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 CALIFORNIA COURT OF APPEAL, FOURTH DISTRICT

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Following a nine-week bench trial, a state trial court found that, over the course of a nearly 20-year period, petitioners repeatedly disseminated false and misleading statements marketing their medical products to both patients and doctors. The question presented is:

Whether petitioners lacked fair notice, for purposes of the Due Process Clause, that the trial court could treat each of their false or misleading communications as a separate violation under state statutes prohibiting "any . . . untrue or misleading" advertising. Cal. Bus. & Prof. Code §§ 17200, 17500.

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STATEMENT

This case arises from a state court judgment holding petitioners responsible for taking "active, willful measures for nearly twenty years to suppress information and conceal serious risk and complication information from physicians and patients" about certain medical devices manufactured and sold by petitioners. Pet. App. 126a. Unless otherwise noted, the information in this Statement comes from the trial court's extensive findings of fact, *see id.* at 113a-543a, or the California Court of Appeal's description of those findings, *see id.* at 1a-103a.

1. Petitioner Johnson & Johnson and its subsidiaries, petitioners Ethicon, Inc., and Ethicon US, LLC, have long "manufactured, marketed, and sold pelvic mesh products intended to treat two conditions that can affect women—stress urinary incontinence (SUI) and pelvic organ prolapse (POP)." Pet. App. 4a. SUI is a condition experienced by approximately one-third of women. *Id.* at 5a. It is "characterized by urine leakage during everyday activities such as laughing, coughing, sneezing, or exercising." *Id.* at 4a-5a. POP is a "disorder whereby the muscles and tissue in the pelvis weaken and cause pelvic organs to prolapse (i.e., descend) into, and sometimes outside of, the vagina." *Id.* at 5a.

There are "a range of surgical and non-surgical treatment options available for both SUI and POP." Pet. App. 118a. For example, "patients can perform pelvic floor exercises known as kegel exercises to strengthen the muscles around the urethra." *Id.* at 5a. "They can also insert a device called a pessary into the vagina to stop urine leakage." *Id.* In addition, POP can be treated "through the use of a pessary or a hormone estrogen cream" or "through a native tissue

repair whereby sutures are inserted to support the top of the vagina." *Id.*

In the late 1990s, petitioners began manufacturing and marketing pelvic mesh as an alternative to the approaches discussed above. Pet. App. 4a-6a. When a patient opts for pelvic mesh, a doctor must surgically implant a synthetic material (polypropylene) into the patient's pelvis. *Id.* at 6a; *see id.* at 116a-120a. "When the mesh functions as intended, it elicits an acute inflammatory response that causes scar tissue to grow through the mesh's pores and incorporates the mesh into the patient's body." *Id.* at 6a. The goal of the procedure is to help prevent urine leakage or provide additional support for the pelvic organs. *Id.*

"[F]rom the time [that petitioners] launched" their mesh products, they were aware of serious risks of "severe, long-term complications." Pet. App. 119a; *see id.* at 12a-14a, 119a-120a. According to a number of physicians and medical experts—including petitioners' own medical directors—those complications can include "chronic pain, dyspareunia [genital pain associated with sexual activity], decreased sexual function, partner pain (hispareunia), mesh exposure through the surface of the vagina, mesh erosion into another organ, distortion and shortening of the vagina, urinary problems, and urinary and bladder infections." *Id.* at 13a; *see id.* at 141a, 142a-143a (table collecting the many risks and complications that "the company knew about . . . since the time of launch"). Petitioners were also aware that there is often "no exit strategy": "when severe complications arise, some patients may need to undergo multiple invasive surgeries to attempt to remove the mesh, and even with removal the complications may never be fully resolved." *Id.* at

182a; *see id.* at 249a (discussing "the 'essential irreversibility' of mesh complications").[1]

In light of those and other risks, the FDA took an escalating series of actions to protect patients. In 2011, for example, the FDA released a public health notification stating that "serious complications associated with surgical mesh for POP repair are not rare." Pet. App. 133a (internal quotation marks omitted). In 2012, the FDA "issued orders requiring [petitioners] to conduct" additional studies on the risks of complications from several of their mesh products. *Id.* at 134a-135a. And in 2019, "the FDA banned all transvaginal POP mesh devices from the United States market because the FDA found that their safety and effectiveness had not been established." *Id.* at 137a.

2. In 2016, following an extensive, multi-year investigation, California's Attorney General sued petitioners in state court for misleading patients and doctors about the risks of their mesh products. Pet. App. 114a-115a. The State alleged that petitioners violated two California statutes prohibiting "any . . . untrue or misleading" advertising.[2] In an "extremely

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[1] *See also, e.g.*, Pet. App. 246a (describing patients with such severe pain during sex that it "'caused . . . partner[s] to leave,'" "'essentially ruin[ing] [their] life of intimacy'"); *id.* at 244a-245a (similar); *id.* at 246a (patients "suffering urinary dysfunction caused by mesh to the point where they are forced to 'intermittently self-catheterize . . . throughout the day in order to empty [their] bladder[s],'" forcing them to "stay close to the bathroom at all times") (internal quotation marks omitted); *id.* (patients with pain so "irreversible and severe" that "they ended up in wheelchairs") (internal quotation marks omitted).

[2] The first statute bars "any . . . untrue or misleading advertising." Cal. Bus. & Prof. Code § 17200. The second prohibits the dissemination of "any statement . . . which is untrue or misleading" for marketing purposes. *Id.* § 17500.

thorough, 128-page statement of decision," based on testimony and evidence admitted during a nine-week bench trial, *id.* at 11a, the trial court agreed with the State and imposed civil penalties for petitioners' "willful," years-long "campaign of deceptive marketing," *id.* at 250a.

The trial court based its liability findings on three principal forms of communications disseminated by petitioners from 2008 (the earliest date petitioners could be held liable under the relevant statutes of limitations) through 2017:

First, petitioners included "packets of information" called "instructions for use" (or "IFUs") with their mesh devices. Pet. App. 9a. Those packets contained information that doctors "read and rel[ied] on . . . when counseling and treating patients," *id.* at 18a, including "clinical performance results . . . and adverse reactions associated with the device," *id.* at 9a. Among many false or misleading statements in the IFUs—each described in detail on pages 159a through 185a of the petition appendix—petitioners disclosed certain relatively minor risks while omitting any reference to "some of the most significant risks," including "lifelong/chronic pain," "lifelong/chronic dyspareunia," "pain to partner," and "the need for mesh removal which may not resolve the complications from mesh." *Id.* at 167a. As the trial court explained, "[b]y only disclosing an incomplete list of risks. . . tell[ing] half the story—the benign half"—petitioners misled doctors about "the whole picture of possible mesh risks." *Id.* (emphasis omitted).

Second, petitioners targeted doctors with a variety of other "marketing communications," Pet. App. 10a, including both "written communications" (such as product brochures and advertisements in medical

journals) and "oral communications" (such as conference presentations and sales pitches during meals between doctors and sales representatives), *id.* at 65a. The trial court found these communications to be unlawful for many of the same reasons that the IFUs were "deceptive and misleading." *Id.* at 186a; *see id.* at 185a-190a. One "doctor-directed marketing material," for example, trumpeted the results of several questionable studies funded by petitioners, "advertis[ing] a 97% overall success rate . . . and negligible complications rates without disclosing any of the dangerous properties or the serious long-term risks caused by the mesh." *Id.* at 189a n.25; *see also id.* at 66a (referring to the trial court's "23-page violations appendix cataloguing the precise manner by which each and every written or online marketing communication was likely to deceive doctors").

Third, petitioners "directed deceptive marketing straight to the consumer," promising patients that pelvic mesh offered "a quick, easy cure." Pet. App. 191a. A number of petitioners' advertisements, for example, marketed mesh surgery as a "minimally invasive 30-minute procedure" "providing significant lifestyle benefits to women by restoring their ability to have a fulfilling sex life and to engage in physical activity." *Id.* (internal quotation marks omitted). At the same time, such advertisements often "misstated, downplayed, and omitted the known risks." *Id.* at 192a. One brochure considered by the court featured Olympic speed skater Bonnie Blair, suggesting that pelvic mesh surgery would enable patients to live an "athletic" lifestyle. *Id.* at 198a; *see id.* at 121a. The brochure directed patients to what it called a "'complete description of risks'"—a list that "in reality disclosed none of mesh's most serious complications." *Id.* at 198a, 245a; *see also id.* at 198a-199a (testimony from

patient explaining how the Blair advertisement "piqued her interest" in a "medical procedure [that] . . . [she] wasn't otherwise looking for," ultimately leading her to suffer "chronic pain and dyspareunia that cost her the ability to work, [engage in] physical activity and [have a] sex life").

To count the total number of violations, the trial court looked to evidence "quantif[ying] instances of circulation or dissemination" of each type of marketing communication discussed above. Pet. App. 221a. In particular, the court "credit[ed] . . . [the] methodology . . . and calculations" of expert forensic accountant Travis Armstrong, who used data provided by petitioners during discovery to calculate the total number of violations. *Id.* at 224a; *see id.* at 223a-242a. In crediting Armstrong's calculations, the court emphasized that he produced an "undercount[]," *id.* at 247a n.62—a "conservative[]" "lower-bound of the number of violations," *id.* at 224a, 236a-237a—because "for certain gaps of time, [petitioners] did not have internal company data necessary for . . . calculat[ing] the number of deceptive IFUs and marketing communications that [they] disseminated," *id.* at 87a n.17; *see id.* at 223a-224a, 263a.

Finally, the trial court imposed a per-violation civil penalty of $1,250, half of the $2,500 maximum penalty authorized by the governing statutes. Pet. App. 243a. The court held that this amount was appropriate in light of petitioners' "serious, knowing, and willful misconduct over a period of close to twenty years." *Id.* The court stressed, among other things, that "[i]nternal communications presented at trial show[ed] that [petitioners] intentionally concealed and misrepresented risk information" to increase sales of their

mesh products. *Id.* at 247a; *see, e.g.*, *id.* at 248a (marketing director's refusal to provide patients with more information because "it would be 'dig[ging] her own grave' to reveal to customers that mesh might ever need to be removed"). In the court's view, this deceptive conduct was "particularly egregious" because it involved "selling a permanent implant with no exit strategy while hiding its risks." *Id.* at 249a; *see id.* ("patients . . . were deprived of the ability to make an informed decision in the first place [and] will not get a second chance").

3. The California Court of Appeal affirmed in part and reversed in part, largely upholding the trial court's judgment while reducing the total penalty award. Pet. App. 1a-103a.

The appellate court first addressed—and rejected—a number of petitioners' state-law challenges to the trial court's liability findings. The court disagreed, for example, with petitioners' contention that their IFUs were unlikely to deceive doctors because doctors were "already aware of the risks." Pet. App. 32a; *see id.* at 48a-62a. Reviewing "substantial evidence" in the record, *id.* at 48a, the court held that the trial court properly found (among other things) that doctors regularly "read and rely on IFUs," *id.*; that doctors "expect IFUs to list the full range of complications associated with medical devices," *id.* at 49a; that the relevant IFUs "did not list the full range of complications," *id.*; and that "many practicing doctors went to medical school or completed their residency programs before [petitioners] released [their] pelvic mesh products," making the doctors unfamiliar with the risks of those products, *id.* at 51a; *see id.* at 55a (emphasizing that the "trial court strongly discredited" testimony from petitioners' witnesses suggesting that

"doctors . . . are familiar with the range and severity of pelvic mesh complications").

The court also rejected petitioners' argument that they were entitled to a statutory safe-harbor defense because "the FDA authorized, or at a minimum permitted, certain IFUs and marketing communications." Pet. App. 72a. As a former FDA Commissioner explained at trial, the FDA merely conducted a "limited review" to determine whether petitioners' devices were substantially equivalent to devices already on the market. *Id.* at 76a; *see id.* at 75a-77a. The FDA "even instructed" petitioners that its review "did not mean that the FDA had made a determination that [petitioners'] devices complied" with applicable federal safety standards. *Id.* at 77a (alterations omitted).[3]

As to the penalty award, the court reduced the total award by about $42 million, concluding that there was insufficient evidence to support liability for one subcategory of violations. Pet. App. 69a. While "there was evidence showing that [petitioners] trained [their] sales representatives to convey uniform marketing

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[3] The FDA process that petitioners referenced below—and continue to discuss before this Court, *e.g.*, Pet. 8-9—is "referred to as section '510(k) approval.'" Pet. App. 75a. As Judge Sykes recently explained in one of a number of other cases filed against petitioners for misconduct related to their production and marketing of pelvic mesh, *see id.* at 56a-62a (collecting cases), "[m]ost medical devices enter the market" through this process, which often has "nothing to do with product safety," *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1004 (7th Cir. 2020). Indeed, "the FDA has promulgated a disclaimer that § 510(k) clearance 'does not in any way denote official approval of [a] device"—and it is "unlawful for a device manufacturer to make such a representation." *Id.* at 1005; *see generally Medtronic, Inc. v. Lohr*, 518 U.S. 470, 492-493 (1996) (discussing the 510(k) process).

messages," *id.* at 67a—as well as evidence showing that such training "promoted the disclosure of misleading information," *id.* at 68a; *see, e.g.*, *id.* at 216a-217a—the appellate court was "unable to find evidence in the record" demonstrating that "every single one of [petitioners'] thousands of oral communications with doctors included false or misleading statements," *id.* at 66a, 67a-68a. The court thus struck from the aggregate violation figure the approximately 33,500 violations based on petitioners' oral communications to doctors. *Id.* at 69a.

The court upheld the penalty award in all other respects. As relevant here, it concluded that the trial court properly "counted each deceptive IFU and marketing communication as a separate violation." Pet. App. 87a. The appellate court invoked California precedent approving the same "per-communication methodology." *Id.* at 88a; *see id.* at 89a-93a (citing *People v. Morse*, 21 Cal. App. 4th 259, 272-274 (1993)). It also emphasized that petitioners' communications were "highly-targeted" (Pet. App. 92a): they were "explicitly written" and disseminated in carefully chosen mediums to reach or appeal to "patients who were suffering from SUI or POP," or to "doctors who were considering whether to implant [petitioners'] device[s] or were preparing to do so." *Id.* at 91a.

The court next rejected petitioners' contention that there was insufficient evidence to support the total number of violations found by the trial court. Pet. App. 92a n.18. While petitioners "complain[ed] [that] the forensic accountant's calculations were inflated because he extrapolated one salesperson's history to the entire sales staff and failed to account for brochures that were ordered but not distributed," the appellate court pointed out that petitioners failed to

provide data in their discovery responses that would have enabled more precise calculations. *Id.* "Additionally," the court noted, petitioners "never suggested a method to discount the expert's calculation," in "either the trial court or on appeal." *Id.* For those reasons, and because the calculation of violations "was likely an undercount" in any event, *id.* at 87a, the court upheld the trial court's calculation, *id.* at 92a.

Finally, the court rejected petitioners' due process challenge to the penalty award. Pet. App. 97a-99a. Petitioners argued that they "lacked fair notice" that the trial court might impose an aggregate award exceeding $300 million because, according to petitioners, that amount was larger than awards upheld in prior "reported decision[s]" involving the same statutes. *Id.* at 97a. As the appellate court explained, however, the relevant California statutes "expressly define the maximum amounts a violator can be punished per violation—$2,500." *Id.* at 98a. And nothing in the statutory text or any prior appellate decisions suggested that the awards in prior cases "somehow [established] the outer limit of penalties that may be properly imposed." *Id.* (internal quotation marks omitted).[4]

Petitioners sought review before the California Supreme Court, arguing (among other things) that it should "resolve a conflict" among intermediate state

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[4] The appellate court also rejected petitioners' argument that the trial court violated the federal Due Process Clause by applying "unprecedented" standards in determining whether a communication qualified as deceptive. Pet. App. 97a; *see, e.g.*, *id.* (explaining that, contrary to petitioners' assertion, the trial court never "requir[ed] [petitioners] to warn consumers of all risks associated with its products regardless of consumers' existing knowledge").

appellate courts "over the proper standard for identifying distinct violations" under the State's false advertising laws. Pet. for Rev. 27; *see id.* at 27-37. The petition was denied. Pet. App. 544a.

ARGUMENT

As the trial court found, for "nearly twenty years," petitioners took "active, willful measures . . . [to] conceal serious risk and complication information from physicians and patients." Pet. App. 126a; *see id.* at 113a-543a. Petitioners now ask this Court to grant plenary review and hold that they lacked fair notice that each of their deceptive communications could be treated as a distinct violation of state statutes barring "any . . . untrue or misleading" advertising. Cal. Bus. & Prof. Code §§ 17200, 17500. That argument does not implicate any division of authority among state or federal appellate courts. And there is no need here for the Court to evaluate "the degree of fair notice scrutiny applicable to different types of laws," Pet. 18, because petitioners' argument would fail under any of the standards of scrutiny identified in the petition. Nor is this case an appropriate vehicle for addressing the legal and policy concerns raised by petitioners (*see id.* at 29-39) about *other* States' "unfair and deceptive acts and practices" statutes.

1. Petitioners' principal argument is that they "lacked fair notice of how the California courts would count statutory violations" for purposes of determining the appropriate civil penalty under state false advertising laws. Pet. 24; *see id.* at 22-29. This Court has repeatedly denied petitions raising context-specific constitutional challenges to civil penalty awards

and damages judgments.[5] It should do the same here. Petitioners do not contend that the decision below creates or deepens any conflict among state or federal appellate courts. Moreover, the particular fair-notice argument that petitioners seek to present in this Court was not properly preserved below; is intertwined with questions of state law; and lacks merit.

To be preserved for review in this Court, federal issues must be "either addressed by, or properly presented to, the state court that rendered the decision" below. *Adams v. Robertson*, 520 U.S. 83, 86 (1997). Here, the California Court of Appeal addressed and rejected petitioners' various state-law challenges to the trial court's calculation of statutory violations. *Supra* pp. 9-10. It also addressed petitioners' contentions that their federal due process rights were violated because they lacked adequate notice that aggregate penalties could exceed $300 million, *supra* p. 10, or that the trial court would apply certain standards in determining whether a particular communication qualified as "deceptive," *supra* p. 10, n.4. But the appellate court did not address—and petitioners did not properly preserve—the separate due process argument that they now seek to present in this Court: that

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[5] *See, e.g.*, *M & N Fin. Corp. v. Dep't of Fair Emp. & Hous.*, 142 S. Ct. 2714 (2022) (No. 21-1285); *Monsanto Co. v. Pilliod*, 142 S. Ct. 2870 (2022) (No. 21-1272); *Lent v. Cal. Coastal Comm'n*, 142 S. Ct. 1109 (2022) (No. 21-563); *Fowler v. Sec. & Exch. Comm'n*, 142 S. Ct. 590 (2021) (No. 21-591); *Johnson & Johnson v. Ingham*, 141 S. Ct. 2716 (2021) (No. 20-1223); *G & M Realty L.P. v. Castillo*, 141 S. Ct. 363 (2020) (No. 20-66); *Ashland Specialty Co. v. Steager*, 139 S. Ct. 2714 (2019) (No. 18-1053); *Ortho-McNeil-Janssen Pharms., Inc. v. S.C. ex rel. Wilson*, 577 U.S. 1093 (2016) (No. 15-600); *Gosselin World Wide Moving v. U.S. ex rel. Bunk*, 574 U.S. 819 (2014) (No. 13-1399).

California's false advertising statutes failed to provide sufficient notice that each of petitioners' deceptive communications could be treated as a distinct "statutory violation[]." Pet. 24.[6]

Even setting aside that defect, petitioners' new due process argument would not warrant review because it lacks merit and is inextricably bound-up in case-specific facts and state-law issues. The governing statutes expressly prohibit the dissemination of "*any* . . . untrue or misleading" advertisements. Cal. Bus. & Prof. Code §§ 17200, 17500 (emphasis added). Consistent with that language, California courts have previously adopted a "per-communication methodology" for counting violations, Pet. App. 88a, treating each "marketing communication[] that contained a false or misleading statement" as a separate violation, *id.* at 91a; *see id.* at 90a (citing *People v. Morse*, 21 Cal. App. 4th 259, 272-274 (1993)); *see also People v. Dollar Rent-A-Car Sys., Inc.*, 211 Cal. App. 3d 119, 131-132 (1989). Anyone reading the statutes and relevant precedent (*cf.* Pet. 25) would reasonably conclude that

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[6] Petitioners devoted about three pages of their opening brief in the Court of Appeal to arguments involving the federal Due Process and Excessive Fines Clauses. C.A. Opening Br. 69-71. The due process argument now advanced by petitioners appears nowhere in those pages. *See id.* While petitioners hinted at the new argument in one sentence on page 53 of their appellate reply brief, that was not sufficient to preserve it. *See Gormley v. Gonzalez*, 84 Cal. App. 5th 72, 82 (2022) ("arguments raised for the first time in a reply will not be considered"). Nor did petitioners remedy their failure to preserve the argument when they later devoted one paragraph to it in their petition for review before the California Supreme Court. *See* Pet. for Rev. 39; *see generally* Shapiro et al., *Supreme Court Practice* § 3.18(b), p. 3-59 (11th ed. 2019) ("Where a federal question is initially raised in a petition . . . filed in the highest state court, . . . the jurisdiction of the Supreme Court cannot attach.").

each false or misleading advertisement could be deemed a violation.

Petitioners principally respond by arguing that "the California courts" have disagreed on the proper violation-counting method, "depriv[ing] businesses of fair notice of how violations will be assessed." Pet. 26. But even if petitioners were right about disagreement in the relevant state case law, *but see infra* pp. 14-16, that would not provide a basis for *this* Court's intervention. This Court is "reluctant to grant review of cases turning on state statutes or constitutions where state decisions on the issues are . . . in confusion." Shapiro et al., *Supreme Court Practice* § 4.10, p. 4-32 (11th ed. 2019). Responsibility for resolving tension in the decisions of intermediate state appellate courts "rests with the highest state court," not this one. *Id.* And here, the California Supreme Court considered and denied petitioners' request for it to address a purported "conflict in the Courts of Appeal" over the proper method of calculating violations under the State's false advertising laws. Pet. for Rev. 33; *see supra* pp. 10-11.

That denial was for good reason: petitioners are not correct that the relevant state precedent, "up until now," required trial courts to employ violation-counting methods other than the per-communication approach applied below. Pet. 25. In all but one of the state decisions invoked by petitioners, *see id.* at 25-26, state intermediate appellate courts merely affirmed trial courts' discretion to adopt alternative, more lenient violation-counting approaches. Those decisions did not prohibit trial courts from counting "additional violations" under a per-communication approach. *E.g.*,

Morse, 21 Cal. App. 4th at 274 n.26 (rejecting a reading of the case law similar to the one advanced by petitioners before this Court).[7]

Petitioners cite only one decision rejecting a per-communication approach, but it is inapplicable to the circumstances here. *See* Pet. App. 90a-91a. In *People v. Superior Court (Olson)*, 96 Cal. App. 3d 181, 185 (1979), the defendant published a false advertisement in several newspapers with a circulation greater than one million, thereby authorizing aggregate penalties "in excess of two and a half billion dollars" under a per-communication approach, *id.* at 197. In the court's view, the defendant's conduct was not sufficiently culpable to justify such a large award under the "the due process prohibition against 'oppressive' or 'unreasonable' statutory penalties." *Id.* at 198. The court thus construed the relevant statute to require a different method for counting violations when the per-communication approach would authorize an unconstitutionally excessive award. *Id.*; *see Morse*, 21 Cal. App. 4th at 273-274. Here, "unlike . . . in *Olson*," petitioners disseminated numerous distinct types of deceptive

[7] *See also People v. Overstock.com, Inc.*, 12 Cal. App. 5th 1064, 1087 (2017) (affirming trial court's decision to assess penalties based on "the number of days" that the defendant's misrepresentations appeared online, without addressing whether the court could have instead applied a per-communication approach); *People v. JTH Tax, Inc.*, 212 Cal. App. 4th 1219, 1255 (2013) (affirming decision to base aggregate violations on estimated readership or viewership of misleading print and television advertisements, without addressing whether the trial court could have instead used total "circulation numbers"); *see id.* at 1252-1255; *People v. Toomey*, 157 Cal. App. 3d 1, 22 (1984) (affirming calculation based on estimate of sales triggered by misleading communications, without addressing whether the trial court could have instead applied a per-communication approach); *People v. Witzerman*, 29 Cal. App. 3d 169, 180 (1972) (similar).

marketing materials to thousands of consumers over a nearly 20-year period. Pet. App. 91a; *see supra* pp. 4-7. Petitioners do not (and could not) contend that the total award authorized by the per-communication approach applied below is unconstitutionally excessive.

Petitioners also argue that the State's false advertising statutes "unequivocally" required the trial court to quantify and exclude from the aggregate violation count any misleading communications that went unread by doctors and patients, such as sales brochures and other materials that were "thr[own] away" or "not hand[ed] out or distribute[d]" after petitioners sent them to hospitals or sales representatives. Pet. 25, 27 (internal quotation marks omitted). But California courts have consistently rejected such arguments, *see, e.g.*, *Morse*, 21 Cal. App. 4th at 272-274, which would allow an advertiser to escape liability for (among other things) mailing out thousands of misleading solicitations unless a trial court could somehow quantify and discount the number treated as "junk mail" and thrown away before being read, *id.* at 274 n.25. Requiring "individualized proof" that consumers read, viewed, or otherwise received each deceptive statement would "be 'so onerous as to undermine the [statutes'] effectiveness . . . as an enforcement tool.'" *People v. JTH Tax, Inc.*, 212 Cal. App. 4th 1219, 1254 (2013); *see Dollar Rent-A-Car Sys.*, 211 Cal. App. 3d at 131; Pet. App. 40a, 222a.

And even if there were some ambiguity or tension in the relevant statutes and precedent, that would not suffice to create a fair notice problem. The Due Process Clause bars enforcement of certain statutes lacking any "ascertainable standard[]" whatsoever. *Cameron v. Johnson*, 390 U.S. 611, 615 (1968); *see, e.g.*, *Giaccio v. Pennsylvania*, 382 U.S. 399, 403 (1966).

"[P]erfect clarity and precise guidance have never been required." *United States v. Williams*, 553 U.S. 285, 304 (2008) (internal quotation marks omitted); *cf. Sessions v. Dimaya*, 138 S. Ct. 1204, 1232 (2018) (Gorsuch, J., concurring in part and concurring in the judgment).

Finally, petitioners raise several objections to how the State's expert calculated statutory violations. Pet. 26-28; *see id.* at 26, 27 (criticizing the expert's "extrapolat[ion] from a single sales representative's testimony" and "estimate[] . . . of hospital newsletters"). Those objections relate to state-law evidentiary issues. As discussed above, *supra* p. 6, the trial court credited the expert's "methodology, extrapolations, estimates and calculation[s]." Pet. App. 224a. And the Court of Appeal rejected petitioners' state-law challenges to the trial court's evidentiary findings—in part because petitioners "never suggested a method to discount the expert's calculation." *Id.* at 92a n.18; *see supra* pp. 9-10. Petitioners' dissatisfaction with those rulings does not provide a basis for plenary review in this Court.

2. Petitioners also contend that the Court should grant certiorari to clarify "what due process strictures apply to state statutes that . . . [authorize] civil penalties," Pet. 19, and to address a host of concerns with unfair and deceptive acts and practices (UDAP) laws across the country, *id.* at 29. This case is not a suitable vehicle for addressing those issues.

a. Whether the fair-notice standard that applies to statutes with "civil penalties at stake" is characterized as "robust" or not, Pet. i, petitioners' due process argument would fail. The relevant statutory text and state precedent provided ample notice to petitioners that each of their many deceptive marketing communications violated the law. *Supra* pp. 13-17. And this

Court is generally loathe to grant review of issues that would have no impact on "the ultimate outcome of the case." *Supreme Court Practice*, *supra*, § 4.4(f), p. 4-18.

The Court also generally denies certiorari where, as here, the decision below contains no reasoned discussion of the relevant issues. *Cf. Manuel v. City of Joliet*, 137 S. Ct. 911, 922 (2017) (this Court is "a court of review, not of first view") (internal quotation marks omitted). Because the due process argument that petitioners now seek to present was not properly advanced below, *supra* pp. 12-13 & n.6, the California Court of Appeal had no occasion to address the appropriate "degree of fair notice scrutiny" when evaluating that argument, Pet. 18. As for the due process arguments that petitioners did raise below—such as their contention that they lacked fair notice that the aggregate penalty award might exceed $300 million, *supra* p. 10 & n.4—the Court of Appeal agreed with the State that such arguments failed under *any* standard of scrutiny. *See* Pet. App. 96a-99a; C.A. Respondent's Br. 66-67. So there was no need for the lower court to consider whether the appropriate form of vagueness scrutiny would be "robust" or comparatively "weak." Pet. 17, 19.

In any event, petitioners misunderstand this Court's fair-notice precedent. Petitioners contend that the "degree of fair notice scrutiny applicable to" civil penalty regimes (as opposed to criminal laws) "remains a critical open question" under this Court's cases. Pet. 18. While the Court has, at times, suggested that "the Constitution tolerates" a greater "degree of vagueness" in civil rather than criminal statutes, *e.g.*, *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498 (1982), the standard it has applied in both contexts is remarkably

similar, *compare A.B. Small Co. v. Am. Sugar Ref. Co.*, 267 U.S. 233, 238-239 (1925) (asking whether civil statute prescribed "a rule or standard which was so vague and indefinite that no one could know what it was"), *with Williams*, 553 U.S. at 304 (asking whether criminal statute provided "person[s] of ordinary intelligence a reasonable opportunity to know what is prohibited"). Similarly, it is not at all clear that the "'greater leeway'" afforded to civil statutes in the decades-old state appellate decisions collected by petitioners (Pet. 19-20) made any difference to the outcome of those cases. The analysis in those decisions suggests, to the contrary, that the relevant statutory language was sufficiently clear to withstand even a "robust" form of vagueness scrutiny. *See, e.g*, *Scott v. Ass'n for Childbirth at Home, Int'l*, 88 Ill. 2d 279, 289 (1981) (rejecting vagueness challenge on the ground that "words [such] as 'deception,' 'false pretense,' 'misrepresentation,' and 'fraud' . . . are words commonly used and understood by the general public and by businessmen").[8]

b. Petitioners' final argument for certiorari is that the supposed vagueness of UDAP statutes—which have been adopted by 49 of 50 States—presents a "serious nationwide problem." Pet. 29; *see id.* at 29-39. Of course, the only question on which this Court could grant plenary review concerns the terms of *California*'s statutes. And for the reasons explained above, *supra* pp. 13-17, California's prohibition of "any . . .

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[8] *See also State ex rel. Nixon v. Telco Directory Publ'g*, 863 S.W.2d 596, 600 (Mo. 1993) (similar); *Mother & Unborn Baby Care of N. Tex., Inc. v. State*, 749 S.W.2d 533, 541 (Tex. App. 1988) (similar); *Dep't of Legal Affs. v. Rogers*, 329 So. 2d 257, 264-265 (Fla. 1976) (similar); *State v. Ralph Williams' Nw. Chrysler Plymouth, Inc.*, 82 Wash. 2d 265, 279 (1973) (similar).

untrue or misleading" advertising is not impermissibly vague. Cal. Bus. & Prof. Code §§ 17200, 17500.

Nor do California's false advertising statutes contain all of the features that petitioners consider problematic in statutes in other States. Indeed, petitioners repeatedly acknowledge as much.[9] If petitioners have concerns about statutes in other States, they should raise those concerns with the Legislatures of those States or litigate them in a case arising from one of those States. *See, e.g.*, Pet. 32-33, 37 (discussing litigation arising out of Mississippi, Hawaii, and South Carolina).

Petitioners are correct that California's false advertising statutes are similar to other States' laws in that they do not impose all "elements of a tort claim." Pet. 33. But that does not make such laws unconstitutionally vague. And there are compelling policy reasons for a false advertising statute to deviate from traditional tort principles. "The common law of tort placed significant barriers in the path of a consumer who had been misled by a seller," imposing requirements of scienter and reliance that were "difficult" and "expensive" for injured purchasers to prove. Pridgen & Alderman, *Consumer Protection and the Law* §§ 1:1, 2:11 (2022-2023 ed.); *see id.* § 2:5. The predictable

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[9] *See* Pet. 35 (noting that "California does not follow th[e] approach" of allowing the "private plaintiffs' bar" to "develop the theories of liability . . . and then litigate the state's enforcement action in exchange for a contingency fee") (internal quotation marks omitted); *id.* at 29 (discussing state statutes with "[b]road, flexible prohibitions of unfair and deceptive practices," rather than specific prohibitions of untrue and misleading advertising) (internal quotation marks omitted); *id.* at 32 (discussing state statutes that, unlike those at issue here, authorize penalties of up to $50,000 per violation).

result was that "fraudulent advertising was everywhere countenanced," Hess, *History and Present Status of the "Truth-in-Advertising" Movement*, 101 Annals Am. Acad. Pol. & Soc. Sci. 211, 211 (1922), making "purchase . . . a game of chance," Hamilton, *The Ancient Maxim Caveat Emptor*, 40 Yale L.J. 1133, 1187 (1931). To protect consumers, as well as honest businesses frustrated by their inability to distinguish themselves from unscrupulous competitors, dozens of States enacted laws prohibiting "advertising contain[ing] any untrue, deceptive, or misleading . . . representation." Petty, *The Historic Development of Modern U.S. Advertising Regulation*, 7 J. of Hist. Rsch. in Marketing 524, 530 (2015) (internal quotation marks omitted); *see id.* at 530-531. Petitioners provide no sound basis to second-guess that state-level policy consensus—and no legal argument that would justify plenary review by the Court in this case.

CONCLUSION

The petition for a writ of certiorari should be denied.

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