No. _____

IN THE SUPREME COURT OF THE UNITED STATES

MARCO GONZALEZ,
APPLICANT,

v.

SALEM SHAHIN, MD; CAROL GILMORE, MD; RICHARD MARTIN, MD; PAUL ANDELIN, MD; JEFFREY ADAMS, PA-C; MERCY MEDICAL CENTER; MCKENZIE COUNTY HEALTHCARE SYSTEMS, INC.,
RESPONDENTS.

APPLICATION FOR AN EXTENSION OF TIME WITHIN WHICH TO FILE A PETITION FOR A WRIT OF CERTIORARI TO THE EIGHTH CIRCUIT

To the Honorable Brett M. Kavanaugh, Circuit Justice for the United States Court of Appeals for the Eighth Circuit:

Pursuant to Rules 13.5 and 30.2 of this Court, Marco Gonzalez applies for a 30-day extension of time, to and including January 19, 2024, within which to file a petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eighth Circuit in this case. The judgment of the court of appeals was entered on August 16, 2023, App. 13, and a petition for rehearing en banc was denied on September 21, 2023, App. 14. Unless extended, the time for filing a petition for a writ of certiorari will expire on December 20, 2023. This Application is being filed more than ten days prior to that due date. The jurisdiction of this Court would be invoked under 28 U.S.C. 1254(1). A copy of the opinion of the court of appeals is attached, which is reported at 77 F.4th 1183. App.1-12.

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BACKGROUND

Congress has long insisted on an extensive testing regime to assure the safe use of pharmaceutical drugs by enacting the Federal Food, Drug, and Cosmetic Act (FDCA), ch. 675, 52 Stat. 1040, as amended, 21 U.S.C. § 301 *et seq*. *Wyeth v. Levine*, 555 U.S. 555, 566 (2009). Since 1962, Congress placed the burden on manufacturers "to demonstrate that its drug was 'safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling' before it could distribute the drug." *Id*. at 567. That responsibility was further enhanced in 2007, when Congress granted the Food and Drug Administration statutory authority to require a manufacturer to change its drug label based on safety information that becomes available after a drug's initial approval. *Id*.

Detailed regulations require that a drug's label contain recommended dosages, note critical differences among population subsets, as well as provide other clinically significant clinical pharmacologic information, contraindications, and warnings and precautions that include "information that would affect decisions about whether to prescribe a drug, recommendations for patient monitoring that are critical to safe use of the drug, measures that can be taken to prevent or mitigate harm," and a "list of the most frequently occurring adverse reactions, . . . along with the criteria used to determine inclusion (e.g., incidence rate)." 21 C.F.R. § 201.57(7)-(11); *see also* 21 U.S.C. §§ 355(b), (d). A drug's label must bear "such adequate warnings against use . . . as are necessary for the protection of users." 21 U.S.C. § 352(f)(2).

The information produced and the warnings required for prescription drugs are largely intended for use by medical professionals so that they can gauge the appropriateness of prescribing a drug in any particular situation. Under the "learned intermediary" doctrine, the vast majority of states treat that information as necessary for physicians, rather than patients. *See Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 158 (Tex. 2012) (listing decisions in 35 states adopting the doctrine, and then adding Texas to that list). Typically, where the learned intermediary doctrine prevails, a doctor's deviation from the warning labels is treated as "prima facie evidence of negligence." *Mulder v. Parke Davis & Co.*, 181 N.W.2d 882, 887 (Minn. 1970). Although the number of states adopting the doctrine has since expanded, even in states that have not adopted the learned intermediary doctrine, such as North Dakota, the jurisdiction at issue in the instant case, a physician's deviation from a drug's instructions constitutes prima facie evidence of negligence. *Winkjer v. Herr*, 277 N.W.2d 579, 585 (N.D. 1979).

In this case, Applicant Marco Gonzalez brought a medical-malpractice action against a number of health-care providers because of their negligent treatment with Bactrim and their failure to discontinue use of Bactrim, an antibiotic, and their failure to evaluate, diagnose, and treat his adverse reaction to Bactrim which caused him to develop Stevens-Johnson Syndrome (SJS), a dangerous and well-recognized complication of Bactrim that causes burns to the mucous membranes, including the eyes. App.1-4.

Due to limited experience with SJS, the defendants merely looked for a rash as a telltale sign, found none, and continued prescribing Bactrim. They did not consult any medical literature, including the Physician's Desk Reference (PDR),[1] which would have tipped them off to the signs and symptoms of the adverse reaction, and Gonzalez's severe injury could have been avoided. Only after Gonzalez called 911 from his own hospital bed and was subsequently transferred to a burn unit did he receive the treatment he needed and the cessation of the Bactrim prescription. App. 33-34.

TWO ISSUES ARE RAISED BY DECISION BELOW

1. A significant part of the evidence supporting Gonzalez's negligence claim was the warning label, approved by the FDA as necessary to market the drug and to use it safely. Undisputed evidence established that the defendant physicians failed to consult that warning label, even though it was readily available in the PDR.

2. As is standard practice in most district courts, the parties and judge consulted on an appropriate instruction to the jury – here on the meaning and relevance of warning labels. Upon admission of the PDR, the court gave the jury the agreed-upon instruction, Final Jury Instruction 19, which included a statement to the jury that the warning label did not constitute conclusive evidence of the medical providers' standard of care.

[1] The Physician's Desk Reference is a widely used compendium of drug information that is "published annually and supplemented quarterly," "distributed to the medical profession free of charge, at the expense of the drug manufacturers," and can be "prima facie evidence of the standard of care in using the drug." 82 A.L.R.4th 166 (Originally published in 1990).

3. Following that expected instruction, however, the court added additional commentary of its own which it described to the jury as "additional instruction." The court told the jury that it was concerned that the label be given too much weight and that most courts do not permit the label to go back into the jury room to prevent overreliance on it. App. 24-26.

4. The court added:

> Keep in mind these are written by drug companies and lawyers that include all sorts of information to protect principally drug companies from having a lawsuit like this; so they'll include all sorts of information in those documents. Because if they know of a concern and they don't put it into an insert like that and they have a lawsuit as a result, it's a The case that I'm sure [plaintiff's counsel] Mr. Leventhal would love to take on behalf of somebody who is injured as a result of that type of conduct. So keep it in perspective.

App. 25.

5. The Court rejected a subsequent objection that it was prejudicial in that it diminished the import and purpose of the label, while introducing "facts" that no expert witness or any other record evidence supported. The objection also asserted that it denigrated plaintiff's counsel and his reliance on the label. The court rejected the objection, describing what it said as merely "common sense" and therefore appropriate. App. 28-31.

6. District court judges, of course, have broad discretion to comment on evidence, provided the comments do not interfere with the jury's role as factfinder, *Russel v. Anderson*, 966 F.3d 711, 722 (8th Cir. 2020), because the Constitution assures that juries remain the authority that makes credibility determinations,

weighs evidence, and draws legitimate inferences from the facts, not the judge. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

7. Indeed, nearly a century ago, Chief Justice Hughes, writing for this Court, noted that a judge's comments have "inherent limitations," must "be exercised in conformity with the standards governing the judicial office," and cannot "assume the role of a witness" or "distort [the evidence] or add to it." *Quercia v. United States*, 289 U.S. 466, 470 (1933). The Eighth Circuit, relying on *Quercia*, has noted that a judge's comments to a jury are "'necessarily and properly of great weight'" and "'[their] lightest word or intimation is received with deference, and may prove controlling.'" *United States v. Brandom*, 479 F.2d 830, 835 (1973) (quoting *Quercia*, 289 U.S. at 470).

8. Upon a motion for a new trial, the district court judge here excused his comments once again as "appropriate" about drug companies seeking to avoid liability, but otherwise, in suggesting a greedy motive on plaintiff's counsel, abandoned his claim of "common sense" by describing it as a "bade [sic] joke" and of such brevity that it could not have weighed heavily with the jury. App. 16-18. The judge also asserted that any prejudicial effect was "effectively cured" by a generic instruction given prior to the jury's deliberation that told the jury "at the close of trial, 'I have not intended to suggest what I think your verdict should be by any of my rulings or comments during trial." App. 18. Jurors were left to guess what, if anything, that boilerplate instruction referenced.

9. When the Eighth Circuit reviewed this issue, it agreed with Gonzalez that the comment was "ill-advised." App. 8. Still, "[o]n the whole," it held the jury instructions did not prejudice the verdict against Gonzalez.

10. This Court has long recognized the outsized influence that judicial comments can have on juries. *See Galloway v. United States*, 319 U.S. 372, 400 (1943) (citing *McLanahan v. Universal Ins. Co.*, 26 U.S. (1 Pet.) 170 (1828)). Rather than rely on judicial direction of juries to determine facts, the Constitution values neutral tribunals where "juries are the best judges of facts," as John Jay once charged. *Id.* at 399 (quoting *Georgia v. Brailsford*, 3 U.S. (3 Dall.) 1, 4 (1794)).

11. The comments not only influenced the jury and rendered the tribunal less than neutral, but also told jurors that warnings that form the key element of the federal government's entire drug safety regime were merely a conceit designed to shield manufacturers from liability and were of little importance in actual health care, implicating far more than this one trial.

12. Other circuits have suggested that more pointed and clear instructions that any comments by the judge on the evidence were unintentional and should be disregarded because jurors are the sole judges of the facts are needed to palliate any untoward effects. *See, e.g., Logue v. Dore*, 103 F.3d 1040, 1046 (1st Cir. 1997); *Montgomery v. Gen. Acc. Ins.*, 114 F.3d 1176 (4th Cir. 1997) (requiring judge to do so in sufficient proximity to the comment made); *Wilson v. Bicycle S., Inc.*, 915 F.2d 1503, 1508 (11th Cir. 1990).

13. The Eighth Circuit gave the issue a limited review because it found the notice of appeal untimely, while the motion for a new trial, containing the same issue, appropriate for appellate review. App. 7-9.

14. That ruling created a significant conflict with this Court's holding in *Bowles v. Russell*, 551 U.S. 205, 210-13 (2007), and reiterated in *Hamer v. Neighborhood Hosing Serv. of Chicago*, 583 U.S. 17, 19 (2017), which held that "a time limit prescribed only in a court-made rule . . . is not jurisdictional" but "is, instead, a mandatory claim-processing rule subject to forfeiture if not properly raised by the appellee." *Id.*

15. Here, after the jury returned its defense verdict on November 18, 2021, the district court granted, without objection from the defendants, Gonzalez's request of an extension of time to file post-trial motions by January 13, 2022. Gonzalez moved for a new trial within that timeframe, but that motion was denied on April 27, 2022. App. 5-6. Gonzalez filed his notice of appeal on May 13, 2022. App. 5.

16. Fed. R. App. P. 4(a)(1)(A) provides that a notice of appeal must be filed with the "district clerk within 30 days after entry of the judgment or order appealed from."

17. Despite this Court's holdings in *Bowles* and *Hamer* that this requirement is non-jurisdictional, the Eighth Circuit continues to treat the 30-day deadline as "mandatory and jurisdictional." *Perficient, Inc. v. Munley*, 43 F.4th 887, 889 (8th Cir. 2022).

18. Following that in-circuit ruling, the Eighth Circuit, in the decision below, held that the unobjected-to extension of time to file post-trial motions and the subsequent filing of a notice of appeal after the district court denied the motion for a new trial and awarded costs, deprived the appellate court of jurisdiction over the full array of issues Gonzalez raised as to the final judgment. App. 7.

19. Unlike the Eighth Circuit and the Fourth Circuit, *see Bracey v. Lancaster Foods LLC*, 838 F. App'x 745, 748 (4th Cir. 2020), other circuits have adopted a non-jurisdictional approach to evaluating the timeliness of notices of appeal in light of *Hamer*. *See, e.g., Georgia-Pac. Consumer Prod. LP v. NCR Corp*., 40 F.4th 481, 487 (6th Cir. 2022); *Demaree v. Pederson*, 887 F.3d 870, 877 (9th Cir. 2018); and *In re IPR Licensing, Inc.*, 942 F.3d 1363, 1371 (Fed. Cir. 2019). The conflict between the circuits is deep, and the Eighth Circuit's decision below renders it even more acute.

Reasons For Granting An Extension of Time

20. The extension of time requested here is requested for good cause and necessary because Gonzalez has only engaged Supreme Court counsel in the past week and more time than is available is necessary in order to familiarize counsel with the substantial record, lengthy trial, and prepare a petition for certiorari to detail the conflicts with sister circuits.

21. The remaining time for drafting a petition for certiorari, absent this modest extension of time, coincided with other professional and personal obligations of counsel, including completing a settlement of a Fair Housing Act matter on December 1 involving client homeowners, a homeowner's association, and the

Department of Justice; filings and review of a new court order issued December 4 in *BNSF Railway v. Magin*, No. 2:22-CV-00068 (E.D. Mo.); preparation of a response to a motion to dismiss due December 8 in *Doe v. Archbishop of Washington*, No. C-16-CV-23-004497 (Md. Cir. Ct.); preparation of an opening brief due December 13 in *Ware v. Best Buy*, No. 1-23-1326 (Ill. App. Ct.); and upcoming travel on December 9 for a nephew's wedding in Hawaii.

Counsel respectfully submits that an extension to prepare the petition in this case would allow Applicants to sharpen the issues for review.

Respectfully submitted,

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