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; 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

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Supreme Court Case No.:

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

Consolidated with:

A-18-781820-C and
A-18-782023-C

PETITION UNDER NRAP 21 FOR WRIT OF MANDAMUS

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;

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Attorneys for Petitioners

CORPORATE DISCLOSURE STATEMENT

Pursuant to NRAP 26.1, the Petitioners make the following corporation disclosures:

Petitioner Teva Parenteral Medicines, Inc. and Sicor Inc. are indirect, wholly owned subsidiaries of Teva Pharmaceutical Industries Ltd., a publicly traded corporation.

Petitioner Baxter Healthcare Corporation is a publicly traded corporation, has no parent corporation, and no publicly held company owns 10% or more of its stock.

Petitioner McKesson Medical-Surgical Inc. is a publicly traded corporation, has no parent corporation, and no publicly held company owns 10% or more of its stock.

Petitioners have been represented by the following law firm in the proceedings below:

GREENBERG TRAURIG LLP

HYMANSON & HYMANSON

DATED this 16th day of April 2020.

GREENBERG TRAURIG LLP

/s/ Tami D. Cowden

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VERIFICATION

The undersigned declares under the penalty of perjury that she is counsel for Teva Parenteral Medicines, Inc., f/k/a Sicor, Inc.; Baxter Healthcare Corporation; and McKesson Medical-Surgical, Inc. and has read the attached Petition for Writ of Mandamus and that the factual assertions therein are true and correct to the best of her own knowledge, or supported by exhibits contained in the Appendix filed herewith, and that as to such matters so supported, she believes them to be true. This verification is made pursuant to NRS 15.010.

DATED this 16th day of April 2020.

/s/ Tami D. Cowden
Tami D. Cowden

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Petitioners Teva Parenteral Medicines, Inc.; Baxter Healthcare Corporation; and McKesson Medical-Surgical, Inc. (collectively, "Petitioners" or "Teva") respectfully submit this Petition for Writ of Mandamus ("Petition").

INTRODUCTION AND STATEMENT OF RELIEF SOUGHT

Petitioners respectfully request that this Court issue a writ of mandamus directing the district court to dismiss these consolidated cases in their entirety. Such an order is warranted because Plaintiffs' state-law claims are preempted by federal law, U.S. Const. art. VI, cl. 2, and the courts below erred in refusing to follow binding and indistinguishable United States Supreme Court precedent on a matter of controlling federal law. Indeed, if this Court does *not* intervene, the result will be that the federally preempted claims of nearly 800 individual plaintiffs will proceed into full-blown fact and expert discovery, motions practice, and lengthy, expensive, and time-consuming trials—all of which is impossible to reconcile with well-established principles of judicial economy and efficiency. This Court should therefore grant the writ and order the district court to dismiss Plaintiffs' claims in their entirety.

By way of background, this consolidated litigation arises out of the medical-monitoring and emotional-distress injuries that Plaintiffs allegedly suffered due to their treatment at one or more of non-party (and deceased) Dr. Depak Desai's

endoscopy centers.[1] None of these nearly 800 Plaintiffs ever contracted a disease relating to those treatments. Rather than tether their claims to any alleged physical injury, these uninfected Plaintiffs instead filed suit on the theory that Petitioners (who manufactured and/or sold the *generic* drug propofol) should have known that the doctors and other healthcare providers at Desai's endoscopy clinics (with whom Petitioners had no relationship) would ignore the FDA-approved product labeling and choose to criminally misuse 50 mL vials of propofol, and should have therefore stopped selling their FDA-approved 50 mL products to clinics like Desai's.

But Plaintiffs' speculative theory of liability cannot overcome a threshold legal barrier, which is that their claims are all squarely preempted by federal law. As the United States Supreme Court held in *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 570 U.S. 472 (2013), and *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), the Hatch-Waxman Act's amendments to the Federal Food, Drug, and Cosmetic Act (FDCA) preempt *any* state-law claim seeking to permit a jury—as opposed to a specialized regulatory agency like the federal Food and Drug Administration (FDA)—to require *generic* pharmaceutical manufacturers like Petitioners to: (1) alter the design or

[1] Originally, three different sets of Plaintiffs filed lawsuits, predicated on substantially identical theories of liability, and Petitioners accordingly filed three separate motions to dismiss—each of which was denied by a different district court judge. The three cases have since been consolidated, with all Plaintiffs represented by one law firm; one set of Plaintiffs is also represented by an additional law firm.

formulation of a drug product, (2) enhance the warning labels affixed to the drug product, or (3) "stop selling" the drug product to avoid liability.

Put slightly differently, *Bartlett* and *Mensing* together hold that the Hatch-Waxman Act categorically forbids a generic pharmaceutical manufacturer from changing the design or label to comply with a state-law duty, and if a conflict arises as between state and federal duties, that conflict cannot be avoided by forcing the manufacturer to stop selling its product. Given that this is precisely what Plaintiffs' liability theory seeks to achieve, their claims are preempted by federal law. *Bartlett*, 570 U.S. at 488 ("We reject this 'stop-selling' rationale as incompatible with our pre-emption jurisprudence. Our pre-emption cases presume that an actor seeking to satisfy both his federal and state-law obligations is not required to cease acting altogether in order to avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be 'all but meaningless.'") (quoting *Mensing*, 564 U.S. at 621).

Bartlett and *Mensing* also make clear that it is immaterial whether a plaintiff *captions* her claims as sounding in one tort theory (for example, breach of implied warranty) as opposed to another (for example, failure to warn) because *every* state-law tort claim asserted against a *generic* drug manufacturer necessarily targets either the product's warnings or its design, and thus necessarily seeks to enforce duties that are preempted by federal law. For that reason, court after court around the country

has recognized that it is the substance of the claim, not its form, that determines whether that claim is or is not preempted.[2]

In the wake of the landmark decisions in *Bartlett* and *Mensing*, literally hundreds of courts—***including multiple state appellate courts and every federal circuit to have passed on the question***—have followed suit and have dismissed literally thousands of state-law claims exactly like the claims asserted in these cases against generic drug manufactures like Petitioners.[3]

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[2] *See, e.g.*, *Wagner v. Teva Pharms. USA, Inc.*, 840 F.3d 355, 358-59 (7th Cir. 2016) (noting that "[a]lthough *Mensing* and *Bartlett* dealt with failure to warn and design defect claims, respectively, federal courts have extended their rationale to similar state law claims, [because] … federal law preempts [a plaintiff's state-law tort] claims regardless of how they are styled in her complaint.") (citing *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1139-40 (8th Cir. 2014) (preempting breach of implied warranty cases); *Johnson v. Teva Pharms. USA, Inc.*, 758 F.3d 605, 613-14 (5th Cir. 2014) (holding express warranty claim preempted); *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 475-76 (5th Cir. 2014) (finding strict liability and breach-of-warranty claims preempted); *Moretti v. PLIVA, Inc.*, No. 08-cv-396-JCM, 2012 WL 628502 (D. Nev. Feb. 27, 2012) (dismissing state law claims for strict liability, negligence, breach of express and implied warranties, consumer fraud, and deceptive trade practices), *aff'd sub nom. Moretti v. Wyeth, Inc.*, 579 Fed. App'x 563, 565-66 (9th Cir. 2014).

[3] *See, e.g.*, *Haney-Williams v. Glaxosmithkline LLC*, No. 17-cv-2900, 2019 WL 7284737, at *5 (D. Nev. Dec. 27, 2019) (finding state-law tort claims against generic drug manufacturer preempted under *Mensing*); *Wagner*, 840 F.3d at 358 ("[F]ederal law preempts state tort laws when the generic drug manufacturer could not have abided by [its] duty [of sameness] without: (1) changing the drug's formula; (2) changing the drug's label; or (3) withdrawing the generic drug from the market altogether."); *In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig.*, 756 F.3d 917, 928 (6th Cir. 2014) (noting that *Bartlett* and *Mensing* had provided "clear pronouncements" that state-law tort claims are preempted and the stop-selling theory lacks merit); *Johnson v. Teva Pharms. USA, Inc.*, 758 F.3d at 613 (same); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, 751 F.3d 150, 164 (3d

Notwithstanding this overwhelming body of authority, the district courts below summarily denied Petitioners' motions to dismiss—*without offering any substantive analysis supporting their outlier decisions*. Moreover, while the district courts issued orders containing no substantive legal reasoning, their statements at oral argument on Petitioners' motions to dismiss reflect views expressly prohibited by the holdings in *Bartlett* and *Mensing*. During one argument, the *Bridges* district court observed from the bench—in direct contradiction of *Mensing* and *Bartlett*—that "it could be fundamentally unfair if Defendants, as generic manufacturers and distributors of pharmaceuticals, were not permitted to make changes to its labels or be able to be held liable for alleged injuries to users of their generic medicine under the theories of recovery set forth in Plaintiffs' Complaint." The court also questioned why Petitioners "could not have just ceased selling*"* the product at issue "had they

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Cir. 2014) (noting that the plaintiffs "are trying to resurrect the 'stop-selling' theory, under which the Generic Defendants can only avoid state-law liability by halting their sales of alendronate sodium," "[b]ut *Bartlett* categorically rejected that theory, and that ends the argument"); *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 476 (4th Cir. 2014) ("[C]ourts may not avoid preempting a state law by imposing liability on a generic manufacturer for choosing to continue selling its product."); *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378, 398 (6th Cir. 2013) (same); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1290 (10th Cir. 2013) (same); *Trejo v. Johnson & Johnson*, 13 Cal. App. 5th 110, 155 (2017) (Defendants "could [not] be required to stop selling Motrin in order to avoid state liability," and the "[p]laintiff's design defect claim accordingly is preempted."); *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 365-66 (Iowa 2014) ("In *Bartlett*, the Supreme Court rejected the 'stop selling' argument because 'if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption … would be all but meaningless.") (some quotation marks omitted).

wished to avoid any liability under state tort laws." Shortly thereafter, the *Bridges* court summarily denied the motion from the bench, and later entered an order denying the motion to dismiss. Subsequently, the district courts in *Adams* and *Abadjian* then followed suit. All of these decisions fly in the face of *Mensing* and *Bartlett* and every federal circuit to address the issue, and mandamus should be granted to require dismissal of these federally preempted claims.

Indeed, unless this Court intervenes now, discovery, motions practice, and trials will blaze forward in cases involving the claims of nearly 800 different individuals—which unquestionably and unjustifiably will impose a tremendous and unneeded burden on this State's judicial system and venire pool. Nor would waiting for an eventual post-judgment appeal solve the problem. Again, the whole point of *Bartlett* and *Mensing* is that claims like those pressed here cannot proceed to trial ***at all***, because if they did, it would create a patchwork quilt of lay jury determinations constantly second-guessing the FDA's expertise, leading to endless inconsistency and a legal and regulatory framework that would be unworkable in the extreme. Forcing Petitioners to litigate these cases to conclusion in the trial courts before seeking relief in this Court would be neither plain, nor speedy, nor adequate at all. And although one of the district courts below claimed that granting "a motion to dismiss … [is] a drastic remedy," *see* VII App. 1492 at 9:14-17, that position ignores the fact the United States Supreme Court expressly and unanimously held in 2019

that "th[e] question of pre-emption is one for a ***judge to decide, not a jury***," *Merck Sharpe & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019) (emphasis added),[4] and ignores that *Mensing* itself was also decided at the motion-to-dismiss stage. *See Mensing*, 564 U.S. at 610-11.

The upshot here is straightforward: Plaintiffs' lawsuits are preempted by federal law, and this Court should therefore grant the writ and direct the trial court presiding over this consolidated litigation to dismiss these lawsuits in their entirety.

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).

ISSUES PRESENTED

A. Whether this Court should grant the writ given that Petitioners have no plain, speedy, or adequate remedy for the district court's failure to dismiss these cases with prejudice as a matter of law?

[4] Indeed, even Plaintiffs themselves admit that a "pre-emption issue … is primarily a question of law that should be decided by a judge, not a jury." II App. 372, at 11:24-27.

2. Whether this Court should grant the writ given that the courts below committed manifest legal error in refusing to adhere to the binding precedent from the United States Supreme Court on a question of federal law?

STATEMENT OF THE CASE AND THE FACTS

A. Petitioners Had No Involvement in the Well-Documented Criminal Misconduct by Dr. Desai and Those Working at His Endoscopy Centers

This now-consolidated case was filed a decade after the unfortunate events surrounding the late Desai and his endoscopy centers came to light. As the Court is well aware, Desai and his employees engaged in the deliberate and intentional re-use of single-use injection syringes, failed adequately to clean previously used colonoscopy and endoscopy scopes, and consciously chose to use single-patient anesthesia vials on multiple patients—all as part of a criminal scheme to defraud insurance companies and the federal government for financial gain, with the conscious disregard for patient safety, and thereby spreading infection. These facts are widely known and not disputed.

But it is critical to note that Petitioners here ***had no involvement*** with the late Desai or with his endoscopy centers' criminal conduct. Rather, Desai chose to criminally misuse a pharmaceutical product that Petitioners happened to manufacture and distribute, and to wholly disregard the explicit FDA-approved warnings accompanying the product.

Also widely known, of course, is that Desai and several of his employees were indicted on federal charges of conspiracy and assorted forms of health-care fraud, all related to Desai's intentional schemes to increase profits by performing endoscopic procedures using unsafe sanitary practices, cutting costs in an extreme fashion, including by, as relevant here, using medication left over from single-patient vials on subsequent patients, and reusing syringes. I App. 81-82, ¶¶ 19-20. And as is also widely known, Desai eventually pleaded guilty to those federal conspiracy and health-care fraud charges. *Id.* at 90.[5]

B. Propofol and Its Product Packaging

Propofol is the generic name for the name-brand drug known as Diprivan®, which the FDA long ago approved for use as an anesthetic in outpatient surgical procedures. I App. 5, ¶ 21. Its general clinical pharmacology is described as follows:

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[5] Desai and two of his nurse employees were also indicted on Nevada criminal charges based on the harm caused by their unsafe practices. *Id.* at 100-103. One nurse pleaded guilty and testified against the remaining defendants. *Id*. at 106-113, 124-125. Following a jury trial, Desai was convicted on twenty-seven counts based on his purposeful multi-dosing of propofol—in deliberate disregard of the clear warnings on the single-patient product's label—conduct that resulted in the infection of numerous patients with hepatitis (though, to be clear, not Plaintiffs). The offenses of which Desai was found guilty included second-degree murder (later reversed by this Court based on a decision to decline treatment by the victim), and multiple counts of criminal neglect of patients and performance of acts in reckless disregard of the persons resulting in substantial bodily harm. *Id.* at 127-162, 164-171, 187-192; *see also, e.g., Desai v. State,* 133 Nev. 339, 398 P.3d 889 (2017); *Desai v. Eighth Judicial Dist. Ct.* 128 Nev. 892, 381 P.3d 606 (2012). The nurse employee was convicted on multiple counts of the latter offenses as well. I App. 127-162, 173-180, 182-185.

> Propofol injectable emulsion is an intravenous sedative-hypnotic agent for the use in the induction and maintenance of anesthesia or sedation. Intravenous injection of a therapeutic dose of propofol produces hypnosis rapidly with minimal excitation, usually within 40 seconds from the start of an injection (the time for one arm-brain circulation). As with other rapidly acting intravenous anesthetic agents, the half-time of the blood-brain equilibration is 1 to 3 minutes, and this accounts for the rapid induction of anesthesia.

I App. 215. Propofol's indications and usage include "both induction and/or maintenance of anesthesia as part of a balanced anesthetic technique for *inpatient and outpatient surgery*." *Id.* at 219 (emphasis added). Both the brand-name and generic forms of the drug are approved and tightly regulated by the FDA, and the product, unsurprisingly, is available by prescription only. *Id.* at 215.

C. Petitioners' Propofol Products

Petitioners manufactured and distributed generic propofol in three vial sizes—20, 50, and 100 mL—all of which are conspicuously labeled for single patient use. *Id.* at 225.[6] The content of the packaging is produced by the brand-name manufacturer and strictly regulated by the FDA, and Petitioners are proscribed by federal law from unilaterally changing it from the labeling required for the brand-

[6] For ease of comparison, a 50 mL vial contains approximately 1½ ounces of propofol. *See,* National Institute of Standards and Technology, "Approximate Conversions from Metric to U.S. Customary Measures," https://www.nist.gov/pmL/weights-and-measures/approximate-conversions-metric-us-customary-measures, last viewed January 11, 2019 (advising approximate conversion from milliliter to ounce by multiplying the number of milliliters by 0.03).

name equivalent. The outside of the boxes in which the propofol was distributed included the following clear statements:

- Use strict aseptic technique.[7]
- Contamination can cause fever, infection/sepsis, and/or other life-threatening illness.
- Single patient use.
- Begin use promptly after opening. Discard within specified time limit. [See package insert].
- Do not use if contamination suspected.

Sterile, nonpyrogenic

20 x 50 mL single-patient infusion vials

I App. 235-238 (capitalization in original).

The figure below represents the label in use at all relevant times:

[7] "Strict aseptic technique " means "the use of surgical practices that restrict microorganisms in the environment and prevent contamination of the surgical wound. … Called also sterile technique." *Medical Dictionary for the Health Professions and Nursing*. S.V. "aseptic technique," https://medical-dictionary.thefreedictionary.com/aseptic+technique, last viewed Jan. 13, 2020.

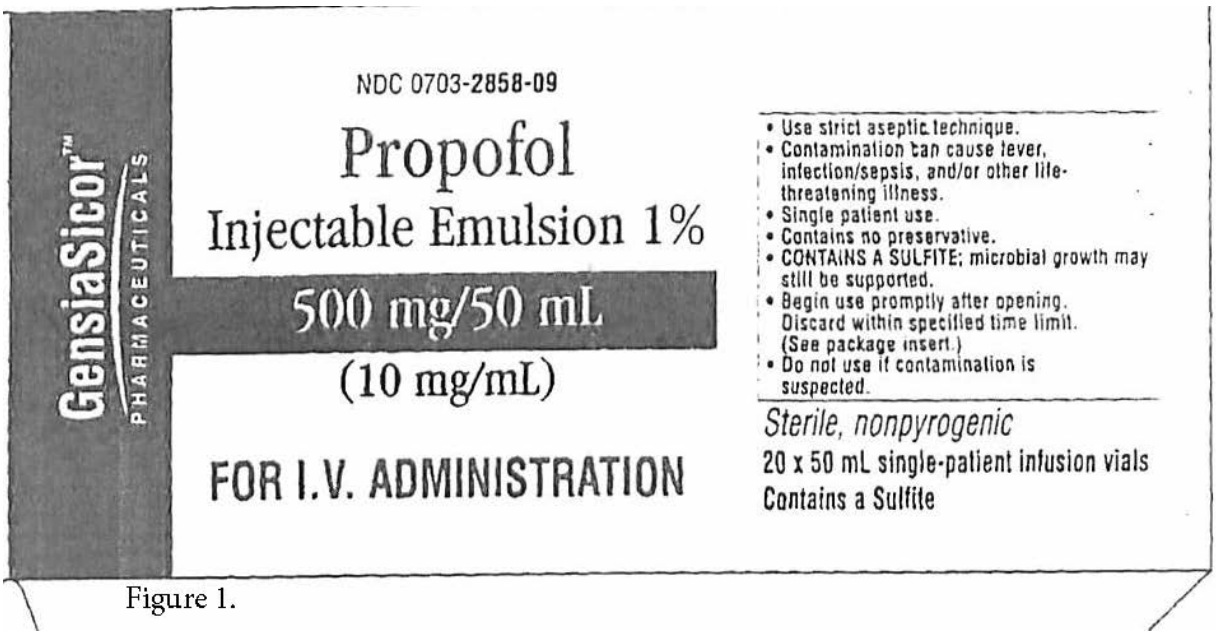

Figure 1.

I App. 235-238.

The content of the product labeling is likewise strictly regulated by the FDA, and Petitioners were not at liberty to change it either. As relevant here, the package insert included the following language, precisely as represented in the labeling:

> **STRICT ASEPTIC TECHNIQUE MUST ALWAYS BE MAINTAINED DURING HANDLING. PROPOFOL INJECTABLE EMULSION IS A SINGLE-USE PARENTERAL PRODUCT WHICH CONTAINS SODIUM METASULFITE (0.25MG/ML) TO RETARD THE RATE OF GROWTH OF MICROORGANISMS IN THE EVENT OF ACCIDENTAL EXTRINSIC CONTAMINATION. HOWEVER, PROPOFOL INJECTABLE EMULSION CAN STILL SUPPORT THE GROWTH OF MICROORGANISMS AS IT IS NOT AN ANTIMICROBIALLY PRESERVED PRODUCT UNDER USP STANDARDS. ACCORDINGLY, STRICT ASEPTIC TECHNIQUE MUST STILL BE ADHERED TO. DO NOT USE IF CONTAMINATION IS SUSPECTED. DISCARD UNUSED PORTIONS AS DIRECTED WITHIN THE REQUIRED TIME LIMITS (SEE DOSAGE AND ADMINISTRATION, HANDLING PROCEDURES). THERE HAVE BEEN REPORTS IN WHICH**

> **FAILURE TO USE ASEPTIC TECHNIQUE WHEN HANDLING PROPOFOL INJECTABLE EMULSION WAS ASSOCIATED WITH MICROBIAL CONTAMINATION OF THE PRODUCT AND WITH FEVER, INFECTION/SEPSIS, OTHER LIFE-THREATENING ILLNESS AND/OR DEATH.**

I App. 215 (emphases in original). This same warning was repeated in five additional locations in the package insert, each time in all caps and bold face.[8] *Id.* at 217, 218, 220, 223 and 225.

The package inserts also contained the following explanation of the need to utilize strict aseptic technique:

> **Guidelines for Aseptic Technique for General Anesthesia/ Sedation**
>
> Propofol injectable emulsion should be prepared for use just prior to initiation of each individual anesthetic/sedation procedure. The vial rubber stopper should be disinfected using 70% isopropyl alcohol. Propofol injectable emulsion should be drawn into sterile syringes immediately after vials are opened. When withdrawing propofol injectable emulsion from vials, a sterile vent spike should be used. Administration should commence promptly and be completed within 8 hours after the vials has been opened.
>
> Propofol Injectable Emulsion should be prepared for single patient use only. Any unused portions of propofol injectable emulsion reservoirs, dedicated administration tubing, and/or solutions containing propofol injectable emulsion must be discarded at the end of the anesthetic procedure or at 8 hours, whichever occurs sooner. The I.V. line should be flushed every 6 hours and at the end of the anesthetic procedure to remove residual propofol injectable emulsion.

Id. at 225 (emphasis in original).

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[8] The only change in the warnings in the varying locations was to the parenthetical referencing to other parts of the insert.

The package insert also contained a bevy of other information. It included information on the proper dosage and administration of propofol, explained that the actual dosage must be determined on a patient-by-patient basis in light of the chemical information contained in the pharmacological section, and made clear that the exact dose involves consideration of the patient's age, weight, and various other factors specific to the patient. *Id.* at 223.

D. Plaintiffs' Claims

When Desai's practices came to light, thousands of his current and former patients were notified by the Southern Nevada Health District that they may have been exposed to blood-borne pathogens and advised to be tested for such exposure. Plaintiffs here are among those so notified, who allegedly had testing performed and had tested negative. Tolling agreements were reached with the Plaintiffs here pending the outcome of the criminal prosecutions.

In 2018, years after the criminal and civil litigation relating to Desai's practices concluded, Plaintiffs filed the complaints at issue here.[9] *See* I App. 1-13, *Adams, et al v. Teva Medicines, Inc., et al.,* Eighth Judicial Dist. Ct. Case No. A-18-778471-C (Dept. 8) (Adams); *id.* at 30-45, *Bridges, et al. v. Teva Medicines, Inc., et al.,* Eighth Judicial Dist. Ct. Case No. A-18-782023-C (Dept. 24) (*Bridges*) (filed by

[9] The *Abadjian* and *Bridges* Complaints each included some plaintiffs—subsequently dismissed—who had not been parties to a tolling agreement. VII App. 1497-1498, 1550-1551.

the same counsel and, other than the identity of the Plaintiffs, containing identical allegations); *id.* at 14-29, *Abadjian, et al. v. Teva Medicines, Inc., et al,* Eighth Judicial Dist. Ct. Case No. A-18-781820-C (Dept. 4) (*Abadjian*) (filed by a different law firm, alleging the same causes of action, and containing identical factual allegations).

According to allegations in their complaints, Plaintiffs each received one or more injections of propofol at one of Desai's clinics in 2004-2008; they received notification of possible exposure; they had the recommended testing performed; and they each tested negative. I App. at 4-5, ¶¶ 12-17. Plaintiffs also allege that patient cross-contamination occurred at various times in other states or countries, stemming from medical personnel using the same syringes on multi-dose vials of medication, including, but not limited to, propofol. *Id.* at 5-8, ¶¶ 20-35. For example, Plaintiffs assert that in 1983 (six years *before* propofol was first approved for use under the brand name Diprivan®*, see id*. at 5, ¶ 21), scientists had reported that hepatitis was spread as a result of administering medication to multiple patients from a single vial. Plaintiffs contend that in 1990, the CDC reported that two surveys had shown that 48% to 90% of anesthesia personnel were failing to use appropriate aseptic techniques in the administration of anesthesia. *See id*. at 6, ¶ 23 (citing the Morbidity and Mortality Weekly Report (MMRW) (June 29, 1990/39(25)) at 426, 247 [*sic*],

433); *see also id.* at 6, ¶¶ 24-25.[10] Plaintiffs then contend that in 1991, Dear Doctor letters were sent regarding Diprivan® and the risks of multiple dose vial contamination.[11] *Id.* at 6, ¶¶ 26-27.

Along like lines, Plaintiffs allege that a 1995 article tied post-operative infections to using multi-dose vials of propofol. *Id.* at ¶ 28. Plaintiffs also assert, without attribution, that "several authors have reported poor compliance with aseptic techniques and infection-control practices by anesthesia personnel." *Id.* at ¶ 29. Plaintiffs contend that various instances of infection were spread through "medication drawn through multi-use vials" in 2002 and 2003, and that in 2003 the World Health Organization urged that single-dose vials should be used. *Id.* at 7-8, ¶¶ 32-34. Plaintiffs also insist that in June 2007, the FDA reported that patients in

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[10] Plaintiffs did not include in their allegations that the same report stated the following:

> The manufacturer of propofol, in conjunction with the FDA, is revising the label and package inserts and notifying all anesthesiologists and nurse anesthetists in the United States to emphasize the importance of using aseptic technique in the preparation and administration of propofol.

MMRW (June 29, 1990/39(25)) 427. The manufacturer referenced here was the brand manufacturer, as the drug was not yet available in generic form at that time. *See also* n.12 *infra.* As shown above, warnings against the multi-dosing alleged by Plaintiffs *has always existed in the generic labeling*.

[11] "Dear Doctor letters" are mass correspondence sent by brand-name manufacturers (not generic manufacturers and/or distributors like Petitioners) to health-care providers regarding important new and updated safety information.

seven facilities across four states had developed "fever, chills and body aches" after receiving propofol, and that "[s]ome facilities where the propofol was administrated used propofol vials, intended for single patient use, on more than one patient." *Id.* at 8, ¶ 35. Notably, Plaintiffs do not allege any report of occurrences of multi-dosing from single-patient vials pre-dating June 2007.

Plaintiffs also allege that Petitioner Teva sought approval to submit an abbreviated new drug application[12] for two sizes of propofol vials, a single dose 10 mL size in 2000 and a 200 mL size in 2001; Plaintiffs alleged that the latter application was denied because of the risk of multi-dosing because, according to the FDA, 20 mL was "the dose of propofol commonly used for induction of anesthesia." *Id.* at 7, ¶ 32.

Despite the fact that Plaintiffs themselves acknowledge that multi-dose use of single-patient medications was reported only sometime in mid-2007, and then only at fewer than seven facilities across the country, Plaintiffs alleged that multiple dose, non-aseptic use of propofol at surgical and endoscopy centers somehow was a foreseeable misuse of a 50 mL vial (regardless of single patient labeling) throughout 2004-2008, the time period during which Plaintiffs purportedly received their

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[12] An "abbreviated new drug application" or "ANDA" is the method by which generic drug manufacturers seek approval from the federal government to manufacture a drug that has already been approved for manufacture and distribution by the brand manufacturer. *See* 21 U.S.C. § 355(j); 21 C.F.R. § 314.92.

injections, and that Petitioners knew or somehow should have known that endoscopy centers would be "tempted" to use Propofol left over from one patient procedure in another. *Id.* at 9, ¶ 39-40. Tellingly, what Plaintiffs do *not* allege is that the entire *purpose* of Desai's scheme—*financial gain through fraud*—was foreseeable.

Based on the above allegations, all of the Plaintiffs assert the following claims as against Petitioners:

1. **Strict product liability**: Plaintiffs allege that propofol in 50 mL size vials was unreasonably dangerous for use in an endoscopy center. I App. 9, ¶ 40. There is no allegation that the propofol itself failed to perform as anticipated for its intended anesthetic use, or that any Plaintiff (or indeed any person) was injured due to any defect in the medication itself. There is no allegation that health-care providers were not provided proper warnings about aseptic procedures. Plaintiffs do not even acknowledge that the 50 mL vials here were clearly labeled for single-patient use.

2. **Breach of the warranty of fitness for particular purpose**: Plaintiffs assert that propofol in 50 mL vials was unfit for use in endoscopy centers, *id.* at 10, ¶ 47. Here, again, there is no allegation as to the fitness of propofol for its purpose of inducing and maintaining anesthesia in endoscopy centers. Plaintiffs do not, and cannot, allege

privity between themselves and Petitioners. And Plaintiffs do not explain how Petitioners' alleged breach of implied warranty does not concern the propofol product labeling.

3. **Negligence**: Plaintiffs allege that Petitioners acted negligently in failing to adhere to their purported duty to not "distribute, market, and package" 50 mL vials to "high turnover ambulatory clinics," *id.* at 11, ¶¶ 50-51. As with their other claims, Plaintiffs again ignore that the Petitioners were expressly authorized by the federal government to market and sell propofol in 50 mL vials to outpatient surgery facilities.

4. **Nevada Deceptive Trade Practices Act**: Plaintiffs allege that Petitioners violated four subsections of Nevada's Deceptive Trade Practices Act, NRS 598.0915, *id.* at 11-12, ¶ 55. Each of the cited subsections prohibit misrepresentations or omissions of material facts regarding the consumer product. *Id.* Plaintiffs did not identify the nature of the purportedly misrepresented facts or omitted information; any individual who purportedly made misrepresentations or failed to disclose material facts; or any individuals to whom the misrepresentations were made, or from whom materials facts were omitted.

5. **"Punitive damages."** Plaintiffs contend that, in selling "larger vials" to endoscopy centers, Petitioners engaged in oppression and/or fraud and acted with or malice, *id.* at 12-13, ¶ 58-59. Although Plaintiffs list their request for punitive damages as a separate claim for relief, there is no such cause of action in Nevada. *See, e.g., Sprouse v. Wentz*, 105 Nev. 597, 602, 781 P.2d 1136, 1138-39 (1989) (noting that a punitive damage award must be based on a claim sounding on tort).

E. Proceedings Below

Petitioners removed all three cases to federal court, asserting the existence of both federal-question and diversity jurisdiction. II App. 382-388; V App. 1101-1108; VI App. 1233-1240. After the removal issues were briefed, the cases were remanded to state court based on the federal district courts' rulings that Petitioners had not established the existence of federal-question or diversity jurisdiction. *Id.*

Following remand to state court, Petitioners timely filed motions to dismiss based on, among other things, federal preemption. *See* I App. 46-250 and II App. 251-361; III App. 469-717 and IV App. 718-788; IV App. 789-967; V App. 968-1082.

The first motion-to-dismiss hearing was held in *Bridges*. VII App. 1583-1586. At the conclusion of the hearing, and as relevant here, the district court observed from the bench—in direct contradiction of *Mensing* and *Bartlett*—that "it could be

fundamentally unfair if Defendants, as generic manufacturers and distributors of pharmaceuticals, were not permitted to make changes to its labels or be able to be held liable for alleged injuries to users of their generic medicine under the theories of recovery set forth in Plaintiffs' Complaint." VII App. 1585, at 3:6-18. The court also questioned why Petitioners "could not have ***just ceased selling*** the 50 mL vials of generic propofol at issue in this case had they wished to avoid any liability under state tort laws." *Id.* at 3:10-12 (emphasis added). After offering those observations, the *Bridges* court summarily denied the motion from the bench, and on November 12, 2019, entered an order denying the motion to dismiss. Petitioners timely sought reconsideration, but that motion was denied on January 17, 2020. VII App. 1587-1590. The district courts in *Adams* and *Abadjian* then followed suit and denied Petitioners' then-pending motions to dismiss, doing so again without any substantive analysis other than the *Adams* court's observation that it was denying Petitioners' motion because "[i]t's a motion to dismiss," and "I think it's a drastic remedy." VII App. 1492, at 9:14-17.

The three cases below eventually were consolidated. VII App. 1564-1567.Plaintiffs have agreed to a stay of all proceedings before the district court until this Court decides whether to take this writ petition.

This petition therefore follows.

STANDARD OF REVIEW

This Court reviews questions of law de novo, even when raised in a writ petition. *Helfstein v. Eighth Judicial Dist. Ct.*, 131 Nev. 909, 913, 362 P.3d 91, 94 (2015). The question whether state law is preempted is a question of law and thus is reviewed de novo. *Rolf Jensen & Assocs., Inc. v. Dist. Ct.*, 128 Nev. 441, 445, 282 P.3d 743, 746 (2012).

REASONS THE WRIT SHOULD ISSUE

The writ should issue because under binding United States Supreme Court precedent (*Mensing*, *Bartlett*, and their progeny), these lawsuits are undisputedly preempted by federal law.

Although Plaintiffs have asserted five ostensibly different causes of action, the reality is that each of those claims is predicated on a single preempted theory of liability: Petitioners supposedly should have known that doctors and other workers at Dr. Desai's endoscopy clinics (who engaged in criminal conduct unbeknownst to Petitioners) would misuse 50 mL vials of propofol, and Petitioners therefore were obligated as a matter of state law to stop selling 50 mL vials of propofol—even though 50 mL vials were (and continue to be) approved for sale by the FDA, indicated for use as an anesthetic in inpatient *and* outpatient surgeries, and even though Petitioners are generic manufacturers and/or distributors, and not brand-name companies.

This theory is squarely foreclosed by the Supreme Court's decisions in *Bartlett* and *Mensing*, which together hold that federal law preempts ***any state-law claim*** that would require a generic pharmaceutical manufacturer 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. As those decisions make clear, the Hatch-Waxman Act categorically forbids a generic manufacturer from changing the design or the label of a generic pharmaceutical product, and the conflict between those state and federal law duties cannot be avoided by forcing the manufacturer to exit the market.

Notwithstanding the Supreme Court's clear, categorical, and controlling holdings on this question of federal law, the courts below refused to dismiss these lawsuits—despite the fact that every "question of pre-emption is one for a judge to decide, not a jury." *Albrecht*, 139 S. Ct. at 1672. That was clear and demonstrable error, and mandamus should issue. After all, this Court repeatedly has recognized that "[a] writ of mandamus is available to compel the performance of an act that the law requires as a duty resulting from an office, trust, or station or to control an arbitrary or capricious exercise of discretion." *Int'l Game Tech., Inc. v. Second Judicial Dist. Ct.*, 124 Nev. 193, 197, 179 P.3d 556, 558 (2008) (citations omitted). Because the courts below were required to dismiss these lawsuits as preempted, and because they failed to comply with that obligation, this Court should grant this

petition and order that all three lawsuits should be dismissed with prejudice as a matter of law.

I. Mandamus is Warranted Because Petitioners Lack a Plain, Speedy, or Adequate Remedy for the District Courts' Erroneous Failure to Dismiss These Lawsuits.

The Nevada Constitution vests this Court with original jurisdiction to issue writs of mandamus. Nev. Const., art. 6, § 4. Mandamus may be granted where the party seeking extraordinary writ relief demonstrates that: (1) an eventual post-judgment appeal does not afford "a plain, speedy and adequate remedy in the ordinary course of law," and (2) mandamus is needed either to compel the performance of an act that the law requires or to control the district court's manifest abuse of discretion. NRS 34.160; NRS 34.170; *see also Tallman v. Eighth Judicial Dist. Court*, 131 Nev. 713, 719, 359 P.3d 113, 118 (2015).

Although it is true this Court generally does not entertain mandamus petitions challenging orders denying motions to dismiss, it is also true that the Court has not hesitated to do so when "an important issue of law needs clarification and considerations of sound judicial economy and administration militate in favor of granting the petition." *City of Mesquite v. Eighth Judicial Dist. Ct.*, 135 Nev. 240, 243, 445 P.3d 1244, 1248 (2019) (internal quotation marks and citations omitted).

That standard is readily satisfied here. First and foremost, the preemption question presented by these cases is an important, threshold, and dispositive issue of

law that is controlled by binding United States Supreme Court precedent, and the district courts' treatment of that question, indeed their open defiance of that precedent, gives rise to troubling federalism concerns that necessitate this Court's prompt resolution.

Second, the sheer magnitude of these cases—which involve the inherently individualized emotional liability and damages issues of nearly 800 different plaintiffs—will impose serious and unnecessary burdens on the Court and the venire pool, which in and of itself weighs heavily in favor of this Court resolving the threshold and purely legal question presented right now.

Third, although one of the district courts below claimed that granting "a motion to dismiss … [is] a drastic remedy," *see* VII App. 1492, at 9:14-17, that ignores the fact the United States Supreme Court expressly and unanimously held just last Term that "th[e] question of pre-emption is one for a judge to decide, not a jury," *Albrecht*, 139 S. Ct. at 1672, and ignores that *Mensing* itself was also decided at the motion-to-dismiss stage, *see Mensing*, 564 U.S. at 610-11. The petition should be granted.

A. An Eventual Post-Judgment Appeal Would Be Neither a Speedy nor an Adequate Remedy.

To be sure, it often is the case that parties who face erroneous trial court rulings can achieve appropriate vindication on a post-judgment appeal. But that does not change the fact this Court has repeatedly recognized that such an eventual appeal

may not provide an adequate and speedy remedy in certain instances, and that determining which side of that divide a particular case resides turns on the underlying proceedings' status, the types of issues raised in the writ petition, and whether a future appeal will permit this court to meaningfully review the issues presented." *D.R. Horton, Inc. v. Dist. Ct.*, 123 Nev. 468, 474-75, 168 P.3d 731, 736 (2007); *see also Rolf Jensen*, 128 Nev. at 444, 282 P.3d at 745-746.

In that regard, *Rolf Jensen* is a near-perfect parallel to this case. There, as here, the petitioner argued that the claims pressed by the plaintiff were preempted by federal law. 128 Nev. at 444, 282 P.3d at 745. Given that federal preemption unquestionably raises "an issue of nationwide magnitude in need of clarification in the courts of this state," and "in light of the relatively early stages of litigation and considerations of sound judicial administration," this Court granted the writ challenging a motion to dismiss. *Id.* at 44, 282 P.3d at 46. This reasoning applies with full force here.

And it is doubly true here given that, as this Court has also explained, writ relief is warranted where resolution of a preemption question would dispose of this entire consolidated litigation. *See, e.g.*, *W. Cab Co. v. Eighth Judicial Dist. Ct.*, 133 Nev. 65, 67-68, 390 P.3d 662, 667 (2017) (considering writ petition that claimed preemption of Minimum Wage Act). Granting the petition and reviewing this case now would obviate the need for the district court and the parties to engage in the

serious outlay of time and expense needed to individually prosecute the claims of the 792 *uninfected* Plaintiffs in this matter—all of which will require the presentation of individualized evidence: (1) relating to the injection(s) of propofol to each Plaintiff; (2) concerning the testing they received for a blood-borne pathogen; (3) confirming that propofol from a 50 mL vial was, in fact, administered to each Plaintiff; and (4) establishing that each individual Plaintiff in fact suffered from the purported emotional distress, fear, and anxiety alleged in these cases.

Suffice to say, launching this case out into the depths of civil litigation without first disposing of this threshold and dispositive legal question would place considerable strain on the time and resources of the State's court system and venire pool, and would force the public and the parties to spend millions of dollars, and years of time in discovery, motions practice, and trial—all just to litigate claims that the United States Supreme Court has already decided cannot proceed as a matter of federal law. Put simply, if ever there were a case for which mandamus were appropriate, this is it.

B. Mandamus Is Appropriate Because the Trial Courts Refused to Dismiss Claims That the Supremacy Clause Clearly Requires Be Dismissed as Federally Preempted.

This Court has long held that writ relief is warranted where a case clearly should have been dismissed but was not. *See, e.g.*, *Smith v. Eighth Judicial Dist. Court,* 113 Nev. 1343, 1345 n. 1, 950 P.2d 280, 281 n. 1 (1997) (holding that where

dismissal under NRCP 41 was required, writ relief was appropriate). That is precisely the situation here. Not only has the United States Supreme Court *twice* held, in no uncertain terms, that any claim seeking to hold a generic drug manufacturer liable for failing to do what federal law prohibited that manufacturer from doing is preempted by federal law, but virtually every single court in the country addressing such a claim since has followed suit.

The decisions below, meanwhile, refused to follow *any* of this authority—whether binding or persuasive. Instead, the district courts here summarily denied Petitioners' motions to dismiss—with no legal reasoning accompanying the decisions, and after offering observations at oral argument that directly contradicted *Mensing* and *Bartlett*. Because the rulings below cannot be reconciled with fundamental preemption principles or binding Supreme Court precedent, this Court should grant the writ and direct the district court to enter judgment in Petitioners' favor.

II. Mandamus is Warranted Because Plaintiffs' Theory of Liability is Preempted by Federal Law and Cannot Proceed.

Each of Plaintiffs' claims is predicated on the theory that Petitioners should be held liable as a matter of state law simply for selling 50 mL vials of propofol to

the Clinics, because selling "propofol in larger vial sizes was unreasonably dangerous for use in an endoscopy surgery center." I App. 24-25, ¶¶ 38-40.

The problem for Plaintiffs, though, is that the Supreme Court has twice rejected this very same theory:

> We reject this "stop-selling" rationale as incompatible with our pre-emption jurisprudence. Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be "all but meaningless."

Bartlett, 570 U.S. at 488 (quoting *Mensing*, 564 U.S. at 621).

These binding precedents should have marked the beginning and the end of these lawsuits. After all, in the wake of *Bartlett* and *Mensing*, hundreds of state and federal courts have followed the Supreme Court's binding precedent and held that any state-law claim targeting a generic drug product like the propofol at issue here is preempted, and that any effort to avoid the preemption problem by insisting the manufacturer stop selling the product is no solution. *See, e.g.*, *Wagner*, 840 F.3d at 358 ("[F]ederal law preempts state tort laws when the generic drug manufacturer could not have abided by [its] duty [of sameness] without: (1) changing the drug's formula; (2) changing the drug's label; or (3) withdrawing the generic drug from the market altogether.").[13]

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[13] *See also In re Darvocet,* 756 F.3d at 928 (*Bartlett* and *Mensing* provide "clear pronouncements" that state-law tort claims are preempted and the stop-selling theory

And courts have had no trouble recognizing that the logic underlying the preemption holdings of *Bartlett* and *Mensing* extends equally to state-law claims asserted against *distributors* of generic drugs, as distributors have no more power to change the design or labeling than do the manufacturers themselves. *See, e.g.*, *Marroquin v. Pfizer, Inc.*, 367 F. Supp. 3d 1152, 1170 (E.D. Cal. 2019) (noting that many "courts have extended *Mensing* to entities that merely distribute prescription drugs, be they generic prescription or brand-name prescription drugs," because "mere distributors lack the ability to make any changes to an FDA approved label, rather only the holder of a New Drug Application (NDA) or the FDA itself can make any change to an FDA approved prescription drug label") (citing, *inter alia*, *Brazil v. Janssen Research & Dev. LLC*, 196 F. Supp. 3d 1351, 1364-65 (N.D. Ga. 2016); *In re Darvocet, Darvon & Propoxyphene Prod. Liab. Litig.*, MDL No. 2226, 2012 WL 2457825, *1 (E.D. Ky. June 22, 2012); *In re Fosamax (Alendronate Sodium)*

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lacks merit); *Johnson*, 758 F.3d at 613 (same); *In re Fosamax*, 751 F.3d at 164 (noting that the plaintiffs "are trying to resurrect the 'stop-selling' theory, under which the Generic Defendants can only avoid state-law liability by halting their sales of alendronate sodium," "[b]ut *Bartlett* categorically rejected that theory, and that ends the argument."); *Drager*, 741 F.3d at 476 ("[C]ourts may not avoid preempting a state law by imposing liability on a generic manufacturer for choosing to continue selling its product."); *Strayhorn*, 737 F.3d at 398 (same); *Schrock*, 727 F.3d at 1290 (same); *Trejo*, 13 Cal. App. 5th at 155 (holding defendants "could [not] be required to stop selling Motrin in order to avoid state liability," and that the "[p]laintiff's design defect claim accordingly is preempted"); *Huck*, 850 N.W.2d at 365-66 ("In *Bartlett*, the Supreme Court rejected the 'stop selling' argument because 'if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption … would be all but meaningless.") (some quotation marks omitted).

Products Liab. Litig. (No. II), MDL No. 2243, 2012 WL 181411, *3-4 (D. N.J. Jan. 17, 2012)); *see also Dennis v. Bayer Healthcare Pharm. Inc.*, No. 18-cv-491, 2020 WL 534307, at *4-5 (W.D.N.C. Feb. 3, 2020) (same and collecting cases).

A. Plaintiffs' Efforts to Avoid the Preemptive Effect of Federal Law Are Unavailing.

In the face of that mountain of precedent, Plaintiffs below offered four arguments for why their claims can nevertheless proceed. None is persuasive, and each should be readily rejected by this Court.

First, Plaintiffs argued that because three Nevada state trial courts held nearly ten years ago that state-law tort claims targeting generic drug manufacturers are not preempted, that the district courts below should hold the same. But every single one of those decisions was issued before *Bartlett* was decided in 2013 (which specifically rejected the "stop-selling" theory pressed by Plaintiffs here); one was issued before *Mensing* was decided in 2011; all three have since been vacated; and all three are impossible to square with *Bartlett* or *Mensing*—as their severe outlier status confirms.

Second, Plaintiffs argued that it is the Supreme Court's decisions in *Wyeth v. Levine*, 555 U.S. 555 (2009), and *Albrecht*, that provide "the current state of the law" on the preemption question, II App. 372, and that those decisions require drug manufacturers asserting a preemption defense to come forward with "clear evidence

that the FDA would not have approved a change to the subject label," *id.* at 373-374. But the preemption questions presented in *Wyeth* and *Albrecht* concerned whether warnings-based claims targeting *brand-name* drug manufacturers are preempted; those cases did not (and had no occasion to) address the statutory "duty of sameness" that prevents generic drug manufacturers from implementing unilateral labeling changes.

Indeed, *Mensing* itself took care to draw this very distinction between the regime governing brand-name products on the one hand, and that governing generic products on the other. In the Court's words:

> [In *Wyeth*], as here, the plaintiff contended that a drug manufacturer had breached a state tort-law duty to provide an adequate warning label. The Court held that the lawsuit was not pre-empted because it was possible for Wyeth, a brand-name drug manufacturer, to comply with both state and federal law. Specifically, the CBE regulation, 21 CFR § 314.70(c)(6)(iii), permitted a brand-name drug manufacturer like Wyeth "to unilaterally strengthen its warning" without prior FDA approval. Thus, the federal regulations applicable to Wyeth allowed the company, of its own volition, to strengthen its label in compliance with its state tort duty.
>
> We recognize that from the perspective of Mensing and Demahy, finding pre-emption here but not in *Wyeth* makes little sense. Had Mensing and Demahy taken Reglan, the brand-name drug prescribed by their doctors, *Wyeth* would control and their lawsuits would not be pre-empted. But because pharmacists, acting in full accord with state law, substituted generic metoclopramide instead, federal law pre-empts these lawsuits. We acknowledge the unfortunate hand that federal drug regulation has dealt Mensing, Demahy, and others similarly situated.
>
> But "it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre." It is beyond

> dispute that the federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers. Indeed, it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public. But different federal statutes and regulations may, as here, lead to different pre-emption results. We will not distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme.

Mensing, 564 U.S. at 624-26 (internal citations and footnotes omitted).

Third, and shifting gears, Plaintiffs then asserted that their liability theory is not foreclosed by *Bartlett* because they are not claiming that state law required Petitioners to cease selling 50 mL vials of propofol altogether, but only to limit the size of vials sold to a portion of the overall market—namely ambulatory care centers.

That is just wordplay. Saying a generic pharmaceutical manufacturer violated state law by selling a certain sized FDA-approved product to a segment of the marketplace is no different than saying that liability should be imposed because that manufacturer refused to stop selling that sized product to a portion of the paying public. As *Mensing* made clear, the manufacturer's federal duty is "to adequately and safely label [its] products for sale," *Mensing*, 564 U.S. at 617, so it has three options: change the label, change the design, or stop selling it. But the Hatch-Waxman Act equally precludes labeling *and* design changes, and so the only way to "cure" the problem as a matter of state law is to stop selling propofol to ambulatory care centers. But as *Bartlett* clearly held, claiming that a generic manufacturer

"should simply have pulled [its product] from the market in order to comply with both state and federal law … is no solution," *Bartlett*, 570 U.S. at 475, and the fact that Plaintiffs seek to limit the scope of their stop-selling theory—at the eleventh hour—makes no analytical difference. *Bartlett* forecloses the stop-selling theory altogether; it is irrelevant whether state law mandates complete cessation or (as Plaintiffs belatedly claim here) partial cessation. It is therefore unsurprising that these very sorts of facile efforts to sidestep *Bartlett* and *Mensing* have been roundly rejected elsewhere, as this very same argument has been shut down in court and after court.[14]

Finally, Plaintiffs argued below that their claims are not preempted because a federal district court judge in Nevada supposedly "rejected [Petitioners'] preemption arguments only weeks ago." II App. 367. That is easily disproven. In truth, that federal court and another in Nevada merely held that Petitioners had not established federal-question or diversity jurisdiction supporting removal; they offered no

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[14] *See, e.g.*, *In re Genentech, Inc., Herceptin (Trastuzumab) Mktg. & Sales Practices Litig.*, 367 F. Supp. 3d 1274, 1289 (N.D. Okla. 2019) (rejecting argument that only certain types of vials should not be sold because generic manufacturers "cannot be forced to stop selling vials that comply with FDA requirements in order to avoid liability under state law"); *Raskas v. Teva Pharms. USA, Inc.*, No. 17-cv-2261, 2018 WL 351820, at *3 (E.D. Mo. Jan. 8, 2018) (rejecting argument that defendants could have "stopped selling metoclopramide to otherwise healthy young people suffering from nausea and vomiting"); *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, 185 F. Supp. 3d 761, 771 (D.S.C. 2016) (rejecting argument that "Defendant should have simply stopped selling the drug to women.").

substantive analysis on the conflict-preemption questions at issue in these cases; and to suggest otherwise as Plaintiffs do is misleading at best. *See* II App. 382-388; V App. 1101-1108; VI App. 1233-1240 (remanding to state court because there was no federal-question jurisdiction under the "complete preemption" doctrine). Because those federal courts resolved the removal question on jurisdictional grounds, they never addressed Petitioners' motions to dismiss or the substantive conflict-preemption arguments upon which those motions were premised.

B. The District Courts' Rationales for Denying Petitioners' Motions to Dismiss Do Not Withstand Scrutiny.

For their part, the courts below offered no substantive rationale for denying Petitioners' motions either. Instead, the most those courts did was to claim that granting a motion to dismiss supposedly is "a drastic remedy," VII App. 1492, at 9:14-17, to question—in direct contravention of *Bartlett* and *Mensing*—why Petitioners "could not have ***just ceased selling*** the 50 mL vials of generic propofol at issue in this case had they wished to avoid any liability under state tort laws," VII App. 1585, at 3:10-12 (emphasis added), and then to express doubt whether "the FDA" intended to treat brand-name and generic manufacturers differently, *see id.* at 3:6-10, Each of those conclusions is seriously flawed on multiple levels.

As an initial matter, to the extent the courts below considered the prospect of granting Petitioners' motions to dismiss to "a drastic remedy," that is impossible to square with *Albrecht*, which vacated and remanded the Third Circuit's decision

precisely "[b]ecause the Court of Appeals treated the pre-emption question as one of fact, not law," when the reality is that the "better positioned decisionmaker" in a preemption case "is the judge," not a jury. *Albrecht*, 139 S. Ct. at 1679-81. And, as mentioned above, *Mensing* itself was decided at the motion-to-dismiss stage.

Moreover, to the extent the courts below premised their determinations on the notion that Petitioners should have "just ceased selling the 50 mL vials of generic propofol at issue in this case … to avoid any liability under state tort laws," VII App. 1585, at 3:10-12, that cannot possibly be squared with *Bartlett*, *Mensing*, or the hundreds of decisions that followed in their collective wake. Again, as the Court explained:

> We reject this "stop-selling" rationale as incompatible with our pre-emption jurisprudence. Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be "all but meaningless."

Bartlett, 570 U.S. at 488 (quoting *Mensing*, 564 U.S. at 621); *see also Palmer v. Liggett Grp., Inc.*, 825 F.2d 620, 627 (1st Cir. 1987) (recognizing that the supposed "choice" of paying monetary damages or altering one's course of conduct is "akin to the free choice of coming up for air after being underwater"); *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1025 (5th Cir. 1994) ("[T]his argument is sophistry. If plaintiffs could recover large damage awards because the herbicide was improperly labeled under state law, the undeniable practical effect would be that state law

requires additional labeling standards not mandated by FIFRA; it cannot be presumed that businesses wish to bring about their own economic suicide.") (emphasis in original); *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 370 (7th Cir. 1993) ("[D]amages actions, just like regulatory mandates, cause companies to modify their economic decisions. It would be silly to pretend that federal lawmakers, seeking to occupy a whole field of regulation, wouldn't also be concerned about the distorting effects of tort actions.").

Finally, the *Bridges* trial court seemed to suggest that it is the *FDA*'s intent that matters. However, the actual source of federal law's preemptive power over claims like those pressed here is the Hatch-Waxman Act, and the text, structure, and history of that statute make clear that treating brand-name and generic manufacturers differently from one another is *precisely* what Congress wanted.

When the Hatch-Waxman Act was passed into law in 1984, the statute expressly (and for the first time) drew sharp distinctions between branded and generic drugs. While companies seeking to market an innovative drug product must submit full New Drug Applications (NDAs) (which require, among other things, clinical trial studies/reports), *Mensing*, 564 U.S. at 612-13 (citing 21 U.S.C. §§ 355(b)(1), (d)), applicants seeking to market copies of those drugs need only file an Abbreviated New Drug Application (ANDA) demonstrating the product's chemical

and biological equivalence to a previously approved drug (called the "reference listed drug"). *Id.* (citing 21 U.S.C. § 355(j)(2)(A)).

To that end, the statute requires ANDA applicants to demonstrate that a proposed generic drug is identical to its branded equivalent in all material respects—that is, that the generic product has the same labeling and design as its branded predecessor. ANDA applicants therefore must prove that the proposed generic drug contains "the same" active ingredient(s); employs "the same" route of administration (*e.g.*, oral or injected); presents "the same" dosage form (*e.g.*, tablet or capsule); exhibits "the same" strength (*e.g.,* 20 mg or 40 mg); and is "bioequivalent" to its branded counterpart, in order to ensure it will "have the same therapeutic effect" as the branded equivalent. 21 U.S.C. § 355(j)(2)(A)(i)-(iv); *Mensing*, 564 U.S. at 612 n.2 (explaining that each generic drug must be "identical [to its branded equivalent] in active ingredients, safety, and efficacy").

The net result of those requirements is that generic product design must be materially identical to that of its branded counterpart—which explains why, as *Mensing* recognized, generic product labeling must also be "'the same as the labeling approved for the [brand-name] drug.'" *Mensing*, 564 U.S. at 612-13 (quoting 21 U.S.C. § 355(j)(2)(A)(v); citing *id.* § 355(j)(4)(G)); FDA, *Abbreviated New Drug Application Regulations—Final Rule*, 57 Fed. Reg. 17950, 17961 (Apr. 28, 1992)

("[T]he ANDA product's labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for ANDA approval.").

This carefully drawn statutory distinction between brand-name products and generic products—in terms of what is required for approval, and what each is authorized to do post-approval—is far from hypothetical or doubtful. To the contrary, nearly every subsection of Hatch-Waxman's generic-drug provisions reflects Congress's textually manifest goal of ensuring that such drugs are "the same as" their brand-name counterparts, and are readily available in the interstate marketplace. *See, e.g.*, 21 U.S.C. § 355(j)(1)-(2)(A) (requiring generic products to have "*the same*" active ingredient(s), routes of administration, dosage forms, and strengths as previously approved brand-name drugs); *id.* at § 355(j)(4) ("[FDA] shall approve an [ANDA] unless [the sameness criteria are not met]."); § 355(j)(2)(A) (barring the FDA from "requir[ing] that an abbreviated application contain information in addition to that required by [the sameness] clauses.").

Precisely in order to ensure generic manufacturers take full advantage of the abbreviated pathway, Hatch-Waxman creates a lucrative incentive for generic applicants to both challenge competition-blocking patents and submit ANDAs at the earliest chance: It rewards the first generic applicant that submits an ANDA that challenges a patent which covers the referenced name-brand drug with a 180-day exclusivity period during which no other ANDA for that drug can be approved. *Id.*

at § 355(j)(5)(B)(iv). And the courts repeatedly have recognized that Congress intended to drive marketplace competition by ensuring not only that generic products can enter interstate commerce, but that they actually do so—both early and often. *See, e.g., Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1305 (D.C. Cir. 2010) ("This promise of initial marketing exclusivity is thus intended to increase competition by expediting the availability of generic equivalents."); *Teva Pharms., USA, Inc. v. Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008) ("The legislative purpose underlying [180-day exclusivity] is to enhance competition by encouraging generic drug manufacturers to challenge the patent information provided by NDA holders in order to bring generic drugs to market earlier.").

Suffice to say, the district courts' apparent disbelief that brand-name and generic manufacturers should be treated differently flies in the face of the Hatch-Waxman Act, and contradicts the very controlling Supreme Court precedent that carefully interpreted and applied that legislative landscape in *Bartlett* and *Mensing*. Nor is this some small matter. On the contrary, the reality is that accepting the apparent views of the court below "would take [away] the very ability to achieve the law's congressionally mandated objectives that the Constitution, through the operation of ordinary pre-emption principles, seeks to protect." *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 872 (2000).

And the FDA's own actions over time confirm that this differential statutory and regulatory treatment was intentional. Although FDA regulations permit brand-name manufacturers to make unilateral labeling changes, *see* 21 C.F.R. § 314.70(c)(6)(iii)(A) (the so-called "CBE Provision"), those regulations grant generic drug manufacturers no corresponding ability to do so. In fact, and in a direct political reaction to *Bartlett* and *Mensing*, the FDA years ago proposed a rule that would have permitted, for the first time, generic drug manufacturers to make unilateral labeling changes by using the CBE Provision. *See* FDA, *Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products*, 78 Fed. Reg. 67985 (Nov. 13, 2013). But after over five years of Agency deliberation—including the taking of written and oral testimony from a bevy of interested stakeholders—the FDA announced in December 2018 that it was withdrawing the proposed rule, and took care to explain that it was doing so because "[t]he concerns raised in the comments reflect significant competing interests, and FDA acknowledges that the proposed rule, if finalized, would present significant potential downsides. In light of those potential downsides, the Agency does not believe that finalizing the proposed rule would be an appropriate use of Agency resources." FDA, *Withdrawal of Proposed Rule on Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products*, 83 Fed. Reg. 64299, 64301 (Dec. 14, 2018). No less than Congress then, the FDA has

expressly recognized that brand-name and generic manufacturers are not only treated differently, but that there are important reasons *why* they are treated differently.

In the end, the core point that matters here is that there is no serious question that Congress intentionally created a statutory and regulatory regime under which brand-name products are treated differently than generic products like the propofol at issue here, and there is no question that the FDA itself understands and abides by that distinction. Accordingly, because the courts grounded their summary denials of Petitioners' motions to dismiss on premises that are incompatible with the text, structure, and history of the Hatch-Waxman Act, incompatible with FDA's own regulations, and incompatible with binding United States Supreme Court decisions on question of federal law such as *Mensing* and *Bartlett*, those district court orders are clearly erroneous and cannot stand as a matter of law. A writ should therefore issue and Plaintiffs' claims should be dismissed in their entirety as dictated by *Bartlett*, *Mensing*, and their progeny.

CONCLUSION

This Court traditionally grants immediate review where issues of federal preemption are involved, and doing so here will both resolve important issues of statewide importance and preserve judicial resources by disposing of this entire case involving nearly 800 plaintiffs right now. The courts below had a clear duty to

dismiss these cases, yet failed to do so. Mandamus should therefore issue and these lawsuits should be dismissed in their entirety.

Respectfully submitted this 16th day of April 2020.

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CERTIFICATE OF COMPLIANCE WITH NRAP 28 AND 32

I hereby certify that this Petition complies with the formatting requirements of NRAP 32(c)(2), the typeface requirements of NRAP 32(a)(5) and the type style requirements of NRAP 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using MS Word 2010 in Times New Roman 14, with double spacing. The brief contains approximately 10,236 words.

Finally, I hereby certify that I have read this Petition, 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, NRAP 21(a)(3). I understand that I may be subject to sanctions if the accompanying Petition is not in conformity with the requirements of the Nevada Rules of Appellate Procedure.

Respectfully submitted this 16th day of April 2020.

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CERTIFICATE OF SERVICE

Pursuant to NRAP 25.1 certify that I am an employee of GREENBERG TRAURIG, LLP, that in accordance therewith, on April 16, 2020, I caused a copy of ***Petition Under NRAP 21 For Writ of Mandamus*** to be served via U.S. Mail, first class postage prepaid, and via the 8th Judicial District Court's e-service system, to

Glen J. Lerner, Esq. GLEN LERNER INJURY ATTORNEYS 4795 South Durango Drive Las Vegas, NV 89147 *Attorneys for Real Parties in Interest*	Peter C. Wetherall, Esq. WETHERALL GROUP, LTD. 9345 w. Sunset Rd., Ste. 100 Las Vegas, NV 89148 *Attorneys for Real Parties in Interest*
With courtesy copies via email (pursuant to March 20, 2020 order of the Chief Judge of the EDJC that courtesy copies be submitted via email) :	
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