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; (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.,	§	***Submitted to***: **Judge Thad Balkman**
Defendants.	§	

STATE OF OKLAHOMA } S.S.
CLEVELAND COUNTY }
FILED
MAY 03 2019
In the office of the
Court Clerk MARILYN WILLIAMS

THE STATE'S RESPONSE TO JANSSEN'S MOTION IN LIMINE #10
(To Exclude The 2004 FDA Warning Label)

INTRODUCTION

Public trial is deeply woven into the fabric of our judicial system. Fundamental to its ethos. Public trials are the backdrop to Atticus Finch's defense of Tom Robinson and Clarence Darrow's cross-examination of William Jennings Bryan. And the reason why courts across the Nation, including this one, are located in the town square. "With us, a trial is by very definition a proceeding open to the press and to the public." *Richmond Newspapers v. Virginia*, 448 U.S. 555, 599, 100 S. Ct. 2814, 2840 (1980) (Stewart, J. concurring). Yet Defendants want to bar the Court's doors and suppress the evidence from ever seeing the light of day.

Motions *in limine* are not appropriate in bench trials. The whole point of a motion *in limine* is to make sure that potentially prejudicial evidence and statements never get to the fact finder (jury) because any damage cannot be undone. Here, the Court is the fact finder. And Defendants, not the State, have taken every single item they can think of, written it down, alerted the fact finder, told the fact finder about it, used bold headings, and will argue about it in open court. So, rather than keep any complained-of statements or evidence secret, Defendants have deliberately drawn the only fact finder's attention to it. That defeats the entire purpose of a motion *in limine.*

To be clear, Defendants' Motions in *Limine* are not about this fact finder. Quite the contrary, these Motions *in Limine* are solely about preventing an open, public trial—part of a metastasizing effort to shield their conduct from the public eye. First J&J and Teva improperly designated well over 90% of their production confidential—***over 3 million documents***—despite assurances to the Court that they would not blanket designate.[1] Then they fought tooth-and-nail to

[1] This number doesn't event take into account the 100,000+ blank documents produced by J&J that simply state, "Withheld as Not Responsive." Defendants' production is an astonishing abuse the Protective Order by any measure, but especially considering that J&J has no competitive interest in documents created before 2016 when it divested its global "pain management franchise." *See* State's Mtn. to De-Designate, Feb. 26, 2019.

prevent the public from seeing *any* of their documents by moving on two separate occasions to exclude cameras from the courtroom. And they sought to move the trial. And every time a document is shown to the Court—or a witness' testimony is played—they clear the courtroom. Now they file motions to seal masquerading as "Motions *in Limine*."

For all of Defendants' claims that the State has no case, they sure are worried about the evidence seeing the light of day. But Defendants eviscerated any argument about concealing evidence from the public based on a fear of statements impacting unknown foreign jurors when they publicly stated to all the unknown jurors that the State's case is baseless. They did not have to make those statements. But they did:

> Sabrina Strong, attorney for Johnson & Johnson and its subsidiary Janssen Pharmaceuticals, issued a statement to NPR and other media outlets saying the move by Hunter showed that most of the claims were without merit . . . . "We will continue to defend against the remaining baseless and unsubstantiated allegations."

https://www.npr.org/2019/04/04/710101827/oklahoma-drops-some-claims-to-refocus-lawsuit-against-opioid-makers. And, having done so, Defendants opened the door. As the Court saw just last Friday in Defendants' own documents: when they speak, they have a duty not to omit material information. Telling the whole world that the State's claims are baseless certainly blew that door wide open.

Beyond their title, Defendants' Motions do not even pretend to be motions *in limine*. Indeed, Defendants make no bones about the fact that these are not motions to keep information away from a jury. Quite the contrary, these Defendants' purpose is clear. "[T]he concern is not about the judge in this case but exposure of prejudicial information to millions of Americans, including countless prospective jurors in hundreds of matters pending against Janssen and J&J across the country." Janssen MIL No. 12 at 4; *see also* Jansen MIL Nos. 1, 5, 8, 9, 10, 13; Teva MIL Nos. 2, 3, 4, 5, 6, 7, 10. There is no case, none, that says the Court can consider hypothetical,

non-existent future trials in other states, that may never be conducted, under unknown laws and rules, when deciding what the State can use at this bench trial. Even if Defendants' motions were motions *in limine*, they fundamentally misunderstand the Court's duty to the public.

It is not the Court's job to shield the public—hypothetical jurors in other forums or otherwise—from information. Quite the opposite. Centuries of English-American judicial tradition charge the Court with empowering the public through access to trial and to information. *See generally Richmond_Newspapers v. Virginia*, 448 U.S. 555, 100 S. Ct. 2814 (1980). The justifications for this obligation are manifold and recognized in Oklahoma:

> [T]here are vital social interests served by the free dissemination of information about events having legal consequences and about legal proceedings themselves. The public has a right to know about threats to its safety and measures aimed at assuring its security. It also has a legitimate interest in the conduct of judicial proceedings, particularly in matters of general public concern. Furthermore, the subject matter of legal proceedings is often of direct significance in debate and deliberation over questions of public policy.

In re in re the Okla. Bar Ass'n to Amend the Rules of Prof'l Conduct, 2007 OK 22, ¶ 4, 171 P.3d 780, 855. There is no more important judicial event in Oklahoma than this case. Indeed, the Court recognized this mandate when it allowed cameras in the courtroom over the very same protests regurgitated in Defendants' Motions *in Limine*: "'A trial is a public event. What transpires in the courtroom is public property . . . . Those who see and hear what transpired can report it with impunity. There is no special perquisite of the judiciary which enables it, as distinguished from other institutions of democratic government, to suppress, edit, or censor events which transpire in proceedings before it." Aug. 22, 2018 Order at 2 (citing *Craig v. Harney,* 331 U.S. 367,67 S.Ct. 1249,91 L.Ed. 1546 (1947)).

The public's right to access does not end at the trial either. Rather, "the privilege extends, in the first instance, to materials on which a court relies in determining the litigants' substantive

rights." *FTC v. Standard Fin. Mgmt. Corp.*, 830 F.2d 404, 408 (1st Cir. 1987). This right includes presumptive access to all documents used at trial. *See Shadid v. Hammond*, 2013 OK 103, ¶¶ 1-2, 315 P.3d 1008 (Taylor, J. concurring) ("Court records are public records . . . . Sealing a public record should be a very rare event that occurs in only the most compelling of circumstances."). Indeed, the Court's Protective Order envisions no restriction on the use of "Confidential" information at trial, and restriction on the use of "Highly Confidential – Attorneys' Eyes Only" information only "by a separate stipulation and/or court order." *See* Amended Protective Order, ¶ 16 (Apr. 16, 2018). Defendants' arguments that the Court must protect the public from the evidence is entirely backward.

Defendants repeatedly trumpet other false narratives in support of their argument that the Court should conceal evidence from the public. They argue that the State seeks to punish Defendants where no punitive claim exists. Likewise, they argue that the State unfairly seeks to have Defendants alone pay for the entire opioid crisis. It does not. The legislature has expressly carved out joint and several liability for cases like this one, 23 O.S.§ 15, and the State brought its case accordingly. It's not unfair, it's the law. Defendants could have joined additional parties. *See* Scheduling Order (Jan. 29, 2018). They did not. They could have produced or sought evidence of other causes. They did not. And they can try to seek contribution for a 17-billion-dollar Judgment (or whatever amount the Court decides) from all the phantom causes of the crisis that they claim exist when this case is over. They did not do this because—in all likelihood—Defendants have a joint defense agreement with every manufacturer in the national cases, and they have refused to allege or testify that any drug company had anything to do with causing this crisis. All of these actions were part of Defendants' strategy. That strategy may have been a bad one, but it doesn't mean that this case is unfair. And it doesn't mean that the Court should whitewash the record of

all the evidence Defendants don't like.

LEGAL STANDARD

Even in Defendants' inverted world where the Court functions to conceal information from the public, their Motions *in Limine* must fail. Motions *in limine* are not concerned with considerations of the general public, only the jury. *Middlebrook v. Imler, Tenny & Kugler, M.D.'s Inc.*, 1985 OK 66, ¶ 12, 713 P.2d 572, 579 ("The function of a motion in limine is to preclude introduction of prejudicial matters ***to the jury***." (emphasis added)). Of course, this is a bench trial. There is no Oklahoma jury to prejudice here. And in a bench trial, the rationale underlying pre-trial motions *in limine* does not apply. Where there is no jury, to the extent the evidence is prejudicial to the moving party, the judge has already seen it, and any benefit of shielding the evidence from the eyes of the trier of fact is absent. *See id.*

Likewise, there is no efficiency to be gained, as a party aggrieved by an order in limine must make an offer of proof of the excluded matter at trial. *Id.* For these reasons, trial courts are advised to deny motions *in limine* in non-jury cases:

> In the trial of a nonjury case, it is virtually impossible for a trial judge to commit reversible error by receiving incompetent evidence, whether objected to or not. An appellate court will not reverse a judgment in a nonjury case because of the admission of incompetent evidence, unless all of the competent evidence is insufficient to support the judgment or unless it affirmatively appears that the incompetent evidence induced the court to make an essential finding which would not otherwise have been made. On the other hand, a trial judge who, in the trial of a nonjury case, attempts to make strict rulings on the admissibility of evidence, can easily get his decision reversed by excluding evidence which is objected to, but which, on review, the appellate court believes should have been admitted.

9A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 2411 (3d ed. 2008) (quoting *Builders Steel Co. v. CIR*, 179 F. 2d 377, 379 (8th Cir. 1950)).[2] As stated more pointedly

[2] *See also* Am. Jur. 2d *Trial* § 45 (2015) ("[T]he use of a motion in limine to exclude evidence in a case tried by the court without a jury has been disapproved on the grounds that it can serve no useful purpose in a nonjury case…granting of such a motion in a bench trial constitutes an error.");

by one trial court, "This is a bench trial, making any motion in limine asinine on its face." *Cramer v. Sabine Transportation Co.*, 141 F. Supp. 2d 727, 733 (S.D. Tex. 2001)).

A party seeking to exclude evidence in limine bears a heavy burden even in a jury trial. Under Oklahoma law, all relevant evidence is admissible unless otherwise prohibited, and the standard for relevance is very liberal. *See* 12 O.S. § 2402; *United States v. Leonard*, 439 F.3d 648, 651 (10th Cir. 2006). Relevant evidence is defined as, "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." 12 O.S. § 2401. "[A] fact is 'of consequence' when its existence would provide the fact-finder with a basis for making some inference, or chain of inferences, about an issue that is necessary to a verdict," but it only need to have "any tendency" to do so. *United States v. Jordan*, 485 F.3d 1214, 1218 (10th Cir. 2007). Accordingly, "court[s] are often reluctant to enter pretrial rulings which broadly exclude evidence, unless it is clear that the evidence will be inadmissible ***on all potential grounds***." *Martin v. Interstate Battery Sys. of Am., Inc.*, No. 12-CV-184-JED-FHM, 2016 WL 4401105, at *1 (N.D. Okla. Aug. 18, 2016) (emphasis added); *Middlebrook*, 1985 OK 66, ¶ 12 ("Error is committed, if at all, when in the course of the trial the court rules on the matter.").

Defendants are using motions in limine collectively to attempt to silence the State, stifle

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United States v. Heller, 551 F.3d 1108, 1111-12 (9th Cir. 2009) (stating that the need for a motion *in limine* became moot once the defendant waived his right to a jury trial); *LaConner Assocs. Ltd. Liab. Co. v. Island Tug and Barge Co.*, No. C07-175RSL, 2008 U.S. Dist. LEXIS 109863, at *2 (W.D. Wash. May 15, 2008) (when ruling on motions *in limine*, a court is forced to determine the admissibility of evidence without the benefit of the context of trial); *Capitol Neon Signs, Inc. v. Indiana Nat'l Bank*, 501 N.E.2d 1082, 1083 (Ind. Ct. App. [4th Dist] 1986) ("The trial court erred when it granted CNSI's motion in limine. Such motion has no place in a court trial."). The more prudent course in a bench trial, therefore, is to resolve all evidentiary doubts in favor of admissibility. *See Commerce Funding Corp. v. Comprehensive Habilitation Servs., Inc.*, No. 01 Civ 3796 (PKL), 2004 U.S. Dist. LEXIS 17791, at *5 (S.D.N.Y. Sept. 3, 2004); *Balschmiter v. TD Auto Fin., LLC*, No. 13-CV-1186-JPS, 2015 U.S. Dist. LEXIS 66629, at *4-5 (E.D. Wis. May 21, 2015).

justice, and prevent the admission of any evidence whatsoever. Motions in limine should not be used as gag orders. The Court ordered a televised trial on August 22, 2018. For purposes of deciding Defendants' motions in limine in this bench trial, the Court should not consider other states' laws, unknown jurors, or other hypothetical trials in other jurisdictions that may never happen. The Motions *in Limine* should be denied.[3]

ARGUMENT

Janssen/J&J seek an order excluding from trial any evidence, reference, or argument related to the September 2, 2004 FDA Warning Letter (the "2004 FDA Warning Letter") because such statements are (1) impermissible hearsay, and (2) unfairly prejudicial. Janssen/J&J's arguments are legally wrong and have no place in this bench trial where prejudice exclusions are improper, as Janssen/J&J admit.[4] Moreover, this is a classic "open door" situation, where Defendants have relied on the FDA and its labels as evidence of preemption, yet Defendants now want to shield from trial an official warning letter issued by the FDA. And, as Defendants know, the State is not seeking to use the 2004 FDA Warning Letter to show Defendants are liable for the warning itself, but instead, to show how and why the statements Defendants made are not permissible despite the labels on their products. Nor is this issue limited to one card, as Defendants contend. Instead, such statements were made repeatedly in local calls and national marketing.

Defendants' conduct in response to the warning letter also is relevant. They disseminated

[3] Because the Court ordered the Parties to address each *limine* topic individually, and the State does not know which response the Court will read first, the State has included this Introduction and Legal Standard section into each of its responses.

[4] Janssen/J&J harp upon the fact that FDA warning letters are not a "final agency determination of improper marketing." Unlike the State of West Virginia attempted to do in *State ex rel. McGraw v. Johnson & Johnson*, however, the State of Oklahoma is <u>not</u> asserting that the 2004 Warning Letter constitutes a preclusive legal determination that statements in the file card were false and misleading under the doctrine of collateral estoppel. 704 S.E. 2d 677 (W. Va. 2010). Instead, the State merely seeks to use the 2004 Warning Letter as some evidence in this bench trial, and it is admissible for the reasons explained herein.

the "Dear Doctor" letter, evidence that is clearly relevant and admissible in this trial. In short, Defendants' motion to exclude evidence related to the 2004 FDA Warning Letter is baseless and should be denied.

1. The 2004 FDA Warning Letter is Admissible Under the Public Records Exception to the Hearsay Rule

Despite the fact that this is a bench trial in which the typical concerns regarding hearsay are inapplicable,[5] Janssen/J&J nonetheless argue the 2004 FDA Warning Letter is inadmissible hearsay. But Janssen/J&J concede, as they must, that certain public records and reports fall within an exception to the hearsay rule—12 O.S. §§ 2803(8). Courts have correctly recognized that FDA warning letters fall squarely within the public records exception of the hearsay rule and encourage courts to admit this evidence:

> Advanced Bionics argues that these documents are inadmissible hearsay. These documents are hearsay, but admissible under the public records exception to the hearsay rule located in Fed. R. Evid. 803(8). This rule provides that records of a public office that set out 'a matter observed while under a legal duty to report' or 'factual findings from a legally authorized investigation' are excepted from the hearsay prohibition if these documents are sufficiently trustworthy. Fed. R. Evid. 803(8). These documents report factual findings and matters observed under the FDA's investigatory authority. While courts are divided on the admissibility of evaluative reports under this exception, ***the Advisory Committee notes to this rule encourage courts to admit this evidence*** unless 'sufficient negative factors are present.' Fed. R. Evid. 408 advisory committee's notes. These negative factors are (1) the timeliness of the investigation, (2) the special skill or experience of the official, (3) whether a hearing was held, and (4) possible motivational problems. *Id.* The Court finds that only one of these factors-holding a hearing-weighs against the trustworthiness of these documents. However, when balanced with the other three factors, the trustworthiness indicators are sufficient to support admissibility of the evidence. ***FDA officials conducted the investigation themselves as a neutral party with motivations to protect public health and safety. Therefore, the Court finds these documents sufficiently reliable to be excepted***

[5] *See, e.g., Weaver v. State*, 121 P.2d 1016, 1017 (Okla. Crim. App. 1942) (finding admission of hearsay not prejudicial to defendant under the facts and circumstances of the case, "since it was tried before the court without a jury and there was sufficient evidence offered by the state to connect defendant with possession of the whisky without resort to inadmissible statements.").

from the hearsay rule.

Sadler v. Advanced Bionics, Inc., 2013 U.S. Dist. LEXIS 42256, *5-7 (W.D. Ky. Mar. 26, 2013); *see also Guthrie v. Ball*, No. 1:11-cv-333-SKL, 2014 U.S. Dist. LEXIS 148900, at *9 (E.D. Tenn. Oct. 17, 2014) ("Courts have held that FDA warnings . . . are admissible under the public records hearsay exception in Rule 803(8)") (citations omitted); *Sabel v. Mead Johnson & Co.*, 737 F. Supp. 135, 141 (D. Mass. May 14, 1990) (finding FDA letter recommending a warning label admissible as a public record where it was based on an investigation pursuant to the FDA's regulation of the safe marketing of prescription drugs). Here, the State is not an agency seeking to use its own documents, so satisfying trustworthiness indicators would not even be required. But even if it were, like in *Sadler*, at least three of the four "trustworthiness indicators" support admission of the 2004 FDA Warning Letter. Indeed, the burden is on Janssen/J&J, as the party opposing admission of the 2004 FDA Warning Letter, to demonstrate its untrustworthiness. Janssen/J&J have failed to even attempt to meet that burden. As such, the 2004 FDA Warning Letter is plainly admissible under the public records exception to the hearsay rule. *See, e.g., In re Bard IVC Filters Prods. Liab. Litig.*, 2018 U.S. Dist. LEXIS 33263, *313-314 (D. Az. Mar. 1, 2018) ("The warning letter reports the FDA's factual findings and matters observed under the agency's investigatory authority, and Janssen/J&J have not shown that the letter lacks trustworthiness.").[6]

[6] Janssen/J&J argue the public records exception does not cover "factual findings resulting from special investigation of a particular complaint, case or incident." But this only applies if that agency, *i.e.*, the FDA, is using the records against a party. That is not the case here. Janssen/J&J claim this language has been applied to hold that FDA warning letters arise from just such a special investigation, therefore rendering them hearsay after all. Janssen/J&J's support for this argument lies in a single opinion issued by the Arkansas Supreme Court, *Ortho-McNeil-Janssen Pharm., Inc. v. State*, 432 S.W.3d 563 (Ark. 2014). There, the State of Arkansas "relied almost exclusively on the content of the [warning] letter to prove its claim under the DTPA." 432 S.W.3d at 574. That clearly is not the case here. The State of Oklahoma is not relying "exclusively" on the content of the 2004 FDA Warning Letter to prove its claim of nuisance. Instead, the State is offering the 2004

2. The 2004 FDA Warning Letter Should not be Excluded as Prejudicial

In a final attempt to exclude the 2004 FDA Warning Letter from this bench trial, Janssen/J&J weakly argue such evidence would cause Janssen/J&J "severe undue prejudice." However, this argument has no place in this bench trial where prejudice exclusions are improper, as Janssen/J&J acknowledge. *See* Mot. at 6 (citing *United States v. Kienlen*, 349 Fed. Appx. 349, 351 (10th Cir. 2009) ("Other circuits have held, and we agree, that excluding evidence in a bench trial under 'Rule 403's weighing of probative value against prejudice [is] improper.' *Gulf States Utils. Co. v. Ecodyne Corp.*, 635 F.2d 517, 519 (5th Cir. 1981); *see also Schultz v. Butcher,* 24 F.3d 626, 632 (4th Cir. 1994) (stating that, in bench trials, 'evidence should not be excluded under 403 on the ground that it is unfairly prejudicial')).

Moreover, Janssen/J&J's concerns are admittedly not about this case and this judge—but about "exposing prejudicial information to millions of Americans, including countless prospective jurors in hundreds of matters pending against Janssen and J&J across the country." Mot. at 6. But Janssen/J&J's fears of being exposed to the public at large do not constitute grounds for excluding evidence—especially when that evidence is an admissible public record issued by a neutral federal agency with "motivations to protect public health and safety." *Sadler*, 2013 U.S. Dist. LEXIS 42256, at *6-7. Moreover, Janssen/J&J will have ample opportunity to show that the statements in the 2004 FDA Warning Letter are mere observations. And the Court, as the factfinder, can determine whether to temper any undue weight as to opinions contained in the 2004 FDA Warning Letter. As such, the 2004 FDA Warning Letter should not be excluded as prejudicial in this bench trial.

FDA Warning Letter as some evidence, the weight of which this Court can determine as the trier of fact.

CONCLUSION

For the reasons set forth above, the State respectfully requests the Court deny Janssen's Motion *in Limine* #10 in its entirety, and for such further relief the Court deems proper.

Respectfully submitted,

Michael Burrage, OBA No. 1350
Reggie Whitten, OBA No. 9576
WHITTEN BURRAGE
512 N. Broadway Avenue, Suite 300
Oklahoma City, OK 73102
Telephone: (405) 516-7800
Facsimile: (405) 516-7859
Emails: mburrage@whittenburragelaw.com
rwhitten@whittenburragelaw.com

Mike Hunter, OBA No. 4503
ATTORNEY GENERAL FOR
THE STATE OF OKLAHOMA
Abby Dillsaver, OBA No. 20675
GENERAL COUNSEL TO
THE ATTORNEY GENERAL
Ethan A. Shaner, OBA No. 30916
DEPUTY GENERAL COUNSEL
313 N.E. 21st Street
Oklahoma City, OK 73105
Telephone: (405) 521-3921
Facsimile: (405) 521-6246
Emails: abby.dillsaver@oag.ok.gov

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the above and foregoing was emailed on May 3, 2019 to:

Johnson & Johnson, Janssen Pharmaceuticals Inc, Ortho McNeil Janssen Pharmaceuticals Inc., Janssen Pharmaceuticals Inc., Janssen Pharmaceutica Inc.:

Benjamin H. Odom
John H. Sparks
Michael W. Ridgeway
David L. Kinney
ODOM, SPARKS & JONES PLLC
HiPoint Office Building
2500 McGee Drive Ste. 140
Norman, OK 73072

Larry D. Ottaway
Amy Sherry Fischer
FOLIART, HUFF, OTTAWAY & BOTTOM
201 Robert S. Kerr Avenue, 12th Floor
Oklahoma City, OK 73102

Stephen D. Brody
David K. Roberts
Emilie Winckel
O'MELVENY & MYERS LLP
1625 Eye Street NW
Washington, DC 20006

Charles C. Lifland
Jennifer D. Cardelus
Wallace M. Allan
Sabrina H. Strong
Esteban Rodriguez
Houman Ehsan
O'MELVENY & MYERS LLP
400 S. Hope Street
Los Angeles, CA 90071

Michael Yoder
Jeffrey Barker
Amy J. Laurendau
O'MELVENY & MYERS LLP
610 Newport Center Drive
Newport Beach, CA 92660

Daniel J. Franklin
Ross Galin
Desirae Krislie Cubero Tongco
Vinvent Weisbnad
O'MELVENY & MYERS LLP
7 Times Square
New York, NY 10036

Amy Riley Lucas
Jessica Waddle
O'MELVENY & MYERS LLP
1999 Avenue of the Stars, 8th Floor
Los Angeles, California 9006

Allergan Plc, Actavis Plc, Actavis Inc., Watson Laboratories Inc., Watson Pharmaceuticals Inc., Actavis Llc, Actavis Pharma Inc., Watson Pharma Inc.:

Robert G. McCampbell
Travis J. Jett
Nicholas V. Merkley
Ashley E. Quinn
Jeffrey A. Curran
GABLEGOTWALS
One Leadership Square, 15th Floor
211 North Robinson
Oklahoma City, OK 73102-7255

Brian M. Ercole
Martha Leibell
Melissa Coates
MORGAN, LEWIS & BOCKIUS LLP
200 S. Biscayne Blvd., Suite 5300
Miami, FL 33131

Steven A. Reed
Harvey Bartle IV
Jeremy A. Menkowitz
Evan K. Jacobs
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921

Mark A. Fiore
MORGAN, LEWIS & BOCKIUS LLP
502 Carnegie Center
Princeton, NJ 08540

Steven Andrew Luxton
MORGAN, LEWIS & BOCKIUS LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004

Michael Burrage