No. 22-447

IN THE

Supreme Court of the United States

JOHNSON & JOHNSON, ET AL.,
Petitioners,

v.

STATE OF CALIFORNIA,
Respondent.

On Petition for a Writ of Certiorari to the Court of Appeal of California

BRIEF OF *AMICI CURIAE* OF THE NATIONAL ASSOCIATION OF MANUFACTURERS, AMERICAN TORT REFORM ASSOCIATION, AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*[1]

The National Association of Manufacturers (NAM), American Tort Reform Association (ATRA), and Pharmaceutical Research and Manufacturers of America (PhRMA) submit this brief as *amici curiae* in support of Petitioners. *Amici* share a collective concern that state attorneys general and courts have imposed civil penalties under state unfair or deceptive acts and practices (UDAP) laws in an unpredictable and excessive manner that violates the constitutional rights of defendants.

The NAM is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 States. Manufacturing employs more than 12.9 million men and women, contributes $2.77 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for nearly two-thirds of all private-sector research and development in the Nation. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

ATRA is a broad-based coalition of businesses, corporations, municipalities, associations, and professional firms that have pooled their resources to promote reform of the civil justice system with the

[1] Counsel of record for all parties received timely notice of amici's intent to file this brief and have consented to its filing. No counsel for any party authored this brief in whole or in part, and no person or entity other than *amici* and their counsel contributed funds for its preparation or submission.

goal of ensuring fairness, balance, and predictability in civil litigation. ATRA files *amicus curiae* briefs in cases involving important liability issues.

PhRMA is a voluntary, nonprofit association representing the country's leading research-based pharmaceutical and biotechnology companies.[2] PhRMA's mission is to advocate public policies encouraging innovation in life-saving and live-enhancing new medicines. PhRMA's member companies are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives, and they have led the way in the search for new cures. PhRMA's members make significant contributions to serve the collective goals of enhancing and lengthening human life. Since 2000, PhRMA members have invested more than $1 trillion in the search for new treatments and cures.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case is emblematic of the subjective and arbitrary manner in which states impose civil penalties under their UDAP laws, which are vague with respect to the conduct that can give rise to a violation and the amount of penalties the state will impose. The total civil penalty here could have been $2,500, $2,500,000, $250,000,000, or $2,500,000,000; California law provides no objective standards. As a result, the State was able to impose hundreds of millions of dollars in civil penalties related to medical devices and risk communications already subject to extensive federal oversight. Granting the Petition

[2] PhRMA's members are listed at www.phrma.org/about#members (last visited Dec. 6, 2022).

would allow the Court to provide bounds for when punishment from aggregating per violation civil penalties becomes constitutionally infirm.

The lack of notice as to the legality of conduct under UDAP laws, unpredictability of the penalty, and lack of proportionality between the size of the fine and objectivity and severity of the alleged deception raise constitutional concern. In this case, California's attorney general brought an action against manufacturers of pelvic mesh medical devices, which were used to treat stress urinary incontinence and pelvic organ prolapse. At the time, the Food and Drug Administration (FDA) categorized these devices as Class II medical devices, meaning that their design and labeling—including benefit-risk information—were cleared by the FDA. In addition, the FDA studied mesh devices and provided guidance to manufacturers on their risk communications. Nevertheless, the State alleges Petitioner marketed its mesh products in ways it believed minimized or omitted certain risks in violation of California's Unfair Competition Law (UCL) and False Advertising Law (FAL). Both statutes provide that the State can seek up to $2,500 *per violation*, but neither statute provides guidance for what constitutes a violation and how violations can be aggregated. State attorneys general and courts have nearly limitless discretion, creating the due process concerns evidenced in this case.

Here, the attorney general computed the statute's per violation provision to seek nearly $1 billion in penalties, presumably to maximize its litigation leverage.[3] Faced with the threat of such liability, many

[3] *See* Daniel Siegal, *Breaking Down J&J and California's $1B Pelvic Mesh Trial*, Law360, July 12, 2019 (reporting the

companies opt to settle regardless of the merits of the claims. Petitioner defended its marketing activities, and the trial court imposed a lower, but still stunning, sum of $344 million based on 153,351 violations of UCL and 121,844 violations of the state's FAL. The California Court of Appeal affirmed after remitting the civil penalty to $302 million. The California Supreme Court denied review.

The arbitrary way this fine was calculated at each stage highlights the constitutional concerns here. Neither the State's nor court's calculations had anything to do with whether a communication was likely to deceive a real person. For example, the court counted each printed piece of marketing paper estimated to have been shipped to California as a separate violation, regardless of whether the piece was actually sent to and read by a doctor or potential patient. The court added separate violations based on the circulation of each healthcare provider newsletter, speculating that the publication could have passed on misleading information on the Petitioner's pelvic mesh products, even if it did not. The court included additional violations for each instruction sheet included in a product's package and each conversation that hypothetically occurred between a sales representative and healthcare provider at certain events.[4] Then, the court counted many viola-

state sought civil penalties totaling $960 million in a pretrial brief); *see also* Daniel Siegal, *Calif. Tells Judge J&J Must Pay $800M for Mesh Marketing*, Law360, Sept. 26, 2019 (indicating the state requested $800 million at trial).

[4] This was the only portion of the civil penalty eliminated by the Court of Appeal, which drew the line at punishing a company for communications that may have never occurred.

tions twice, as the State sought civil penalties under two different, overlapping statutes, the UCL and FAL.

The court failed to tie the fines to concrete communications between Petitioner and California doctors or potential patients, whether they were likely to be misled, or whether patients experienced complications rather than benefited from the devices. Entities engaging in lawful commerce, particularly of mass-marketed items, must not be left to the arbitrary whims of state officials enforcing vague laws untethered from how objective or severe the consumer deception or risk they are alleging. Petitioner has a due process right to have fair notice of the conduct that gives rise to civil penalties and the scope of the potential punishment.

Amici respectfully urge the Court to grant certiorari to provide constitutional boundaries on a state's imposition of civil penalties. The Court should require states to provide fair notice of the scope of civil penalties they can impose and, consistent with the Court's punitive damages and Excessive Fines Clause jurisprudence, ensure such fines are rooted in predictability and proportionality.

REASONS FOR GRANTING THE WRIT

I. The Court Should Grant Certiorari to Place Rational Boundaries on the Unpredictable and Near Limitless Imposition of "Per Violation" Civil Penalties

California's and many other states' UDAP laws provide little notice as to the degree of punishment a state can inflict when it alleges that a marketing practice could deceive consumers. As here, when

states impose civil penalties by arbitrarily aggregating "per violation" fines, it raises serious due process concerns that are ripe for this Court's review.

UDAP laws can provide a state with a valuable way to protect consumers by seeking injunctions to stop unfair or deceptive business practices before they cause harm and, when consumers have lost money, obtain restitution. *See generally* Cary Silverman & Jonathan L. Wilson, *State Attorney General Enforcement of Unfair or Deceptive Acts and Practices Laws: Emerging Concerns and Solutions*, 65 U. Kan. L. Rev. 209, 240 (2017). These laws also authorize an attorney general to request that a court punish companies that violate the law and deter others from engaging in similar conduct by seeking civil penalties. *See id.* Many of these state laws, including California's UCL, allow an attorney general to seek, and a court to impose, a civil penalty for any practice that may mislead someone, even if a business did not intend to deceive the public, actually mislead consumers, or cause any loss. *See id.* at 240-41 (citing *California ex rel. Lockyer v. Fremont Life Ins. Co.*, 104 Cal. App. 4th 508, 516-17 (Cal. Ct. App. 2002)).

Maximum civil penalties under UDAP laws range from $1,000 to $50,000 for each violation with about half of state laws set in the $1,000 to $5,000 range and the other half set at $10,000 or more. *See id.* at 241 (compiling statutes). No matter what level a legislature sets as the statutory maximum, when a court, at the behest of a state attorney general, aggregates civil penalties "for each violation," they can reach extraordinarily high sums. There is no guidance or limit for how states can aggregate per incident violations, subjecting manufacturers and other

entities that mass market their products to arbitrary and excessive civil penalties. Attorneys general may seek civil penalties for each product sold, marketing letter sent, sales call or meeting held, advertisement published or aired, or the estimated circulation or viewership of an advertisement. *See id.* at 242. The government has complete subjective discretion.

Today, UDAP litigation increasingly serves as a substitute for traditional product liability lawsuits. Rather than have the burden of showing that a product's design, instructions, or warnings rendered the product defective and caused a personal injury, these suits can simply allege that a product was not as safe as consumers were led to believe. *See generally* Victor E. Schwartz & Cary Silverman, *The Rise of "Empty Suit" Litigation. Where Should Tort Law Draw the Line?*, 80 Brook. L. Rev. 599, 628-30 (2015) (discussing use of UDAP laws to bring private claims based on unmanifested defects).

Indeed, federal courts have expressed concern that aggregating state civil penalties under UDAP laws raise "serious constitutional and other questions." *See In re Zyprexa Prods. Liab. Litig.*, 671 F. Supp.2d 397, 462 (E.D.N.Y. 2009). In *Zyprexa*, Mississippi's Attorney General had sought a $10,000 civil penalty for each of almost one million estimated Zyprexa prescriptions filled in his state, alleging the medication was improperly marketed for off-label uses and did not fully disclose potential risks. *See id.* at 402. The district court refused to inflict the maximum civil penalty amount absent evidence showing how many patients were harmed, rather than benefited, from the medication. *See id.* at 458-59. Imposing the per violation civil penalties sought, the court

observed, would result "in a multibillion dollar cumulative penalty grossly disproportionate" to both the state's injury and the company's alleged misconduct. *Id.* at 463. "[C]ourts cannot be used as an engine of an industry's unnecessary destruction," Judge Jack B. Weinstein cautioned. *Id.* at 463-64.

This unpredictable aggregation of per violation civil penalties also occurred in state attorneys general actions alleging that the manufacturer of Risperdal, which treats schizophrenia and bipolar disorder, did not adequately disclose risks. *See State ex rel. McGraw v. Johnson & Johnson*, 704 S.E.2d 677, 684 (W. Va. 2010) (seeking a civil penalty for each promotional booklet mailed and sales call); *Ortho-McNeil-Janssen Pharm., Inc. v. State*, 432 S.W.3d 563, 570 (Ark. 2014) (seeking civil penalty under a deceptive practices act for each letter sent to a doctor plus civil penalties for each prescription filled under the state's Medicaid fraud statute); *State ex rel. Wilson v. Ortho-McNeil-Janssen Pharm., Inc.*, 777 S.E.2d 176 (S.C. 2015), *cert. denied*, 136 S. Ct. 824 (2016) (seeking civil penalties for each sample box, letter to doctor, and follow-up call). Each of these actions resulted in millions of dollars in total civil penalties, often untethered to any concrete risk of harm. State supreme courts in West Virginia and Arkansas reversed the lower court's judgments on grounds unrelated to the amount of the civil penalty, while the South Carolina Supreme Court ruling highlighted the lack of any standards for imposing such fines. *Wilson*, 777 S.E.2d at 204-05.

In the South Carolina litigation, the trial court imposed $327 million in civil penalties based on aggregating 553,055 separate violations of the state's

deceptive practices act. *See id.* at 204. The South Carolina Supreme Court found that the manufacturer's conduct likely had "little impact" on physicians who prescribed the medication and an "absence of significant actual harm." *Id.* at 204. Nevertheless, it allowed the finding of liability to stand while addressing the excessiveness of the judgment. Specifically, the state high court remitted the $327 million civil penalty to about $124 million by eliminating alleged violations that occurred beyond the statute of limitations, reducing the penalty imposed for each of 509,499 sample boxes distributed to physicians containing allegedly misleading labeling from $300 to $100 per box, and reducing the penalty imposed for each of 36,000 follow-up visits with doctors from $4,000 to $2,000 since most of these visits involved the same doctors who received letters or samples in the mail. *See id.* at 204. It left undisturbed a $4,000 civil penalty imposed for each letter to a doctor, calling the excessiveness of the fine a "close" question. *Id.* The court offered no explanation as to why the civil penalties arbitrarily selected by the trial court were excessive, but not the remitted amounts.

Adding to the unpredictability of UDAP penalties is that, in some instances, state attorneys general bring UDAP enforcement actions through outside counsel. *See* Silverman & Wilson, 65 Kan. L. Rev. at 217-24 (documenting examples). The use of private lawyers working for the state on a contingency-fee basis infuses a profit motive into the litigation and may further drive a state to seek the highest level and greatest number of per violation civil penalties possible, even when not grounded in the facts. Although California did not use private counsel here, the potential for private firms to profit from pushing

past rational limits of government civil penalties increases the need for the Court to articulate constitutional bounds in this case.

II. The Court Should Provide a Constitutional Backstop to Determine When the Lack of Clarity Under UDAP Laws Leads to Arbitrary Punishment

The Court should grant review to establish constitutional principles that states can use to ensure their civil penalties are objective and rational. As the examples below show, governments can incorporate measures that promote predictability into the statute, while effectively protecting consumers. However, when state law provides unlimited discretion that leads to arbitrary punishment, this Court can provide a constitutional backstop.

A. States Must Provide Notice of Conduct that is Subject to Punishment

It is imperative for states to provide businesses with fair notice of violations, particularly when businesses are subject to civil penalties for any conduct a state attorney general views as an "unfair" or "deceptive" practice. *See* Cal. Bus. & Prof. Code § 17200; *see also* Silverman & Wilson, 65 U. Kan. L. Rev. at 209. Without clarity as to the violation and potential penalty, these laws provide substantial subjective discretion to state attorneys general that is prone to arbitrary punishment.

As this Court has recognized, vague laws may "trap the innocent by not providing fair warning" of unlawful conduct and lend themselves to arbitrary and discriminatory application. *See Grayned v. City of Rockford*, 408 U.S. 104, 108-09 (1972); *see also*

Kolender v. Lawson, 461 U.S. 352, 361-62 (1983) (recognizing that entrusting law enforcement with "full discretion" to interpret a law that fails to establish standards is unconstitutionally vague because it encourages arbitrary enforcement). Before the government takes a person's life, liberty, or property, due process requires the government to provide notice of what behavior is or is not permissible. *See Lanzetta v. New Jersey*, 306 U.S. 451, 453 (1939).

The federal law on which states modeled their UDAP statutes incorporates safeguards that provide notice of unlawful conduct and the potential civil penalties, but these elements were omitted from most state unfair and deceptive practices acts. When Congress empowered the Federal Trade Commission (FTC) to declare unlawful all "unfair or deceptive acts or practices in commerce," it recognized the difficulty in specifying particular prohibited business conduct. Wheeler-Lea Act of 1938, Pub. L. No. 75-447, § 3, 52 Stat. 111 (1938) (codified as amended at 15 U.S.C. § 45(a)(1)). To alleviate concern that the government could apply this vague prohibition arbitrarily, Congress placed the power to determine unfair practices in a nonpartisan Commission. *See* Silverman & Wilson, 65 U. Kan. L. Rev. at 213 (exploring legislative history). Congress intended that the FTC's power under the Act be primarily "preventative and cooperative, not penal." *Id.* (quoting S. Rep. No. 74-1705, at 1 (1936)). To advance this goal, Congress empowered the FTC to immediately stop deceptive practices and seek restitution for consumers, *see* 15 U.S.C. §§ 49(b), 53(b), 57(b), but reserved civil penalties for situations in which a business had fair notice of a violation. *See* 15 U.S.C. § 45(l), (m).

Federal law authorizes the FTC to seek civil penalties when a business had "actual knowledge or knowledge fairly implied on the basis of objective circumstances" that its conduct is unfair and deceptive. *Id.* § 45(m)(1)(A). This actual-knowledge requirement is met after the FTC determines in a proceeding that a company's conduct is unfair or deceptive and the FTC issues a cease-and-desist order. *Id.* § 45(m)(1)(B).[5] The Commission may also establish "actual knowledge" by sending a business a "Notice of Penalty Offenses" that specifies the conduct that the Commission has determined through administrative orders is unfair or deceptive in violation of the Act. *See* Fed. Trade Comm'n, *Notice of Penalty Offenses*, https://www.ftc.gov/enforcement/penalty-offenses (last visited Dec. 14, 2023). Only after a business has actual knowledge of a violation and continues the illegal conduct may the FTC seek civil penalties.

Unlike federal law, California law and most other UDAP laws permit the attorneys general to immediately seek civil penalties. *See* Silverman & Wilson, 65 Kan. L. Rev. at 214. Certain states, though, do provide fair notice similar to the FTC. In Maine, for example, the attorney general must ordinarily give a business at least ten days' notice before bringing an action seeking a temporary or permanent injunction or restitution for consumers. *See* Me. Rev. Stat. Ann. tit. 5, § 209. Maine law authorizes a civil penalty of up to $10,000 for each violation of the terms of an in-

[5] The FTC can also seek civil penalties when a business violates a Commission order. *See* 15 U.S.C. § 45(l). This order provides notice that continuation of certain conduct is subject to fines.

junction. *Id*. As a result, businesses operating in Maine not only have notice that the government views their conduct as violating the law, but they have an opportunity to address this concern before being punished and are aware of the consequences of failing to do so.[6] In California, however, the state may seek civil penalties of up to $2,500 per violation immediately and, if a business violates an injunction, the government can seek additional civil penalties of up to $6,000 for each day the prohibited conduct continues. *See* Cal. Bus. & Prof. Code §§ 17206(a), 17207(a).

Further, about half of state consumer protection laws limit civil penalties to knowing, willful, or intentional violations. *See* Silverman & Wilson, 65 Kan. L. Rev. at 241 n.216 (compiling statutes). By contrast, California authorizes the state to impose civil penalties regardless of whether the violation stemmed from a known violation or a practice that, only in retrospect, was found to have the potential to mislead consumers. "Willfulness" is just one of many factors that a court may consider when *assessing the amount* of the civil penalty for each violation of the UCL. *See* Cal. Bus. & Prof. Code § 17206(b).[7]

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[6] Rhode Island eliminated a similar safeguard in 2021. *See* R.I. Laws Ch. 21-329 (amending R.I. Gen. Laws § 6-13.1-8 to strike language limiting availability of civil penalty to violations of the terms of an injunction).

[7] Section 17206(b) provides: "In assessing the amount of the civil penalty, the court shall consider any one or more of the relevant circumstances presented by any of the parties to the case, including, but not limited to, the following: the nature and seriousness of the misconduct, the number of violations, the persistence of the misconduct, the length of time over which the

State attorneys general and other government agencies can also provide notice of conduct that it considers unfair or deceptive through rulemaking. Many UDAP laws provide attorneys general with rulemaking authority, allowing them to specifically prohibit certain conduct. *See, e.g.*, Silverman & Wilson, 65 Kan. L. Rev. at 212 n.18 (compiling statutes). Rulemaking can provide the business community with notice that certain practices are considered unfair or deceptive, and provide guidance regarding how civil penalties will be determined, before subjecting them to punishment.

This case provides an opportunity for the Court to consider whether a UDAP law, used by the government to impose hundreds of millions of dollars in civil penalties, violates due process when a defendant did not have notice that its conduct violated the statute or of the consequences of a violation.

B. The Court Should Place Rational Bounds on "Per Violation" Civil Penalties

As the examples above show, and this case illustrates, governments aggregate violations in a multitude of ways, resulting in a total civil penalty that is arbitrary and unpredictable. States can provide fair notice of the consequences of a UDAP violation, just as governments do in other contexts. The Court need not choose which path a state takes, but can require them to act rationally and predictability when it inflicts punishment.

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misconduct occurred, the willfulness of the defendant's misconduct, and the defendant's assets, liabilities, and net worth."

An option that states can use, as seen under the FTC Act and Maine law, is to impose civil penalties for each day that a business violates an injunction or otherwise continues conduct that it knows violates the statute. The FTC Act defines "each violation" as permitting the FTC to seek a civil penalty for "each day" that the company continues violating the Act. 15 U.S.C. § 45(m)(1)(C). "Each day" of continued noncompliance is a "separate violation." *Id.*; *see also* 15 U.S.C. § 45(l) (providing that "[e]ach separate violation of [an FTC order] shall be a separate offense, except that in a case of a violation through continuing failure to obey or neglect to obey a final order of the Commission, each day of continuance of such failure or neglect shall be deemed a separate offense"). While the FTC can seek, and has obtained, large civil penalties (in addition to relief for injured consumers), the fines are tethered to conduct that a company knows is a violation of the Act and the number of days a defendant has violated an injunction, rule, or order.[8] *See, e.g.*, Fed. Trade Comm'n, News Release, *FTC Charges Twitter with Deceptively Using Account Security Data to Sell Targeted Ads*, May 25, 2022 (announcing settlement including $150 million civil penalty for violating 2011 FTC order).

States can also compute "each violation" for civil penalty purposes based on an estimate of how many people the practice actually misled or harmed, even if the UDAP law authorizes a state attorney general

[8] The maximum civil penalty under the FTC Act is $46,517 for each violation, a level substantially higher than under the California law. *See* 87 Fed. Reg. 1,070, 1,070 (Jan. 10, 2022) (providing notice of 2022 inflation-adjusted civil penalties for unfair and deceptive practice violations).

to prevent harm before it occurs. Punishment should be closely tied to the number of people the defendant likely misled or injured, not the number of pieces of paper sent to a state or the circulation of a newsletter regardless of whether it included an alleged misstatement.

In addition, states can adopt an upper limit on the aggregation of "per violation" penalties. UDAP laws, including California's UCL and FAL, provide for a civil penalty "not to exceed" a certain amount per violation, but lack any upper limit on the total civil penalty. Cal. Bus. & Prof. Code §§ 17206(a), 17500. Other state and federal laws include a safeguard against unlimited punishment. Several federal laws that provide for civil penalties, including those regulating consumer product safety, set a maximum civil penalty for a series of related violations. For example, Congress increased the maximum civil penalty for "each such violation" of the Consumer Product Safety Act (CPSA) from $5,000 to $100,000 in 2008. *See* Consumer Product Safety Improvement Act of 2008, Pub. L. No. 110-314, § 217 (amending 20 U.S.C. § 2069(a)(1)). But that law also includes a maximum civil penalty "for any related series of violations" that Congress increased from $1,250,000 to $15,000,000. *See id.*[9] The Federal Hazardous Substances Act (FHSA) and the Flammable Fabrics Act (FFA) have an identical civil penalty provision, in-

[9] In addition, the CPSA reserves civil penalties for "knowing" violations and ties violations to "each consumer product involved." 15 U.S.C. § 2069(a)(1).

cluding a statutory maximum. 15 U.S.C. §§ 1194(e)(1), 1264(c)(1).[10]

Many federal laws governing transportation safety also include a maximum civil penalty for a related series of violations, which provide notice to businesses of the potential size of a civil penalty and helps avoid civil penalties that, in the aggregate, reach unconstitutional levels. *See* 87 Fed. Reg. 15,839, 15,846-(Mar. 21, 2022) (setting inflation-adjusted levels for civil penalties for violations of several statutes enforced by the Department of Transportation).

Of course, states are perfectly capable of setting similar limits on aggregate civil penalties. In fact, California does so in other areas. *See, e.g.*, Cal. Health & Safety Code § 18021 (providing a civil penalty for knowing violation of a mobile home construction safety law of up to $1,000 per violation, defined as each manufactured home or mobile home, "except that the maximum civil penalty may not exceed one million dollars ($1,000,000) for any related series of violations occurring within one year from the date of the first violation"); Cal. Pub. Util. Code § 4457(a) (providing a civil penalty for violations of federal pipeline safety standards of not more than $1,000 for each day of a violation, or failure to file the report or respond to a directive, but not to exceed $200,000 for "a single violation or related series of violations"). When legislatures fail to set aggregate maximum-authorized civil penalties, or permit states to double

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[10] The inflation adjusted maximum civil penalty for violations of the CPSA, FHSA, and FFA is $120,000 for each violation and $17,150,000 for any related series of violations, in 2022. *See* 86 Fed. Reg. 68,244 (Dec. 1, 2021).

count violations under multiple statutes for one set of actions, courts must step in. *See State v. United Parcel Serv., Inc.*, 942 F.3d 554, 599-600 (2d Cir. 2019).

This Court should grant certiorari to consider constitutional bounds for aggregating "per violation" civil penalties when state laws, due to their vague terms, allow governments to inflict arbitrary and unanticipated punishment.

III. The Court Should Provide Consistency between Safeguards Governing Arbitrary and Excessive Punishment in Other Areas and Civil Penalties

Fair notice, predictability, and proportionality between the harm and penalty are hallmarks of this Court's jurisprudence evaluating the constitutionality of punishment. The Court should grant review so that it can draw from the constitutional principles it has applied in the contexts of punitive damages and civil forfeitures to place similar bounds on the aggregation of "per violation" civil penalties.

A. Proportionality Between Punishment and Harm is Key to Addressing the Stark Unpredictability of Punitive Damage Awards and Evaluating Excessiveness

When punitive damages became increasingly unpredictable, this Court stepped in to provide meaningful bounds to safeguard due process. This case provides the Court with the opportunity to offer comparable guardrails or "guideposts" to determine when a civil penalty crosses the constitutional line.

As Justice Sandra Day O'Connor recognized, before the 1960s, punitive damages were "rarely as-

sessed" and usually "small in amount." *TXO Prod. Corp. v. Alliance Res. Corp.*, 509 U.S. 443, 500-01 (1993) (O'Connor, J., dissenting) (citing Dorsey D. Ellis, Jr., *Fairness and Efficiency in the Law of Punitive Damages*, 56 S. Cal. L. Rev. 1, 2 (1982)). By the 1980s, punitive damage awards had risen dramatically in size and frequency, particularly in product liability claims. *See* John Calvin Jeffries, Jr., *A Comment on the Constitutionality of Punitive Damages*, 72 Va. L. Rev. 139, 142 (1986); George L. Priest, *Punitive Damages and Enterprise Liability*, 56 S. Cal. L. Rev. 123, 123 (1982). After observing that punitive damages had "run wild" in *Pacific Mutual Life Insurance Co. v. Haslip*, 499 U.S. 1, 18 (1991), the Court adopted a series of due process protections and found that awards could be unconstitutionally excessive. *See Honda Motor Co. v. Oberg*, 512 U.S. 415, 420 (1994).

In *BMW of North America, Inc. v. Gore*, the Court provided three "guideposts" for determining whether a punitive damages award is unconstitutionally excessive. 517 U.S. 559, 575-85 (1996). These guideposts include (1) the degree of reprehensibility of the defendant's conduct; (2) the ratio of actual damages to punitive damages; and (3) a comparison to civil or criminal penalties that could be imposed for comparable misconduct. *See id.* Indeed, the Court recognized that proportionality between the harm inflicted on the plaintiff and the punishment is "perhaps [the] most commonly cited indicium of an unreasonable or excessive punitive damages award." *Id.* at 580.

The Court later indicated that punitive damage awards that are exponentially higher than the actual harm to the plaintiff (the ratio between punitive and

compensatory damages) are presumptively unconstitutional. *See State Farm Mutual Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 425 (2002) ("[F]ew awards exceeding a single-digit ratio between punitive and compensatory damages, to a significant degree, will satisfy due process."). In *State Farm*, the Court also instructed that punitive damages should be tied to harm the plaintiff experienced and not imposed based on "hypothetical claims" of others. *See* 538 U.S. at 423. The "wealth of a defendant," the Court found, "cannot justify an otherwise unconstitutional punitive damages award." *Id.* at 427 (citing *Gore*, 517 U.S. at 585).

More recently, this Court considered punitive damages in *Exxon Shipping Co. v. Baker*, 554 U.S. 471 (2008). There, the Court identified "[t]he real problem" of punitive damages as their "stark unpredictability." *Id.* at 499. Finding that current approaches that courts use to review outlier awards are often inadequate or ineffective, the Court looked to its experience in the realm of criminal sentencing, where it found quantified limits necessary to rein in "relatively unguided discretion." *Id.* at 505. As this Court observed, "a penalty should be reasonably predictable in its severity, so that even Justice Holmes's 'bad man' can look ahead with some ability to know what the stakes are in choosing one course of action or another." *See id.* at 502 (quoting *The Path of the Law*, 10 Harv. L. Rev. 457, 459 (1897)). The Court's ruling, while decided under federal maritime law, is rooted in the principle that penalties must contain a degree of consistency and predictability.

Each of these decisions offers principles that curb unfettered judicial discretion to impose punishment

and has provided businesses with fair notice of the consequence of their conduct. Today, our country has become "filled with more and more civil laws bearing more and more extravagant punishments," *Sessions v. Dimaya*, 138 S. Ct. 1204, 1229 (2018) (Gorsuch, J., concurring in part and concurring in the judgment), which has led to courts " grappl[ing] with the constitutionality of statutory damages [or penalty] awards challenged in the aggregate," *Wakefield v. ViSalus, Inc.*, 51 F.4th 1109, 1121 (9th Cir. 2022), without the benefit of guidance from the Supreme Court like the Court has provided in the punitive damages context.

The Court should grant certiorari to bring a measure of consistency between these two means of imposing punishment.

B. Proportionality is Central to the Court's Excessive Fines Clause Jurisprudence

The Court can also draw from its Excessive Fines Clause jurisprudence, which provides lessons that apply directly to state-imposed civil penalties. These rulings similarly instruct that penalties that are disproportionate to the offense and unconnected to any injury are constitutionally impermissible.

The Eighth Amendment provides that "excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." The Excessive Fines Clause is "intended to prevent the government from abusing its power to punish." *Austin v. United States*, 509 U.S. 602, 607 (1993). Although the Court has not subjected punitive damages to the Excessive Fines Clause and has instead relied on due process for constitutional safeguards in that context, its rulings indicate that the Excessive

Fines Clause prohibits arbitrary and excessive civil penalties imposed by state governments. In *Browning-Ferris Indus. v. Kelco Disposal, Inc.*, the Court defined a "fine" based on historical considerations as a "payment to a sovereign as punishment for some offense." 492 U.S. 257, 265 (1989). That definition includes civil penalties under UDAP laws.

This Court's recent jurisprudence reaffirms that the Excessive Fines Clause applies to civil forfeitures imposed by state governments that are "at least partially punitive." *Timbs v. Indiana*, 139 S. Ct. 682, 690 (2019) (citing *Austin*, 509 U.S. at 609-10). The question is not whether the statute is civil or criminal, but whether the sanction, even if it serves more than one purpose, constitutes "punishment." *Austin,* 509 U.S. at 610; *see also Timbs,* 139 S. Ct. at 689. This provision prohibits a government from imposing a civil penalty that is "grossly disproportionate to the gravity of a defendant's offense" and "bears no articulable correlation to any injury suffered by the Government." *United States v. Bajakajian,* 524 U.S. 321, 334, 340 (1998).

The civil penalty of over $300 million here meets this criteria. It was imposed by the government. The fine, at least arguably, is grossly disproportionate to the offense of marketing a medical device that provided medical benefits to many patients and whose risk communications were made with FDA oversight, even if in the mind of the California Attorney General some of the materials did not disclose all of the risk information he would have preferred. The basis of the "per violation" penalty has no correlation to any likelihood any person was actually deceived, but is instead based largely on materials that may not

have even reached doctors or consumers, let alone influenced or harmed them. The laws giving rise to this civil penalty scream for judicial scrutiny.

This case offers an opportunity for the Court to consider how principles of fair notice and proportionality apply to state government civil penalties and to provide constitutional standards that prevent arbitrary, unpredictable punishment.

CONCLUSION

For these reasons, *amici curiae* respectfully request that this Court grant the Petition.

Respectfully submitted,

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