Oklahoma, the learned intermediary defense is only available in products liability cases. *See McKee v. Moore*, 1982 OK 71, ¶¶6–8, 648 P.2d 21; *Brown v. Am. Home Prods. Corp.*, No. 1203, 2009 U.S. Dist. LEXIS 30298, at *24 (E.D. Pa. Apr. 2, 2009). This case is not a products liability case. Therefore, the learned intermediary doctrine is not applicable. Moreover, even if it were applicable, the doctrine only shields manufacturers of

prescription drugs from liability "if the manufacturer adequately warns the prescribing physicians of the dangers of the drug." Edwards, 1997 OK 22, ¶8. "To invoke a defense to liability under the learned intermediary doctrine, a manufacturer seeking its protection must provide sufficient information to the learned intermediary of the risk subsequently shown to be the proximate cause of a plaintiff's injury." *Tortorelli v. Mercy Health Ctr., Inc.*, 2010 OK CIV APP 105, ¶27, 242 P.3d 549. Here, Defendants intentionally *misrepresented* the risks of opioid addiction—often contradicting their own labeling—in a sprawling and coordinated marketing campaign targeting doctors and others throughout Oklahoma and the country. Defendants initiated a scheme to change the way physicians think about opioids. Defendants cannot falsely market their drugs to physicians and, at the same time, claim physicians should have known better. As such, even if the learned intermediary doctrine were applicable here (which it is not), Defendants cannot take advantage of the doctrine because they failed to adequately warn of the true risks of opioids, which risks caused the opioid epidemic in Oklahoma.

The State will supplement its Response to this Interrogatory No. 5 as additional documents, information, reports, studies and research is gathered, reviewed and produced as a part of the State's ongoing investigation and reasonably diligent search for information responsive to Defendants' Interrogatories and Requests for Production of Documents.

DATED: February 14, 2018.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the above and foregoing was mailed, postage prepaid, on February 14, 2018 to:

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