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SANDOZ PHARMACEUTICALS CORPORTATION, N/K/A NOVARTIS PHARMACEUTICALS CORPORATION — APPELLANTS

V.

RONALD GUNDERSON, ADMINISTRATOR OF THE ESTATE OF MARY MARGARET GUNDERSON, ET AL — APPELLEES

THE DOCUMENT LISTED BELOW HAS BEEN RECEIVED AND FILED IN THIS OFFICE TODAY IN THE ABOVE CASE:

CHAMBER OF COMMERCE OF THE UNITED STATES FILED MOTION FOR ADMISSION OF HON. JONATHAN D. HACKER, HON. NICOLE A. SAHARSKY AND ROBIN S. CONRAD PRO HAC VICE.

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COMMONWEALTH OF KENTUCKY
SUPREME COURT OF KENTUCKY
2006-SC-000179

SANDOZ PHARMACEUTICALS CORPORATION n/k/a Novartis Pharmaceuticals Corporation — APPELLANT

v.

Appeal from the Jefferson Circuit Court
Action No. 94-CI-04680
Court of Appeals No. 2004-CA-001536-MR

RONALD GUNDERSON, as Administrator of the Estate of Mary Margaret Gunderson et al. — APPELLEES

MOTION FOR ADMISSION *PRO HAC VICE*

The Chamber of Commerce of the United States ("the Chamber"), by counsel, Christopher M. Mussler, moves the Court for leave to admit the following attorneys to appear in the above action *pro hac vice* as co-counsel for the Chamber, which seeks leave to appear as an *amicus* party before the Court in this appeal.

1. **Jonathan D. Hacker.** Mr. Hacker practices at the law firm of O'Melveny & Myers LLP, 1625 Eye Street N.W., Washington, D.C. 20006, and is licensed and admitted to practice before the bars of Maryland and the District of Columbia. He is also admitted to practice before the United States Supreme Court, the United States District Court for the District of Columbia, and the United States Courts of Appeals for the Second, Fourth, Fifth, Sixth, Seventh, Ninth, Tenth, Eleventh, and Federal Circuits. Mr. Hacker is a member in good standing in each of the courts listed.

2. **Nicole A. Saharsky**. Ms. Saharsky practices at the law firm of O'Melveny & Myers LLP, 1625 Eye Street N.W., Washington, D.C. 20006, and is licensed and admitted to practice before the bars of Illinois and the District of Columbia.

COMMONWEALTH OF KENTUCKY
SUPREME COURT OF KENTUCKY
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RONALD GUNDERSON, as Administrator of the Estate of Mary Margaret Gunderson et al. — APPELLEES

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES AS *AMICUS CURIAE* IN SUPPORT OF APPELLANT

Submitted by:

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CERTIFICATE REQUIRED BY CR 76.12(6)

The undersigned does hereby certify that copies of this brief were served upon the following named individuals by U.S. mail, postage pre-paid, on this 22nd day of December 2006: The Honorable Barry Willett, Judge, Jefferson Circuit Court, Sixth Floor Judicial Center, 700 W. Jefferson St., Louisville, KY 40202; Samuel Givens, Jr., Clerk, Kentucky Court of Appeals, 360 Democrat Dr., Frankfort, KY 40601; Edward H. Stopher, Rod D. Payne, Boehl Stopher & Graves, Aegon Center, 400 W. Market St., #2300, Louisville, KY 40202; and Larry B. Franklin, Michael R. Hance, Franklin & Hance, P.S.C., 505 W. Ormsby Ave., Louisville, KY 40203.

Jonathan D. Hacker

STATEMENT OF POINTS AND AUTHORITIES

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PURPOSE OF *AMICUS CURIAE* BRIEF AND ISSUES ADDRESSED

The Chamber of Commerce of the United States of America ("the Chamber") respectfully submits this brief *amicus curiae* in support of Sandoz Pharmaceuticals Corporation ("Sandoz"). A motion seeking leave to file this brief has been submitted concurrently with this brief.

The Chamber is the nation's largest federation of business companies and associations, with an underlying membership of more than 3,000,000 business and professional organizations of every size and in every sector and geographic region of the country. An important function of the Chamber is to represent the interests of its members by filing *amicus curiae* briefs in cases involving issues of national concern to American business.

The Chamber is filing this brief because the rational and equitable administration of punitive damages is a matter of profound concern to the Chamber's members. The Chamber's members welcomed the Supreme Court's decisions in *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), and *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), which they viewed as providing valuable guidance on the scope of conduct for which punitive damages may be imposed, including the rule that punitive damages may not be awarded to punish a defendant for unadjudicated harms to nonparties. In this case, the Kentucky Court of Appeals recognized the possibility that the jury punished Sandoz for just such harms, yet it reversed and remanded for a new trial only on the amount of punitive damages. The Chamber submits that the proper course on this issue was to remand for a new trial on

punitive damages that included both whether punitive damages were warranted and, if so, what amount was necessary to punish and deter the conduct properly at issue.

ARGUMENT

This products liability and medical malpractice case arose out of the death of Mary Margaret Gunderson, who suffered a seizure and died after taking Parlodel® to suppress postpartum lactation. The plaintiffs (her estate and children) alleged that her use of Parlodel® caused her death, and that Sandoz made misrepresentations and omissions in marketing the drug that warranted a substantial award of punitive damages. But plaintiffs did not limit their focus either to the harm suffered by Mrs. Gunderson or to statements made to her prescribing physician. Instead plaintiffs urged the jury to punish Sandoz for alleged (but unproven) harms suffered by *other* Parlodel® users and for misrepresentations made to doctors *other* than Mrs. Gunderson's prescribing physician, who indisputably did not rely on *any* statements from Sandoz about Parlodel® in prescribing the drug to Mrs. Gunderson. The Court of Appeals properly recognized that much of this evidence could not be the basis for punishing Sandoz, and it determined that there must be a new trial on the issue of punitive damages. But the Court of Appeals limited that trial to the question of only the proper *amount* of punitive damages, overlooking the initial, and more fundamental, question of whether a properly instructed jury necessarily would have found that punitive damages were warranted at all.

As the Supreme Court explained in *State Farm*, when a jury considers evidence of unadjudicated harms to nonparties or other unrelated or extraterritorial conduct, there is a serious and inherent risk that the jury will punish the defendant not for the harms it caused to the plaintiff, but for the other dissimilar or unproven conduct. As a result, the

jury must be specifically instructed that it cannot punish the defendant for such conduct. Only that type of instruction can provide jurors the guidance they need to make a rational decision as to whether, and how much, the defendant should be punished for its conduct directed *towards the plaintiff*. Allowing juries to award punitive damages based on unadjudicated harms violates fundamental notions of procedural due process because it does not allow the defendant an adequate opportunity to defend against the alleged harms to others and it subjects the defendant to a risk of multiple punishment.

When a trial court fails to instruct the jury that it may not punish the defendant for harms to nonparties, due process requires a new punitive damages trial on *both* whether to award punitive damages *and* the amount, if any. That is because the appellate court cannot know whether or how the jury used the evidence of unadjudicated harms in its punitive damages determination. The jury could have relied entirely on that conduct as the basis for awarding punitive damages in the first place, or it could have considered the conduct in determining the ultimate amount of punitive damages, or it could have considered the conduct for the purpose (the only arguably allowable one) of assessing the reprehensibility of defendant's conduct toward the plaintiff. There is simply no way to tell. Accordingly, the absence of an instruction barring the jury from imposing punishment for harms to nonparties requires a remand for a new determination of both the amount of punitive damages and whether punitive damages should be awarded at all.[1]

[1] Sandoz preserved this issue for review by requesting a proper jury instruction. *See infra* note 10; *see also* Tape No. 20, 2/26/04, 13:18:08.

A. The Due Process Clause Prohibits Awarding Punitive Damages To Punish A Defendant For Unadjudicated Harms To Nonparties

In a series of cases culminating in *State Farm*, the United States Supreme Court has made clear that there are both substantive and procedural due process limitations on punitive damages awards. 538 U.S. at 416. As a substantive limitation, the Court has held that the maximum permissible amount of punitive damages must be determined by reference to three guideposts – the reprehensibility of the defendant's conduct, the ratio of punitive damages to the plaintiff's harm, and comparable civil and criminal penalties. *Id.* at 419-29; *see also BMW*, 517 U.S. at 574-75. But the Court has also identified critical *procedural* limitations on the assessment of such awards. *See Honda Motor Co. v. Oberg*, 512 U.S. 415, 432 (1994) (noting that basic "procedural safeguards" guard against an arbitrary punitive damages verdict). In particular, the Court has held that punitive damages may not be imposed through a trial process that allows the jury to impose punishment based on conduct that did not harm the plaintiff. *See State Farm*, 538 U.S. at 420-24. It is that holding that frames the constitutional analysis in this case.

In *State Farm*, the plaintiffs urged the jury to award punitive damages because of "business practices for over 20 years," most of which "bore no relation to third-party automobile insurance claims, the type of claim underlying the Campbells' complaint." 538 U.S. at 415. The Court noted that punitive damages "pose an acute danger of arbitrary deprivation of property," and that concern is "heightened when the decisionmaker is presented . . . with evidence that has little bearing as to the amount of punitive damages that should be awarded." *Id.* at 418.

The Supreme Court rejected the notion that alleged harms to nonparties could provide a basis for awarding punitive damages: "A defendant's dissimilar acts,

independent from the acts upon which liability was premised, may not serve as the basis for punitive damages." 538 U.S. at 422. That is because "[d]ue process does not permit courts, in the calculation of punitive damages, to adjudicate the merits of other parties' hypothetical claims against a defendant under the guise of the reprehensibility analysis." *Id.* at 423. Punitive damages may be based only on conduct with "a nexus to the specific harm suffered by the plaintiff." *Id.* at 422. A jury may not "expand the scope of the case so that a defendant may be punished for any malfeasance." *Id.* at 424.[2]

The Supreme Court's command that a defendant may not be punished for dissimilar conduct or unadjudicated harms to nonparties rests on two fundamental due process concerns. The first is the basic right to be heard before being subjected to punishment for assertedly unlawful conduct. *See Boddie v. Connecticut*, 401 U.S. 371, 377 (1971) (due process includes right to "a meaningful opportunity to be heard"). That opportunity to be heard includes the opportunities to "know the claims of the opposing party and to meet them," *Morgan v. United States*, 304 U.S. 1, 18 (1938), and "to present every available defense," *Lindsey v. Normet*, 405 U.S. 56, 66 (1972) (quotation omitted). But the defendant has no such opportunities when punitive damages are awarded for unproven harms to nonparties. The defendant receives no notice of those claims in the complaint, making them purely hypothetical, and plaintiffs are not required to establish the specific elements of those hypothetical claims. As a result, the defendant has no

[2] It bears emphasis that *State Farm*'s analysis is *not* limited to harms suffered by nonparties *out-of-state*. It is a violation of due process "to adjudicate the merits of other parties' hypothetical claims against a defendant" (538 U.S. at 423), no matter where those other parties reside. *See also id.* at 420 (identifying the due process problem as "the reliance upon dissimilar *and* out-of-state conduct evidence" (emphasis added)).

meaningful opportunity to challenge the existence or viability of those claims.[3] Allowing a jury to award punitive damages for those hypothetical claims, in short, deprives the defendant the most basic "process" that is "due" in a civil action.[4]

The second due process concern raised when juries consider harm to nonparties is the risk of multiple punishment. The Supreme Court noted in *State Farm* that consideration of harm to nonparties "creates the possibility of multiple punitive damages awards for the same conduct" – inasmuch as "nonparties are not bound by the judgment some other plaintiff obtains," they can bring their own claims against the defendant and recover punitive damages. 538 U.S. at 423. A defendant thus may be punished over and over again for the same conduct, resulting in punishment that is not only multiplicative, but also exceeds in its aggregate amount the maximum that permissibly could be imposed for the conduct. *See Owens-Corning Fiberglas Corp. v. Malone*, 972 S.W.2d 35, 51 (Tex. 1998) ("[I]f a single punitive damages award becomes unconstitutional when it can fairly be categorized as grossly excessive . . . it follows that the aggregate amount of multiple awards may also surpass a constitutional threshold."). Conversely, a defendant also may be punished for conduct that other juries would *not* find unlawful or reprehensible. Either way, the notion that a defendant may be punished not only for the

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[3] It is as if the plaintiff were being allowed to pursue a *de facto* class action, but without satisfying the procedural requirements – especially typicality and predominance – that ensure the defendant is able to mount a full and fair defense to all claims simultaneously. *See Johnson v. Ford Motor Co.*, 35 Cal. 4th 1191, 1210 (2005).

[4] As one leading commentator has explained, because a "defendant can be punished through the mechanism of punitive damages for the harms caused to third parties only if it committed legal wrongs against those parties," punitive damages can be imposed for such wrongs only in proceedings in which the defendant is allowed to contest the allegations, "not litigation in which the plaintiff effectively strips the defendant of all its defenses." Thomas B. Colby, *Beyond the Multiple Punishment Problem: Punitive Damages as Punishment for Individual, Private Wrongs*, 87 Minn. L. Rev. 583, 657 (2003).

harms caused to the plaintiff, but also for harms caused to nonparties, cannot be squared with the basic requirements of due process.

Even though a defendant may not be *punished* for conduct affecting nonparties, there are purposes for which the jury may *consider* such conduct. The Supreme Court has noted, for example, that the effects of a defendant's conduct on others may be relevant in assessing reprehensibility to the extent those effects make the conduct toward the plaintiffs more blameworthy. For example, "[l]awful out-of-state conduct may be probative when it demonstrates the deliberateness and culpability of the defendant's action in the State where it is tortious." 538 U.S. at 422; *see BMW*, 517 U.S. at 576-77 ("repeated misconduct is more reprehensible than an individual instance of malfeasance"). But the question whether repeated or risky conduct affects the reprehensibility of the defendant's conduct *toward the plaintiff* is different from the question whether the defendant should be punished *for* harms caused to other people. In the latter instance, the jury is effectively resolving unadjudicated claims and imposing punishment that could be (and may already have been) imposed in other cases – exactly what the Due Process Clause prohibits. But the distinction is undoubtedly subtle, and without an instruction clearly prohibiting punishment of the second kind, lay jurors may well decide to impose punishment because of what the defendant did to other people, not just because of what the defendant did to the plaintiff. To avoid that risk, juries must be specifically instructed not to impose punishment for unadjudicated harms to nonparties.[5]

[5] The question of how to ensure that a jury appropriately considers alleged harms to nonparties in assessing reprehensibility without improperly punishing a defendant for them is pending before the U.S. Supreme Court. *See Philip Morris USA v. Williams*, No. 05-1256 (argued October 31, 2006). Although *State Farm* made clear that a requested jury instruction limiting punishment to the conduct which harmed the plaintiff must be

B. The Absence Of A Jury Instruction On The Proper Use Of Unadjudicated Harms To Nonparties Requires A Complete New Trial On Punitive Damages

If the trial court fails to instruct a jury that it may not award punitive damages for unproven harms to nonparties, the question of remedy arises.

As an initial matter, simply reducing the punitive damages award cannot cure the jury's improper consideration of alleged harms to nonparties. That remedy confuses the substantive limitation on excessive awards with the procedural limitation on awarding punitive damages for alleged harms to nonparties. If a properly instructed jury returns a verdict that is excessive in light of the defendant's conduct toward the plaintiff and the three factors identified by the Supreme Court, then an appellate court may remedy that problem by reducing the award to the maximum amount permissible under the Constitution. In that instance, the appellate court knows the amount that the jury wanted to award, and it is the appellate court's responsibility to determine the maximum permissible award by applying the legal principles set forth in *State Farm* and *BMW*. *See Cooper Indus., Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424, 436 (2001) (mandating *de novo* review of the constitutionality of punitive damages awards).

When the defect in the verdict is the jury's consideration of alleged harms to others, however, reduction of the award cannot remedy the problem. That is because the reviewing court does not and cannot know whether a jury, given proper instructions as to the use of evidence concerning harm to others, would have returned the maximum amount of punitive damages, some lesser amount, or any amount at all. *See, e.g., City of Middlesboro v. Brown*, 63 S.W.3d 179, 182 (Ky. 2001) (holding that reversal is required

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given, the Court's decision in *Williams* may provide further guidance as to the precise content of that instruction or the proper remedy when such an instruction is not given.

"when the appellate court cannot determine . . . that the verdict was not influenced by the erroneous instruction"). Indeed, as the Supreme Court has recognized, there is a "heightened" risk of an arbitrary punitive damages verdict when a jury is presented with evidence of unadjudicated harm to nonparties. *State Farm*, 538 U.S. at 417-18. Accordingly, when the court fails to instruct the jury not to punish on the basis of such evidence, a new trial on punitive damages is required in order to ensure that the defendant is punished only for conduct that injured the plaintiff, and not for conduct "independent from the acts upon which liability was premised." *Id.* at 422.[6]

The new trial on punitive damages must allow the properly instructed jury to consider both the *initial* question of whether punitive damages are warranted for the defendant's conduct toward the plaintiffs *and* the proper amount of those damages. A jury's decision to award punitive damages is a two-step process. *See* 1 John J. Kircher & Christine M. Wiseman, *Punitive Damages: Law and Practice* § 5:23, at 5-152 (2d ed. 2000). First, the jury determines "whether punitive damages may be assessed" because of the defendant's conduct. KRS § 411.186(1). Second, if the jury finds that punitive damages are warranted, it determines what amount is necessary to punish the defendant for its harm to the plaintiff and to deter the defendant from engaging in similar conduct. *See id.* § 411.186(2) (if jury "determines that punitive damages should be awarded," it then "assess[es] sum of punitive damages" in light of specific factors).

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[6] This Court recognized the appropriateness of the new trial remedy in *Sand Hill Energy, Inc. v. Smith*, 142 S.W.3d 153 (Ky. 2004). After determining that the jury's punitive damages verdict was tainted by its consideration of extraterritorial evidence, the Court ordered a new trial to cure that constitutional error. *See id.* at 157. The question of whether the Constitution requires that the new trial must include both whether punitive damages are warranted and the amount was not squarely before the Court in *Sand Hill*. *See id.* at 165 (question of whether state-law prerequisites for an award of punitive damages were met waived).

A jury's consideration of unadjudicated harms to nonparties may infect both of those steps. First, the jury may have considered alleged harms to others in deciding whether to award punitive damages at all. The jury could, for example, have determined that the defendant's conduct toward the plaintiff was not particularly offensive and does not warrant punitive damages on its own, but that the defendant's conduct toward others was egregious and warrants punitive damages. Or it could have determined that the conduct toward the plaintiff alone did warrant punitive damages. There is simply no way to know. Likewise, a jury may choose an amount of punitive damages based solely on conduct affecting the plaintiffs; it may choose an amount for the conduct toward the plaintiffs and add an amount for conduct to others; or it may calculate the amount based entirely on conduct directed at others. Only the first of those options is constitutionally permissible, yet there is no way for an appellate court to ensure that is what happened. *See, e.g., White v. Ford Motor Co.*, 312 F.3d 998, 1016 (9th Cir. 2002) ("Possibly the jury would have chosen as large an award had it been told to vindicate only the rights of Nevadans, but possibly it would have chosen a substantially lower award."), *amended by* 335 F.3d 833 (9th Cir. 2003).

Because a reviewing court cannot discount the possibility that a properly instructed jury would have reached a different result at either the first or second step, or both, due process requires a new trial as to both steps of the punitive damages inquiry.[7]

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[7] It is no response to this problem that a jury that has found that punitive damages are warranted generally still has the discretion to award zero punitive damages. *See, e.g.*, 1 John J. Kircher & Christine M. Wiseman, *supra*, § 5:23, at 5-152. The ability to award zero punitive damages is not the same as the ability to determine that the defendant should not be liable for punitive damages. If the punitive damages verdict is tainted by evidence of unadjudicated harms to nonparties, the determinations of both punitive damages liability and amount must be reversed. If they are not, it is of little solace to the

C. The Jury Here Considered Two Categories Of Evidence Of Harms To Nonparties, Requiring A New Trial On Whether Punitive Damages Are Warranted And Amount

This case effectively illustrates these cardinal due process principles. Here, as in *State Farm*, the plaintiffs "framed this case as a chance to rebuke [Sandoz] for its nationwide activities," 538 U.S. at 420, and they "relied heavily" on unadjudicated harms to nonparties at trial, Slip Op. 39, including two particular categories of evidence introduced by the plaintiffs that cannot support punitive damages under *State Farm*.

First, the plaintiffs introduced evidence that Sandoz "sought to keep concerns about the drug from coming to the attention of doctors," by "denying the existence of adverse reaction reports to physicians" and "minimizing" the risks of Parlodel®. Slip Op. 37. Specifically, plaintiffs introduced evidence that Sandoz representatives lied to Dr. Prince, an obstetrician in Dallas, *see* Tape No. 6, 02/09/04, 14:12:54; *see also* Slip Op. 39, and "whitewash[ed]" Parlodel®'s adverse effects in conversations with Dr. Kulig, a toxicologist in Denver, *see* Tape No. 5, 02/05/04, 17:10:47. Plaintiffs urged that punitive damages be awarded to punish for these misrepresentations, even though there was "no evidence that Sandoz representatives over-promoted Parlodel® directly to Dr. Armstrong [Mary Gunderson's doctor]." Slip Op. 36. Indeed, Dr. Armstrong testified that he had not received marketing brochures or other written communications from Sandoz, *see* Tape No. 5, 02/06/04, 15:13:52, Sandoz sales representatives "rarely" visited him, Tape No. 5, 02/06/04, 15:10:09, and he based his decision to prescribe Parlodel®

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defendant that the jury could award zero punitive damages on retrial, especially when the jury will likely be instructed that a previous jury has already determined that punitive damages are warranted for the defendant's conduct.

entirely on the "good results" he saw in his patients who had used it, Tape No. 5, 02/06/04, 15:32:55.[8]

This category of conduct could not properly serve as the basis for punishing Sandoz *in this case* because it was not conduct "directed toward the plaintiffs" and it did not cause their injuries. *State Farm*, 538 U.S. at 420. All the evidence about misrepresentations involved *other* users and prescribers of Parlodel®. The Court of Appeals thus properly recognized that Sandoz's representations to other doctors in other states could not be the basis for an award of punitive damages to the plaintiffs. Slip Op. 39-40. And even to the extent that misrepresentations to other doctors might have been relevant to the culpability (and hence reprehensibility) of Sandoz's conduct, *see id.* at 37, 39, that only highlights why the jury should have been instructed not to impose punishment in *this* case *because of* such conduct, since this case did not involve the asserted misrepresentations. If punishment is appropriate for misrepresentations made to others, it can be awarded in other cases brought by those actually affected by the misconduct. The question in this case should have been whether the conduct affecting the plaintiffs warranted punitive damages; while proven misrepresentations to other doctors might have permitted an inference of culpability as to the alleged failure to warn Dr. Armstrong, the jury should have been told that its punishment should be based not on those misrepresentations, but on the conduct directly affecting the plaintiffs.

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[8] Although the cross-claim filed by Dr. Armstrong's estate alleges that Sandoz may have made misrepresentations to Dr. Armstrong, *see* Pls' Ex. 35, Sandoz Appendix ("Sandoz App.") 13, the unsubstantiated allegations in the cross-claim do not constitute evidence. The only evidence on this point was Dr. Armstrong's deposition statements that he received no such misrepresentations. Plaintiffs did not contend otherwise.

The second category of evidence considered by the jury that cannot support an award of punitive damages was evidence of adverse events allegedly suffered by other patients who used Parlodel®. Plaintiffs argued at trial that Parlodel® caused hundreds of other women worldwide to suffer adverse events, and they urged the jury to punish Sandoz for those alleged harms. *See, e.g.*, Tape No. 6, 02/09/04, 14:47:46; Tape No. 9, 02/12/04, 13:09:31, 13:15:33; Tape No. 21, 02/27/04, 14:52:29. Indeed, plaintiffs introduced into evidence Sandoz's nationwide revenues from Parlodel® to assist the jury in determining how to punish Sandoz for the nationwide conduct, *see* Tape No. 9, 02/12/04, 09:25:32, and suggested that the jury punish Sandoz for its operations "all over the world," Tape No. 11, 02/16/04, 11:37:38; *see also* Tape No. 22, 02/27/04, 15:24:38, 15:25:13.

The Court of Appeals recognized that, even though evidence of "other serious adverse reactions associated with Parlodel® almost all of which occurred outside Kentucky" was "introduced to prove that Sandoz had conducted itself reprehensibly," Slip Op. 39-40, there was a serious risk that it would be used to punish Sandoz. That basis for punishment is prohibited by *State Farm*; the jury may not "adjudicate the merits of other parties' hypothetical claims . . . under the guise of the reprehensibility analysis." 538 U.S. at 423. The Court of Appeals thus held that the jury must be instructed that it could not award punitive damages on this basis. Slip Op. 39-40.[9]

[9] Plaintiffs further suggested that punitive damages were warranted because under Kentucky law, Mary Gunderson's husband and parents could not be plaintiffs with their own claims for loss of consortium. *See* Tape No. 22, 02/27/04, 15:35:10. Those harms, like the evidence of adverse events, cannot be used as a basis of punishment under *State Farm* because they are not the "harm suffered by the plaintiff." 538 U.S. at 422.

The Court of Appeals properly recognized that these two categories of evidence could not serve as the predicate for a punitive damages award to the plaintiffs, at least insofar as the evidence involved conduct outside Kentucky. For the reasons in Section A above, however, evidence of dissimilar conduct and conduct toward nonparties cannot support an award of punitive damages no matter where such conduct occurred. The instruction requested by Sandoz – reprinted in the margin[10] – accurately described the law in this respect. That full instruction should be required on remand.

The proceedings on remand should also include more than just the new trial on the *amount* of punitive damages ordered by the Court of Appeals. Slip Op. 39. That limited remand was error, because the jury's consideration of unadjudicated harms to nonparties could have infected both the decision to award punitive damages and the amount chosen. *See supra* Section B.[11] Neither this Court nor the Court of Appeals can

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[10] Proposed Instruction No. 14 stated:

> The law also imposes certain limitations on the evidence that you may consider in determining whether punitive damages are justified in this case.
>
> Punitive damages cannot be used to punish or condemn Sandoz for its alleged nationwide policies or practices. Instead, punitive damages must be based upon conduct that was directed toward the plaintiffs. Therefore, evidence of Sandoz's statements, acts and other conduct directed toward persons other than Mrs. Gunderson cannot form the basis of any punitive damages award in this case.
>
> Furthermore, you may not use punitive damages to punish Sandoz for any conduct outside the state of Kentucky.

Sandoz App. 12.

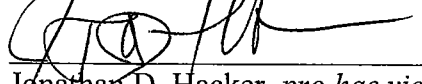
[11] Although the Court of Appeals determined that the evidence supported submission of the issue of punitive damages to the jury, that holding does not mean that the jury's decision to award punitive damages can survive. When a reviewing court finds that the issue of punitive damages is submissible, it has simply made a legal determination that a reasonable jury could find that punitive damages are warranted based on the evidence, but that does not mean that punitive damages must be awarded. *See*,

know whether the jury would have awarded punitive damages at all if it had been instructed not to base punishment on the two categories of evidence involving dissimilar conduct and unadjudicated harms to nonparties. Accordingly, this Court should hold that due process requires a new punitive damages trial – with a properly instructed jury – on both whether punitive damages are warranted and, if they are, what amount of punitive damages is proper.

CONCLUSION

For the foregoing reasons, the Chamber of Commerce respectfully suggests that, if this Court affirms Sandoz's liability for compensatory damages, it remand this case for a new trial on punitive damages, where both the issue of whether punitive damages are warranted and the issue of the amount of punitive damages, if any, are submitted to a properly instructed jury.

Respectfully submitted,



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December 22, 2006

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e.g., 1 Kirchner & Wiseman, *supra*, § 5:23, at 5-152. Here, the Court of Appeals found submissibility, Slip Op. 36-37, but the fact that the punitive damages verdict was tainted by consideration of harms to nonparties means that the jury's determination that punitive damages actually were warranted must be vacated.