**IN THE SUPREME COURT OF THE STATE OF NEVADA**

TEVA PARENTERAL MEDICINES, INC., fka SICOR, INC.; BAXTER HEALTHCARE CORPORATION; and MCKESSON MEDICAL-SURGICAL INC.,

Petitioners,

v.

THE EIGHTH JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA, IN AND FOR THE COUNTY OF CLARK; THE HONORABLE TREVOR ATKINS, DISTRICT JUDGE, DEPT. 8; THE HONORABLE NANCY ALLF, DEPT. 27; and THE HONORABLE JIM CROCKETT, DISTRICT JUDGE, DEPT. 24,

Respondents,

And Concerning:

YVETTE ADAMS; *ET AL*.; SOSSY ABADJIAN, *ET AL*.; and MAUREEN BRIDGES, *ET AL*.,

Real Parties in Interest.

Supreme Court Case No.: 81024



D. Ct. Case No.: A-18-778471-C

Consolidated with:

A-18-781820-C [*Abadjian, et al*.] and A-18-782023-C [*Bridges, et al*.]

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**ANSWER TO PETITION FOR WRIT OF MANDAMUS**

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## NRAP 26.1 DISCLOSURE

The undersigned counsel of record certifies that the following are persons and entities as described in NRAP 26.1(a), and must be disclosed. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

1. Real Parties in Interest as listed below are all individuals.
   YVETTE ADAMS; MARGARET ADYMY; THELMA ANDERSON; JOHN ANDREWS; MARIA ARTIGA; LUPITA AVILA- MEDEL; HENRY AYOUB; JOYCE BAKKEDAHL; DONALD BECKER; JAMES BEDINO; EDWARD BENAVENTE; MARGARITA BENAVENTE; SUSAN BIEGLER; KENNETH BURT; MARGARET CALAVAN; MARCELINA CASTANEDA; VICKIE COLE-CAMPBELL; SHERRILL COLEMAN; NANCY COOK; JAMES DUARTE; and

   SOSSY ABADJIAN; GLORIA ACKERMAN; VIRGINIA ADARVE; FRANCIS ADLER; CARMEN AGUILAR; RENE NARCISO; RHEA ALDER; GEORGE ALLSHOUSE; SOCORRO ALLSHOUSE; LINDA ALPY; JOYCE ALVAREZ; REBECCA L. ANDERSON ANDREI; EMANUEL; TERRIE ANTLES; KELLIE APPLETON-HULTZ; ANTHONY ARCHULETA; ESTEBAN ARELLANOS; RICKIE ARIAS; MARK ARKENBURG; ROGER ARRIOLA; MARIA ARTIGA; ROBIN ASBERRY; WINIFRED BABCOCK; ROBERT BACH; SUSAN F. BACHAND; ELAINE BAGLEY-TENNER; MELISSA BAL; BRYAN BALDRIDGE; RONALD BARKER; RONALD BARNCORD; PEGGY JO BARNHART; DONALD BARTLETT; SHERYLE BARTLETT; JOSEPH BAUDOIN; BARBARA BAXTER; VENUS BEAMON; BARBARA ROBIN BEATTY; RODNEY BEHLINGS; CRISTINA BEJARAN; TOMAS BENEDETTI; VERNA BENFORD; RICHARD BENKERT; MARSHALL BERGERON; DONNA BERGERON; SYLVIA BIVONA; ROBERT BLAIR; HARRY BLAKELEY; DAWN BLANCHARD; BONNIE BLOSS; DARRELL BOLAR; ROY BOLDEN; VICTOR BONILLA; GRACIELA BORRAYES; BILLY BOWEN; SHIRLEY BOWERS; SHIRLEY

BRADLEY; CARLA BRAUER; CAROLYN BROWN; JACK BROWN; LESLIE BROWN; MICHAEL BROWN; ROBERTA BROWN; AMELIA B. BRUNS; CARL L. BURCHARD; TRACI BURKS; ELIZABETH BURTON; ANGELITE BUSTAMANTE- RAMIREZ; ANASTASIO BUSTAMANTE; DOROTHY ANN BUTLER; LEE CALCATERRA; EVELYN CAMPBELL; MARIA CAMPOS; BOONYUEN CANACARIS; MELISSA CAPANDA; MARTIN CAPERELL; PEDRO CARDONA; SUSIE CARNEY; TERESA CARR; BERNARDINO CARRASCO; TRUMAN CARTER; XANDRA CASTO; SPENCE CAUDLE; MARGARET CAUSEY; XAVIER CEBALLOS; ROBERT CEDENO; DINORA CENTENO; ROY CHASE; CARIDAD CHEA; ELSA CHEVEZ; LUCILLE CHILDS; ALICIA CLARK; CAROL CLARK; PATRICIA CLARK; RICHARD COIRO; PERCELL COLLINS, JR.; ERNEST CONNER; SUSAN COREY; PATRICIA CORREA; PAUL A. COULOMBE; AMBER CRAWFORD; RONALD CROCKER; HOWARD CROSS; ROSSLYN CROSSLEY; WILLIAM R. DANIELS.; EVELYN DAVIS; MARY JEAN DAVIS; VIRGINIA A. DAVIS; JESSIE L. DAWSON; EMELYN DELACRUZ; SILVIA DERAS; SHERIDA DEVINE; CLAIRE DIAMOND; JOSE DIAZ-PEREZ; OTIS L. DIXON; EMILIO DOLPIES; PAMELA DOMINGUEZ; EUQENA DOMKOSKI; JOSEPH DONATO; HUGO DONIS; PATRICIA L. DONLEY; LJUBICA DRAGANIC; DELORIS K. DUCK; KATHLEEN J. DUHS; LILLIAN DUNCAN; HAROLD DUSYK; ALLYSON R. DYER, JR.; LOIS EASLEY; DEISY ECHEVERRIA; ROLAND E. ELAURIA; DARIO E. ESCALA; ENGARCIA B. ESCALA; KATHY A. ESCALERA; MARIA ESCOBEDO; TERESA I. ESPINOSA; LEON EVANS; MARY FAULKNER; ABRAHAM FEINGOLD; MURIEL FEINGOLD; OSCAR FENNELL; MARIETTA FERGUSON; WILLIE FERGUSON; DANIEL FERRANTE; CAROLYN FICKLIN; JOE FILBECK; ETHEL FINEBERG; MADELINE C. FINN; ALBERT L. FITCH; ADRIAN FLORES; MARIA FLORES; RAUNA FOREMASTER; JOSEPH E. FOSTER; PHYLLIS G. FOSTER;CYNTHIA D. FRAZIER; VICTORIA FREEMAN; LAWRENCE FRIEL; BONITA M. FRIESEN; NESS FRILLARTE; NANCY C. FRISBY; JODI GAINES; ESPERANZA GALLEGOS; NEOHMI GALLEGOS; BRENDA GARCIA; MARTHA GARCIA; SANDRA GARDNER; MICHAEL GARVEY; E THERESA GEORG; TINA GIANNOPOULOS; ARIS GIANNOPOULOS; WANDA GILBERT; JEAN GOLDEN; GOLOB LUCIANO; PASTOR GONZALES; JESUS GONZALEZ- TORRES; JEFF GOTLIEB; ALLEN GOUDY; BILL GRATTAN; ARNOLD GRAY; BONNIE GRAY; TANIA GREEN; ROY GREGORICH; WILLIE GRIFFIN;

VERNA GRIMES; CANDELARIO GUEVARA; NICHOLAS GULLI; JULIA GUTIERREZ; DENISE F. HACHEZ; SUE HADJES; FRANK J. HALL; TINA HALL; CHARDAI C. HAMBLIN; ROBERT HAMILTON, JR.; JOANN HARPER; DORIS HARRIS; GLORICE HARRISON; SHARA HARRISON; RONALD K. HARTLEY; ESTHER A. HAYASHI; SAMUEL HAYES; CANDIDO HERNANDEZ; MARIA HERNANDEZ; THOMAS HERROLD; LUZ HERRON; SUSAN M. HILL; ISHEKA HINER; ARLENE HOARD; BETH HOBBS; MICHELLE HOLLIS; JAQUELINE A. HOLMES; JAMES HORVATH; ANA HOSTLER; AUGUSTAVE HOULE; CARL II; HOWARD HOVIETZ; RUTH HOWARD; MICHELE HOWFORD; EDWARD L. HUEBNER; LOVETTE M. HUGHES; VIRIGINIA M. HUNTER; PATRICIA HURTADO-MIGUEL; ANGELA HYYPPA; JOSEPH INFUSO; FRANK INTERDONATI; BRIAN IREY; CECIL JACKSON; ROLANDO JARAMILLO; RICHARD JILES; LETHA JILES; CLIFTON JOHNSON; DORIS JOHNSON; JOHNNY JOHNSON; JOYCE JOHNSON; ARNOLD JONES; ANN KABADAIAN; ANTHONY K. KALETA; ARUN KAPOOR; LINDA J. KEELER; MICHAEL F. KELLY; DARRELL KIDD; CONNIE KIM; SOO-OK KIM; TAESOOK KIM; SONDRA I. KIMBERS; ELIZABETH I. KINDLER; IRIS L KING; JOANNA KOENIG; MICHAEL J. KRACHENFELS; CORINNE M. KRAMER; DAVID KROITOR; OLGA KUNIK; KAREN A. KUNZIG; ANEITA LAFOUNTAIN; BARBARA LAKE; BERTHA LAUREL; ANGES G. LAURON; MARIE LAWSON; PHYLLIS LEBLANC; ARLENE LETANG; JAMES A. LEWIS; JOAN LIEBSCHUTZ; MINERVA L. LIM; EDWARD LINDSEY; WILLIAM LITTLE; DOROTHY LIVINGSTON-STEEL; FELISA LOPEZ; IRAIDA LOPEZ; NOE LOPEZ; FLORENCE LUCAS; DARLENE LUTHER; FRANK L LYLES; DEBORAH MADRID; MARWA MAIWAND; DOROTHY J. MAJOR; MARIO MALDONADO; IDA MALWITZ; AUDREY MANUEL; GABRIEL MARES; CAROL A. MARQUEZ.; HUGO MARTINEZ; JORGE B. MARTINEZ; JOSE MARTINEZ; MARY LOUISE MASCARI; LUCY MASTRIAN; LEROY MAYS; LISA MAYS; VIRGINIA A. MCCALL ; STELLA MCCRAY; LAURENCE MCDANIEL; JOHN MCDAVID, JR.; DOLORES MCDONNELL; DENISE ANNE MCGEE; MAE MCKINNEY; JANET MCKNIGHT; FRED MCMILLEN, III; MYRON MEACHAM; AIDA A. MEKHJIAN; CHELSEY L. MELLOR; JIGGERSON MENDOZA; SUSAN MERRELL-CLAPP; JAMES MIDDAUGH; SYLVIA MILBURN; CORINNE MILLER; JANICE MITCHEL; MIKHAIL MIZHIRITSKY; KIRK MOLITOR; MARY MOORE; JOSE MORA; YOLANDA

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2. Identify all parent corporations and any publicly held company that owns 10% or more of the party's stock:

NONE

3. Names of all law firms whose partners or associates have appeared for the party or amicus in the case (including proceedings in the district court before an administrative agency) or are expected to appear in the court:

   Peter C. Wetherall, Esq. – WETHERALL GROUP, LTD.

   Glen Lerner, Esq. – LERNER AND ROWE

4. If any litigant is using a pseudonym, disclose the litigant's true name:

   NONE

DATED this 2nd day of June, 2020.

WETHERALL GROUP, LTD.

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## NRAP 21(a)(3) Routing Statement

The Nevada Supreme Court should retain this writ proceeding, as resolution of these issues will require the consideration of matters of first impression relating to Nevada's products liability law, and federal law's preemption of this state's tort law. *See* NRAP 17(11).

Real Parties in Interest respectfully submit this (consolidated) Answer to the Petition for Writ of Mandamus filed by Petitioners.

## INTRODUCTION AND STATEMENT OF RELIEF SOUGHT

Petitioners ("Defendants" hereafter) seek the outright dismissal of nearly 800 Endoscopy "non-infected" claims on the grounds that each and every cause of action being pursued by Real Parties in Interest ("Plaintiffs" hereafter) is allegedly "preempted by federal law". PET., p. 1. In addition to Plaintiffs' product liability claims, Defendants contend that even Plaintiffs' *negligence* and *DTPA* claims are preempted. Defendants preemption arguments have been rejected by the federal judges who previously presided over these cases (as a result of Defendants' removal of same), and the three District Court judges who denied Defendants' three Motions to Dismiss and one Motion for Reconsideration.

The reason for Defendants' repeated prior defeats is clear: Defendants cannot meet the standard for ("impossibility") preemption which *even they acknowledge* applies here, namely, that state law claims are only preempted where generic pharmaceutical manufacturers are required to: 1) alter the design or formulation of a drug product, 2) enhance the warning labels affixed to the drug product, or 3) "stop selling" the drug product **"altogether"** to avoid liability. PET., p. 2-3; and at p. 4, fn. 3 (citing Wagner v. Teva Pharms. USA, Inc., 840 F3d 355, 358 (7th Cir.

2016). The crux of Plaintiffs' claims, however, and the one most obviously *not* preempted, is that Defendants should not have been selling 50ml bottles of propofol to ambulatory surgical centers such as the subject Endoscopy Clinics, because Defendants knew or should have known from past incidents of double-dipping that selling such large bottles of propofol ***to ambulatory surgical centers specifically*** created a risk and temptation for abuse – precisely of the type that occurred in Clark County and which resulted in the 2008 Hepatitis epidemic here.

As tempting as it is to match Defendants' briefing page-for-page, the resolution of this Writ really requires no further analysis than that. Plaintiffs' Complaints fairly allege that it was imprudent, negligent and reckless for Defendants to sell 50ml bottles of propofol to ambulatory surgical centers whose procedures required only 10-20ml of propofol per patient. Selling FDA-approved single-dose vials to ambulatory surgical clinics (as opposed to multi-use vials) does not render it *impossible* for Defendants to comply with the United States Federal Food, Drug, Device and Cosmetic Act ("FDCA") and Nevada state law.

The "impossibility" preemption defense is simply not available to Defendants here. Holding Defendants responsible for selling the arguably wrong-sized bottle to certain facilities is not the same as imposing a requirement upon them to stop selling "altogether", thus Defendants' argument for "impossibility" preemption fails, and their Writ should be denied.

Dressed up in concerns about judicial overload if Plaintiffs' claims are allowed to go forward, Defendants ask this Court to do the expedient thing and just get rid of these cases. PET., pp. 1, 6. The fact is, these cases have already been consolidated before one judge, and the Parties have already stipulated to: 1) deem these cases complex; 2) appoint The Hon. Jennifer Togliatti, Ret. as Special Master and Settlement Judge, and 3) stay further proceedings pending the outcome of this Writ. APP. VII, pp. 1575-1582. There is minimal burden upon the Courts as yet, and no likelihood of that ever occurring under the steady and experienced guidance of the trial court and Special Master/Settlement Judge.

Nevertheless, Plaintiffs are as eager as Defendants to have this preemption issue resolved, albeit with a denying of the Writ rather than a granting of it. For the more fully-developed reasons that follow, this Writ which seeks the dismissal of the entirety of Plaintiffs' claims should be denied.

## STATEMENT OF THE CASE AND THE FACTS

Plaintiffs herein constitute but a handful of the tens of thousands of recipients of the CDC/SNHD letters sent in 2008 which warned Endoscopy Center patients who treated at specific Gastroenterology Centers in Clark County, Nevada of possible infection with Hepatitis B, Hepatitis C, and HIV. CDC Press Release, APP. V, pp. 1098-99. Plaintiffs herein were encouraged by that letter – and the ensuing

publicity this public health catastrophe occasioned – to get tested for these communicable infections. Plaintiffs herein dutifully obtained the necessary testing, and remained in mortal fear of a life-altering infection until such time as their testing sufficiently confirmed no infection. Thus, Plaintiffs are all "non-infected Endoscopy Plaintiffs" who have sued to obtain compensation for the costs of their testing as well as the pain and suffering associated with their need to be tested, sometimes retested, and awaiting the results before being assured they and their loved ones did not suffer the fate of actual infection created by the aforementioned outbreak which befell so many others. Plaintiffs' cases were all tolled until recently, when the Parties' longstanding efforts to reach a settlement resulted in impasse.

The *Adams* lawsuit was originally filed in state court on July 26, 2018. APP. I, pp. 1-13. The *Abadjian* lawsuit was filed on September 27, 2018. APP. I, pp. 14-29. The *Bridges* lawsuit was filed on October 1, 2018. APP. I, pp. 30-45. Defendants removed all three cases of these cases to federal court on December 10, 2018. Defendants specifically cited in their Notice(s) of Removal "impossibility" preemption as one reason why this case belonged in federal court. Immediately thereafter, on December 17, 2018, Defendants filed a Motion to Dismiss in federal court **virtually identical to the Motions giving rise to this Writ** in *Bridges,* premised predominantly on "impossibility preemption".

Plaintiffs filed their Motions for Remand in each case on January 9, 2019, based solely upon Defendants' failure to meet the amount in controversy requirement for federal jurisdiction. In response, Defendants filed their Oppositions to Plaintiffs' Motions to Remand on January 23, 2019, again arguing extensively that "impossibility" preemption not only warranted federal court jurisdiction, but also the dismissal of Plaintiffs' lawsuit entirely. This was an admittedly clever strategy by Defendants – to telegraph to the federal court judges that they could assume jurisdiction over these cases only to then clear their dockets of them on preemption grounds, but it backfired.

While Plaintiffs' Motions to Remand were pending, the Parties stipulated to stay briefing on Defendants' Motion to Dismiss, as that Motion would be rendered moot (in federal court) if remand back to state court was granted. Thereafter, on April 12, 2019, the Federal District Court, Honorable James C. Mahan presiding, entered an Order granting remand in the *Bridges* case. On August 23, 2019, Judge Mahan entered an Order granting remand in the *Abadjian* case. On August 26, 2019, the Federal District Court, Chief Judge Gloria M. Navarro presiding, entered an Order granting remand in the *Adams* case.

In each federal Order granting remand, the Court felt compelled to address Defendants' multiple efforts to argue that "impossibility" preemption not only

justified federal jurisdiction, but the outright dismissal of Plaintiffs' Complaint. In his two Orders, Judge Mahan stated:

> The court notes that defendants' arguments are unclear, incoherent, and at times confused. **Some paragraphs from defendants' brief appear to assert that the court has jurisdiction because the FDCA preempts plaintiffs' state law claims. To ensure complete adjudication of all pertinent issues that the parties raise, the court will consider this argument**.
>
> The "complete preemption doctrine" allows district courts to exercise federal question jurisdiction over state law claims when a federal statute completely preempts the relevant state law. *Balcorta v. Twentieth Century-Fox Film Corp.*, 208 F.3d 1102, 1107 (9th Cir. 2000) (citation omitted). Courts consider the factual allegations in the complaint and the petition of removal to determine whether federal law completely preempts a state law claim. *Schroeder v. Trans World Airlines, Inc.*, 702 F.2d 189, 191 (9th Cir. 1983).
>
> It is well established that the FDCA does not completely preempt state law. *See Oregon ex rel. Kroger v. Johnson & Johnson*, 832 F. Supp. 2d 1250, 1259–60 (D. Or. 2011); *see also Perez v. Nidek Co. Ltd.*, 657 F. Supp. 2d 1156, 1161 (S.D. Cal. 2009); *see also Alaska v. Eli Lilly & Co.*, No. 3:06-cv-88 TMB, 2006 WL 2168831 at *3–4 (D. Ala July 28, 2006). **Therefore, the court does not have federal question jurisdiction under the complete preemption doctrine**.

*See* Order [Granting Remand] in *Bridges*, dated April 12, 2019. APP. V, pp. 1101-07, internally, at 6:8-22 (bold and underline emphasis added).

Judge Mahan went on to conclude, "[T]he FDCA does not completely preempt plaintiffs' state law claims." *Id*., internal cite is 8:26. Judge Mahan's Order in Abadjian is near identical. *See* Order [Granting Remand] in *Abadjian*, dated August 23, 2019. APP. V, pp. 1146-53, internal cite is 6:25-7:11; and 7:15.

Judge Navarro independently reached the same conclusions in the *Adams* case, albeit while also citing Judge Mahan's Order in *Bridges* with approval. *See* Order [Granting Remand] in *Adams*, dated August 26, 2019. APP V, pp. 1155-66, internal cite is 9:7-10; see also 8:1-9:16.

Immediately upon the remand of the *Bridges* case, Defendants again sought to ply their preemption arguments in state court in essentially identical Motions to Dismiss filed in *Bridges*, *Abadjian* and *Adams*. Following oral argument, Judge Crockett entered his Order denying Defendants' Motion to Dismiss on November 12, 2019. APP. VII, pp. 1493-98. Also following oral argument, Judge Atkin and Judge Allf entered their Orders denying Defendants' Motions to Dismiss on December 23, 2019 (in *Adams*, APP. VII, pp. 1523-24), and January 14, 2020 (in *Abadjian*, APP. VII, pp. 1550-51), respectively. In *Bridges*, Defendants then filed a Motion for Reconsideration, also denied, by Order entered on March 9, 2020. APP. VII, pp. 1587-1590. **In sum, Defendants have serially pursued their "impossibility" preemption grounds for dismissal, accruing two federal judges (on three occasions) and four EJDC rulings against them thus far.**

Consistent with prior lawsuits filed in this litigation, Plaintiffs' Complaints assert claims for: 1) strict products liability; 2) breach of the implied warranty of fitness for a particular purpose; 3) negligence; 4) violation of the Nevada Deceptive Trade Practices Act; and 5) punitive damages.

## STANDARD OF REVIEW

Plaintiffs concur with Defendants' recitation of the standard of review on Writ of Mandamus.

## REASONS WHY MANDAMUS SHOULD BE DENIED

A complaint should be dismissed for failure to state a claim "only if it appears beyond a doubt that [the plaintiff] could prove no set of facts, which, if true, would entitle [the plaintiff] to relief." *Alcantara ex rel. Alcantara v. Wal-Mart Stores, Inc.*, 130 Nev... 252, 256, 321 P.3d 912, 914 (2014), citing *Buzz Stew, L.L.C. v. City of N. Las Vegas*, 124 Nev. 224, 227–28, 181 P.3d 670, 672 (2008).

Defendants' arguments for dismissal boil down to three assertions: First, "Defendants were not the wrongdoers". *PET, at 8-9*. Second, every claim against Defendants must be dismissed because they are preempted by federal law" pursuant to the doctrine of "impossibility" preemption. *Id*., at 28-35. Third, the District Courts' rationales for denying Defendants' Motions to Dismiss do not withstand scrutiny. *Id*. at 35-42.

It is worth noting that Defendants additionally argued in their Motions to Dismiss below that each of Plaintiffs' causes of action are "missing the essential element of causation or is otherwise invalid as a matter of law". *Id*., at 3:16-17. That argument has apparently been abandoned for purposes of this Writ, leaving

Defendants in the untenable position of now arguing that every claim for relief is subject to "impossibility" preemption – not just those sounding in a failure to warn.

None of Defendants' grounds for dismissal have merit, and Mandamus should therefore not be conferred for the reasons that follow.

## I. DEFENDANTS ARE CONFIRMED WRONGDOERS WITH REGARD TO THEIR SALE AND DISTRIBUTION OF PROPOFOL TO THE SUBJECT ENDOSCOPY CLINICS.

Defendants contend that they cannot and should not be liable for the harm done to Plaintiffs merely because others were criminally tried and convicted for contributing to the harm done. Defendants made this same argument while litigating and trying the "infection" Endoscopy cases years ago, and never prevailed before any judge or jury on this point.

### A. Defendants Offer No Statutory or Case Authority Supporting Their Claim of Absolute Immunity Arising Out of the Criminal Acts of Others.

These Defendants' civil liability, and the Endoscopy Clinic owners/operators' criminal liability, are not mutually exclusive. The bad acts of the Endoscopy Clinic owners/operators do not provide immunity to these product Defendants. Despite detailing the criminal proceedings against others which paralleled the civil lawsuits brought here, Defendants have failed to provide any case authority supporting Defendants' absolute immunity from suit for reasons relating to the various criminal convictions. In fact, there is no such case authority. One need look no further than

the Oct. 1 shooting litigation to see that criminal culpability and civil liability can indeed run parallel in the same case.

In the absence of case authority which clearly extends immunity to Defendants due to the criminal acts of Dr. Desai and others, this argument must be rejected. Defendants are free to argue that Dr. Desai's and others' acts constituted supervening causes of the harm to Plaintiffs, but that is an argument for a jury and not this Court to consider on a Writ.

### B. Defendants' Culpability for Contributing to Causing the Endoscopy Catastrophe is Well-Documented.

The gravity of Defendants' wrongdoing is perhaps no better reflected than in the multiple verdicts and judgments obtained against them, for identical grounds as being asserted here, which constitute the largest personal injury verdicts in Nevada history. *See*, *Chanin* Judgment, dated June 1, 2010 w/Verdict(s) dated May 5 and 7, 2010 (APP. V, pp. 1168-75); *Sacks, Arnold, Devito* Judgment, dated November 16, 2011 w/Verdict(s), dated October 6 and 10, 2011 (APP. V, pp. 1177-90); and *Washington* Judgment, dated October 19, 2011 w/Verdict(s) dated October 10 and 12, 2011 (APP V, pp. 1192-1200).

Notably, each of these verdicts was obtained long after the U.S. Supreme Court's seminal preemption decision in *Wyeth v. Levine*, 555 U.S. 555 (2009), a case upon which Defendants here rely. PET. , pp. 31. The *Sacks, et al*. and *Washington*

verdicts were obtained after the U.S. Supreme Court's decision in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) was handed down June 23, 2011, another case upon which Defendants rely extensively. PET., pp. 2, 3, 6, 7, 25, 29, 33, 36, 37, 38, 40, 42. Rather than proceeding to trial on hundreds of other infection cases, or pressing appeals against the aforementioned verdicts in order to vindicate their preemption arguments, these Defendants bought their peace for amounts "widely reported in the media to be hundreds of millions of dollars." https://armadr.com/hon-jennifer-togliatti-ret-2/.

The facts giving rise to these non-infected Plaintiffs' claims are identical to the infection cases, the claims are the same, and the cases relied upon by Defendants in seeking dismissal now are the same as those which were unsuccessfully proffered to various District Court judges previously. The only substantive difference is the damages here are less severe, because these Plaintiffs did not get infected by Hepatitis, they were "only" caused (by the actions of these Defendants) to fear infection for as long a period of time as it took their testing to clear and their concerns to be allayed. These types of damages are actionable. *Sadler v. Pacificare of Nev., Inc.*, 130 Nev.990, 340 P.3d 1264 (2014) (Non-infected Endoscopy claimants suffered a cognizable "injury" despite not being infected and can pursue damage claims, including medical monitoring).

## II. "IMPOSSIBILITY" PREEMPTION DOCTRINE DOES NOT IMMUNIZE DEFENDANTS FROM LIABILITY HERE.

In order to make their untenable argument that every cause of action in Plaintiffs' Complaints need be dismissed – not just those sounding in failure to warn – Defendants mislead in two respects.

### A. None of Plaintiffs' Claims Are Subject to Dismissal on Preemption Grounds, and Certainly Not All of Them.

First, Defendants summarily assert that **all** of Plaintiffs' claims are essentially (product liability) failure to warn claims. In that regard, one need look no further than the distinct elements required of each of Plaintiffs' causes of action to see the fallacy in this argument.

Nonetheless, Defendants' Writ asserts that the entire case at bar should be dismissed because Plaintiffs' causes of action are all essentially failure to warn claims that should be preempted by the FDCA as indicated in *PLIVA* cited *supra*, and *Mutual Pharmaceutical, Co., Inc. v. Bartlett*. 570 U.S. 472 (2013). This is simply untrue.

Plaintiffs' Complaints do present factual statements and allegations about warnings and knowledge with which Plaintiffs charge the Defendants, but it is in the context of alleging the defective design of the vials Defendants provided to the endoscopy clinic at the heart of this case, i.e., multi-dose vials of propofol which

the Defendants and the medical and public health community at large knew subjected patients to infection of blood borne diseases.

It is well established, as recognized by Judge Mahan and Judge Navarro, cited *supra*, that the FDCA does not completely preempt all of a plaintiffs' state law claims, nor does it provide blanket immunity. *In re: Fosamax Products Liab. Litig.,* 965 F.Supp.2d 413, 417-18 (S.D.N.Y. 2013); *Phelps v. Wyeth, Inc., Pliva USA, Inc., et al*., 938 F.Supp.2d 1055, 1061 (D. Or. 2013); *Johnson v. Teva Pharmaceuticals USA, Inc.*, 2012 WL 1866839, at *3 (W.D. La. May 21, 2012) aff'd, 785 F.3d 605 (5th Cir. 2014). In this regard, Plaintiffs' Complaint pleads narrow and precise strict liability design defect and negligence design claims, both of which survive Defendants' federal preemption defense, as these allegations do not offend these generic drug manufacturers' duties of sameness or allege that they should have stopped selling propofol. Put another way, Plaintiffs' causes of action simply do not create a conflict between Defendants' duties under federal law and their duties arising under Nevada state law.

Allegations of a design defect against a manufacturer of a generic drug which could have only been avoided by altering the active ingredients, route of administration, dosage form, strength or labelling of the brand-name drug, are preempted by the FDCA. *Bartlett*, 570 U.S., at 484. The theory is that because the FDCA requires the generic drug to have the same active ingredients, route of

administration, dosage form, strength, and labelling as the brand-name drug on which the generic is based, it is impossible for a generic manufacturer to comply with both federal and state law because it is impossible to lawfully redesign the generic form rendering it different from the brand-name drug to avoid liability; the practice is forbidden under federal law. *Id*. This is called the duty of sameness, a duty to which all generic drug manufacturers are subject. *PLIVA,* 564 U.S., at 613.

Plaintiffs, however, do not allege Defendants should have acted contra to these federal prohibitions. Rather, the plaintiffs allege that had Defendants simply utilized the FDA-approved design that was available to them and branded manufacturers, i.e., single-dose vials, Plaintiffs would not have suffered the injuries they claim. Plaintiffs stand on the facts and allegations in the operative Complaints to be taken as true, but more specifically, the allegations that the single-dose designed vials were available to them while knowing the risk of not utilizing that design to avoid contamination, are as follows:

- Multiple medical, scientific and public health sources reported whilst Defendants manufactured and sold its generic propofol that infections due to multi-dose vial were reported associated with contamination and patient-to-patient infection, and that the practice of re-using these bottles in clinics was well documented. Complaint, at ¶¶ 20, 22, 23, 24, 28, 34.

- In 2001, Defendants submitted and received FDA-approval for single--dose vials of propofol stating that "a smaller size is safer in the at it may reduce the temptation for dosing multiple patients from a single container

thereby reducing opportunities for microbial contamination." Complaint, at ¶ 30.

- Defendants sold its multi-dose vials to the Clinic where Plaintiffs received propofol. ¶ 8.

Selection of the single-dose vial design for sale to ambulatory surgical centers would not have involved altering the active ingredient in propofol, nor are there any allegations in Plaintiffs' complaint that Defendants should have changed the route of administration, the strength of the drug, or the labelling. Selecting the single-dose design also would not have required defendants to alter the dosage form as prohibited by the FDCA without violating the duty of sameness as the single-dose design was already FDA-approved.

### B. Federal Preemption is Not Implicated Where, as Here, Defendants Were Not Required to Stop Selling.

In the midst of satisfying both federal and state law obligations, no generic manufacturer is required to cease acting **altogether** in order to avoid liability. *Bartlett*, 570 U.S. at 488 (bold emphasis added).

Defendants incorrectly assert that, by contending that Defendants should not have sold 50ml. bottles to ambulatory surgical centers like the Endoscopy clinics in question, Plaintiffs are essentially admitting to a (preempted) "stop-selling" theory of liability. In making this argument, Defendants conveniently conflate stopping

selling *altogether* with merely not selling inappropriately large bottles of a product to types of facilities *known to Defendants* to have abused those products by double-dipping. Plaintiffs' contention that Defendants are liable for selling inappropriately large (50ml) bottles to ambulatory surgery clinics is a far cry from the contention that Defendants should have stopped selling propofol – or even 50ml bottles - altogether. Plaintiffs are making neither claim, as Defendants were free to continue selling as much propofol to the subject ambulatory surgical centers as Defendants wanted, they simply (by Plaintiffs' reckoning) could have and should selected the FDA-approved alternative design (i.e., 10-20 ml. bottles) instead of the unsafe larger bottles.

In this regard, Plaintiffs are not engaging in "wordplay" as Defendants allege (PET., at p. 33). If Defendants were correct that stopping selling 50ml bottles of propofol to ambulatory surgical centers (in favor of simply selling smaller bottles) is akin to requiring Defendants to stop selling "altogether", there should be case law supportive of that view, but Defendants offer none. Plaintiffs are making an entirely distinct claim which neither implicates nor violates federal "impossibility" preemption doctrine.

In previous Endoscopy cases litigated after the *Pliva* decision, several EJDC judges also concluded that federal preemption does <u>*not*</u> bar Plaintiffs' claims. *See*, Decision and Order: Plaintiffs' Motion for Partial Summary Judgment on

Preemption Defense for the Dear Doctor Liability … Product Defendants' Pre-Trial Motion #4, Motion for Summary Judgment on Grounds of Federal Preemption on Order Shortening Time, *Sacks, et al. v. Endoscopy Center of Southern Nevada, LLC, et al.*, Dist. Ct. Case # 08A572315 (Consolidated with 08A576071 and 09A583058), entered July 28, 2011 (APP. V, pp. 1202-04); *see also*, Order Denying Product Defendants' Motion in Limine No. 9 to Exclude Testimony, References or Arguments That Challenge the Sufficiency or Adequacy of the Propofol Warnings Federal Law Compelled Product Defendants to Use, *Washington v. Teva Parenteral Medicines, Inc., et al.*, Dist. Ct. Case # A558164, entered September 9, 2011 (APP. V, pp. 1206-08); see also, Order Granting in Part and Denying in Part Product Defendants' Pre-Trial Motion #7 to Admit Evidence and Expert Testimony of the Hatch-Waxman Act, FDA Regulations, Pharmaceutical Industry Practice, and Product Defendants' Compliance Therewith for Propofol, *Washington v. Teva Parenteral Medicines, Inc., et al.*, entered September 20, 2011 (APP. V, pp. 1210-12). These Orders are relevant because: 1) they show that Defendants have unsuccessfully raised these same arguments previously; and 2) Defendants had multiple opportunities to appeal the huge verdicts against them on preemption grounds, but chose to pay hundreds of millions of dollars to settle those and other Endoscopy claims rather than seeking relief from this Court or the U.S. Supreme Court (if necessary) as they are inexplicably doing now.

Plaintiffs have not alleged any fact or claim where avoidance of such would have required Defendants to act in a manner to violate their duties of sameness or require them to stop selling their product. They simply could have elected to utilize the alternative design available to them which would have avoided Plaintiffs' claims. Nevada has adopted the consumer expectation test in determining if a product is defectively designed. *Ford Motor Company v. Trejo*, 133 Nev. 520, 525, 402 P.3d 649, 653 (2017). In the context of proving that a product was defective under the consumer expectation test, an "[a]lternative design is one factor for the jury to consider when evaluating whether a product is unreasonably dangerous." *Ford Motor Company*, 133 Nev. at 525-526 (citing *McCourt v. J.C. Penney Co.,* 103 Nev. 101, 104, P.2d 696, 698 (1987)). Therefore, a plaintiff may choose to support their case with evidence "that a safer alternative design was feasible at the time of manufacture." *Fyssakis v. Knight Equip. Corp.*, 108 Nev. 212, 214, 826 P.2d 570, 572 (1992). Taking all facts and allegations in the complaint as true, this safer alternative was available to Defendants which clears the standard to survive a motion to dismiss for failure to state a claim, i.e., that it is beyond a doubt that Plaintiffs could ever prove facts that would lead to entitlement of relief. *Buzz Stew,* 124 Nev. 224, 181 P.3d 670, 672 (2008).

On identical facts as will be presented in this case (on the issue of Defendants' liability and amenability to suit), these Defendants have appeared in

multiple courts in this jurisdiction, briefed and argued identical legal theories for their absolution, and in each instance those efforts yielded verdicts and judgments against them.

As discussed above, all of Plaintiffs' other claims have previously been allowed to proceed to trial and judgment in this jurisdiction. To the extent there are technical pleading deficiencies that in the Court's view warrant the amending of Plaintiffs' Complaint, Plaintiffs respectfully request the opportunity to cure any arguable deficiencies, as no prejudice to these Defendants would be incurred thereby.

## CONCLUSION

For each of the foregoing reasons, Plaintiffs respectfully request that Defendants' Writ of Mandamus be Denied.

RESPECTFULLY SUBMITTED this 2nd day of June, 2020.

WETHERALL GROUP, LTD.

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## VERIFICATION

The undersigned declares under the penalty of perjury that he is counsel for Real Parties in Interest and has read the attached Answer to Petition for Writ of Mandamus and that the factual assertions therein are true and correct to the best of his own knowledge, or supported by exhibits contained in the Appendix filed by Petitioners, and that as to such matters so supported, he believes them to be true.

This verification is made pursuant to NRS 15.010.

RESPECTFULLY SUBMITTED this 2nd day of June, 2020.

/s/ *Peter C. Wetherall*
Peter C. Wetherall, Esq.

***CERTIFICATE OF COMPLIANCE WITH NRAP 28 AND 32***

I certify that this brief complies with the formatting requirements of NRAP 32(a)(4), the typeface requirements of NRAP 32(a)(5) and the type style requirements of NRAP 32(a)(6). This brief has been prepared in a proportionally spaced typeface using Microsoft Word with 14-point, double-spaced Times New Roman font.

I further certify that this brief complies with the page-or type-volume limitations of NRAP 32(a)(7). Excluding the parts of the brief exempted by NRAP 32(a)(7)(C), it is proportionately spaced, has a typeface of 14 points or more and contains 4,271 words.

I further certify that I have read this answering brief, and to the best of my knowledge, information, and belief, it is not frivolous or interposed for any improper purpose. I further certify that this brief complies with all applicable Nevada Rules of Appellate Procedure, in particular NRAP 28(e), which requires every assertion in the brief regarding matters in the record to be supported by a reference to the page of the transcript or appendix where the matter relied on is to be found.

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I understand that I may be subject to sanctions in the event that the accompanying brief is not in conformity with the requirements of the Nevada Rules of Appellate Procedure.

RESPECTFULLY SUBMITTED this 2nd day of June, 2020.

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## CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I am an employee of Wetherall Group, Ltd. and that on this 2nd day of June, 2020, a copy of the foregoing ANSWER TO PETITION FOR WRIT OF MANDAMUS was electronically filed with the Clerk of the Court for the Nevada Supreme Court by using the Nevada Supreme Court's E-Filing System (Eflex) and served via U.S. Mail, postage prepaid, on the following individuals:

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*/s/* Kristin L. Smith
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