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SERVICE ON THE ATTORNEY GENERAL AND SAN DIEGO DISTRICT ATTORNEY REQUIRED BY BUS. & PROF. CODE §§ 17209 AND 17536.5

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

FOURTH APPELLATE DISTRICT, DIVISION ONE

JOHNSON & JOHNSON, a New Jersey Corporation; ETHICON, INC., a New Jersey Corporation; ETHICON, US, LLC; and DOES 1 through 100, inclusive,

Defendants and Appellants,

v.

THE PEOPLE OF THE STATE OF CALIFORNIA,

Plaintiff and Respondent.

APPEAL FROM SAN DIEGO COUNTY SUPERIOR COURT
EDDIE C. STURGEON, JUDGE | CASE NO. 37-2016-00017229-CU-MC-CTL

APPLICATION OF WASHINGTON LEGAL FOUNDATION FOR LEAVE TO FILE *AMICUS* BRIEF AND *AMICUS* BRIEF IN SUPPORT OF DEFENDANTS AND APPELLANTS

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APPLICATION OF WASHINGTON LEGAL FOUNDATION FOR LEAVE TO FILE *AMICUS* BRIEF

Under Rule 8.200(c) of the California Rules of Court, Washington Legal Foundation (WLF) requests leave to file the accompanying *amicus curiae* brief in support of Defendants and Appellants. Under Rule 8.200(b) of the California Rules of Court, both this application and WLF's proposed brief are timely filed within 14 days of the filing of the final reply brief.

Founded in 1977, WLF is a nonprofit, public-interest law firm and policy center with supporters nationwide, including many in California. WLF promotes free enterprise, individual rights, limited government, and the rule of law. To further those aims, WLF often appears as an *amicus* in California courts. (See, e.g., *T.H. v. Novartis Pharm. Corp.* (2017) 4 Cal.5th 145; *In re Cipro Cases I & II* (2015) 61 Cal.4th 116; *City of Hope Nat'l Med. Ctr. v. Genentech Inc.* (2008) 43 Cal.4th 375.)

WLF has also sued to enforce First Amendment limits on the Food and Drug Administration's (FDA's) authority to restrict manufacturer speech. (*Wash. Legal Found. v. Friedman* (D.D.C. 1998) 13 F.Supp.2d 51, appeal dism'd (D.C. Cir. 2000) 202 F.3d 331.) As a result of that litigation, FDA was enjoined from infringing on manufacturers' First Amendment right to share peer-reviewed medical texts and journal articles about the off-label uses of their FDA-cleared products.

Counsel for WLF has reviewed the parties' merits briefs in this appeal and believes the Court will benefit from *amicus* briefing on the constitutional harms that flow from attaching liability to scientific speech. In particular, the People's reliance on Ethicon's accurate descriptions of published, peer-reviewed scientific literature as a separate basis for liability unconstitutionally infringes on Defendants' First Amendment rights. Yet the trial court imposed a $344 million penalty without even acknowledging, much less addressing,

Defendants' repeated First Amendment objections. That error alone invites reversal or vacatur.

WLF's brief will assist the Court because WLF has considerable expertise on the First Amendment's protections for scientific speech, because those constitutional protections are crucial to the public health, and because WLF's brief can explore these issues in more detail than the parties' briefs.

No party's counsel authored any part of WLF's brief. No one, other than WLF or its counsel, contributed money to fund the preparation or submission of WLF's brief. (See Cal. Rules of Court, rule 8.200(c)(3).) WLF has no direct interest, financial or otherwise, in the outcome of this appeal. Lacking any direct interest, WLF can provide the Court a perspective distinct from that of any party.

WLF asks the Court to grant this application to file the accompanying *amicus curiae* brief.

September 20, 2021 Respectfully submitted,

/S/ *Mollie F. Benedict*

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INTRODUCTION

Scientific knowledge evolves rapidly and often unexpectedly. Yet even taking the long view, "there can be no cast-iron guarantee that the cutting-edge science of today will not represent the discredited alchemy of tomorrow." (Fara, *Science: A Four Thousand Year History* (2009) p. 364.) As quantum physicist Richard Feynman famously put it, "Science is the belief in the ignorance of experts." (Feynman, *The Pleasure of Finding Things Out* (2001) p. 187.) Each new breakthrough in science builds on the failures, discoveries, and criticisms of others. Yet that is precisely why "[s]cientific . . . speech reside[s] at the core of the First Amendment." (*Wash. Legal Found. v. Friedman* (D.D.C. 1998) 13 F.Supp.2d 51, 62 appeal dism'd (D.C. Cir. 2000) 202 F.3d 331.)

In medicine, the right to speak freely on scientific matters is "more than a convenience"; it can "mean the alleviation of physical pain or the enjoyment of basic

necessities." (*Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council* (1976) 425 U.S. 748, 764.) Indeed, the need to ensure the free flow of scientific information is most compelling "in the fields of medicine and public health, where information can save lives." (*Sorrell v. IMS Health, Inc.* (2011) 564 U.S. 552, 566.) The decision below upends these First Amendment principles.

Imposing a penalty larger than all other reported Unfair Competition Law (UCL) and False Advertising Law (FAL) awards combined, the trial court found that *every* communication Defendants made about Ethicon's pelvic-mesh products—whether to doctors or patients, written or verbal—violated California law. Yet as the People conceded on the first day of trial, the "scientific propositions" about pelvic mesh are "very much in dispute" here. (20.RT.2200:3-4.)

When liability turns, as here, on a defendant's speech about scientific matters over which reasonable scientists may disagree, this Court has rejected claims that a scientifically

debatable interpretation of data violates the UCL or FAL. (*Bernado v. Planned Parenthood Fed'n of Am.* (2004) 115 Cal.App.4th 322, 342 ["expressions of opinion about an issue of genuine scientific debate" are "noncommercial speech fully protected under the First Amendment"].) Under that precedent, the decision below cannot stand.

The record here shows that many of Ethicon's statements were either fully supported by peer-reviewed scientific literature or nearly verbatim recitations of scientific findings from published studies. Under the First Amendment, the State may not penalize Defendants for taking sides in a scientific debate. In approving a blanket $344 million penalty, however, the trial court failed even to acknowledge, much less consider, Defendants' repeated and well-founded First Amendment objections. That error alone invites reversal or, at a minimum, vacatur and remand.

If the trial court's ruling is upheld, the State will be empowered to pick winners and losers in legitimate scientific debates. And manufacturers of every stripe risk exposure to

massive liability merely for repeating widely shared, evidence-based scientific views that a plaintiff or government entity may later disagree with. Such liability is not only arbitrary and unconstitutional but also threatens to chill the development and manufacture of innovative products across industries.

ARGUMENT

I. THE FIRST AMENDMENT PRECLUDES PUNISHING, AS FALSE OR FRAUDULENT, SPEECH ON MATTERS OF GENUINE SCIENTIFIC DEBATE.

A. Scientific speech is fully protected under the First Amendment.

Scientific discovery is both cumulative and self-correcting. Science is "advanced by broad and wide-ranging consideration of a multitude of hypotheses, for those that are incorrect will eventually be shown to be so, and that in itself is an advance." (*Daubert v. Merrell Dow Pharm., Inc.* (1993) 509 U.S. 579, 597.) This "constant process of questioning, testing, updating, and sometimes replacing received wisdom is the hallmark of good science." (Volokh, *In Defense of the Marketplace of Ideas* (2011) 97 Va. L. Rev. 595, 597.)

No surprise, then, that scientific speech "reside[s] at the core of the First Amendment." (*Friedman*, *supra*, 13 F.Supp.2d at p. 62.) Under the Constitution's free-speech guarantee, "there is no such thing as a false idea." (*Issa v. Applegate* (2019) 31 Cal.App.5th 689, 705.) The First Amendment "protects scientific expression and debate just as it protects political and artistic expression." (*Bd. of Trustees v. Sullivan* (D.D.C. 1991) 773 F.Supp. 472, 474.)

It makes no difference whether scientific speech is mixed with commercial speech. Just as a newspaper does not lose its First Amendment protection because it is sold for profit (*New York Times v. Sullivan* (1964) 376 U.S. 254, 266), neither do *The Lancet* or *The New England Journal of Medicine* lose theirs. Such speech does not "retain[] its commercial character when it is inextricably intertwined with otherwise fully protected speech"; it remains "fully protected expression." (*Riley v. Nat'l Fed'n of the Blind of N.C., Inc.* (1988) 487 U.S. 781, 796; see also *Sorrell*, *supra*, at p. 557 ["Speech in aid of pharmaceutical marketing . . . is a form of

expression protected by the Free Speech Clause of the First Amendment."].)

Like other scientific fields, medicine requires a robust exchange of views and research findings over time. (*Reilly v. Pinkus* (1949) 338 U.S. 269, 274 ["[I]n the science of medicine, as in other sciences, experimentation is the spur of progress."].) Because scientific debate in medicine is of great public importance, it "occupies the highest rung of the hierarchy of First Amendment values." (*Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.* (1985) 472 U.S. 749, 759.) Medical literature often contains preliminary observations, tentative conclusions, retractions, corrections, and reversals. All this enables physicians and other healthcare providers to make better informed treatment decisions for their patients.

"Choosing what treatments are or are not appropriate for a particular condition is at the heart of the practice of medicine." (*Judge Rotenberg Educ. Ctr. v. FDA* (D.C. Cir. 2021) 3 F.4th 390, 400.) Given the realities of clinical practice, physicians often "must make decisions in the face of

uncertainty and without . . . [the] luxury of awaiting further information." (Noah, *Medicine's Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community* (2002) 44 Ariz. L. Rev. 373, 382.) In any given case, physicians must rely on various sources as well as their own training, experience, and judgment.

Ultimately "it is the physician's role to consider multiple factors, including a drug's [or device's] FDA approval status, to determine the best course of action for her patient." (*United States v. Caronia* (2d Cir. 2012) 703 F.3d 149, 167.) So although a product's FDA-cleared label is a reliable source of information, physicians know that labeling does not always contain the most complete, or even the most accurate information. "Advances in medical knowledge and practice inevitably precede labeling revision by the manufacturer and formal [action] by the [FDA]." (40 Fed. Reg. (Apr. 7, 1975) 15,392, 15,394.)

To exercise their best judgment, then, physicians must have access not only to information that—as here—has

achieved broad scientific consensus, but also to reasonably debatable scientific claims that may fall outside the mainstream. The government has no legitimate—much less compelling—interest in suppressing such information. That is why, for instance, courts have construed the federal Food, Drug, and Cosmetic Act's adulteration and misbranding provisions not to prohibit "the simple promotion of a drug's off-label use because such a construction would raise First Amendment concerns." (*Caronia*, *supra*, 703 F.3d at p. 160; see also *Amarin Pharma, Inc. v. FDA* (S.D.N.Y. 2015) 119 F.Supp.3d 196, 201-202 [emphasizing the "therapeutic—indeed, sometimes life-saving—value of off-label uses"].)

The general rule for speech aimed at physicians is that "the speaker and the audience, not the government, assess the value of the information presented." (*Thompson v. W. States Med. Ctr.* (2002) 535 U.S. 357, 367.) Government attempts at penalizing scientific speech, even speech that is "potentially misleading," warrant exacting First Amendment scrutiny. (*Sorrell*, *supra*, 564 U.S. at p. 571 ["[I]t is all but dispositive

to conclude that a law is content based and, in practice, viewpoint discriminatory."].)

B. The First Amendment shields reasonably debatable scientific claims from liability.

"[T]here are no certainties in science." (*Daubert*, *supra*, 509 U.S. at p. 590.) Many scientific claims are neither true nor false. When a statement comprises a subjective opinion or an interpretation of data rather than an empirically falsifiable fact, "[t]here is no exact standard of absolute truth by which to prove the assertion false and a fraud." (*Am. Sch. of Magnetic Healing v. McAnnulty* (1902) 187 U.S. 94, 104.) Because such matters are "a fruitful source of difference of opinion, even though the great majority may be of one way of thinking, the efficacy of any special method is certainly not a matter for" the government to regulate. (*Id.* at p. 105.)

Put differently, "false . . . does not mean scientifically untrue; it means a lie." (*Wang v. FMC Corp.* (9th Cir. 1992) 975 F.2d 1412, 1421 [explaining that the False Claims Act "would not put either Ptolemy or Copernicus on trial"].) Indeed, "[m]edical researchers may well differ over the

adequacy of given testing procedures and in the interpretation of test results." (*In re Medimmune, Inc. Sec. Litig.* (D. Md. 1995) 873 F.Supp. 953, 966.) Yet under the First Amendment, if a "speaker is expressing a subjective view, an interpretation, a theory, conjecture, or surmise, rather than claiming to be in possession of objectively verifiable facts, the statement is not actionable." (*Haynes v. Alfred A. Knopf, Inc.* (7th Cir. 1993) 8 F.3d 1222, 1227.)

Courts have been especially leery of government efforts to punish, as false or fraudulent, speech describing the "effectiveness of [a] particular method of treatment of disease." (*McAnnulty*, *supra*, 187 U.S. at p. 105; see also *Reilly*, *supra*, 338 U.S. at p. 274 [endorsing "the *McAnnulty* decision as a wholesome limitation upon findings of fraud under the mail statutes when the charges concern medical practices in fields where knowledge has not yet been crystalized in the crucible of experience"].)

Look no further than this Court's opinion in *Bernado v. Planned Parenthood Fed'n of Am.* (2004) 115 Cal.App.4th 322,

in which the plaintiffs sued the leading nonprofit provider of abortion services. Claiming that the defendant's website contained unlawful and misleading statements about the safety of a medical procedure, the plaintiffs sought injunctive relief under the UCL and the FAL. (*Id.* at pp. 327-28.)

Among other things, the plaintiffs alleged that Planned Parenthood had mischaracterized scientific medical literature showing a link between abortion and breast cancer. (*Bernado*, *supra*, at p. 328.) Applying longstanding First Amendment precedent, this Court dismissed the suit, holding that "expressions of opinion about an issue of genuine scientific debate" are "noncommercial speech fully protected under the First Amendment" and thus "not actionable under either the UCL or FAL." (*Id.* at p. 342.)

Indeed, when liability hinges on a defendant's speech about scientific matters over which reasonable scientists may disagree, courts have rejected out of hand the notion that a scientifically debatable interpretation of data was false or fraudulent. (See, e.g., *ONY, Inc. v. Cornerstone Therapeutics,*

Inc. (2d Cir. 2013) 720 F.3d 490, 498 [holding that debatable scientific conclusions based on accurate data cannot violate the Lanham Act's prohibition on false advertising]; *Luckey v. Baxter Healthcare Corp.* (7th Cir. 1999) 18 F.3d 730, 732 [holding that a difference of opinion about whether a particular blood test is "effective" cannot support a claim of fraud under the False Claims Act].) And courts have long rejected as "almost frivolous" the suggestion that scientific claims are "inherently misleading" unless they enjoy "significant scientific agreement." (*Pearson v. Shalala* (D.C. Cir. 1999) 164 F.3d 650, 655.)

To be sure, fabricating data or outright lying about objectively verifiable facts is always actionable as fraud. No reasonable scientist would defend such claims; they are not capable of good-faith debate. But interpretations of data that can be fairly debated by reasonable scientists are different. The First Amendment precludes the chilling of scientific discourse by precluding the government from punishing such speech as false or fraudulent.

To avoid "intrud[ing] on First Amendment values," and because "courts are ill-equipped to undertake to referee such controversies" in science, "statements about contested and contestable scientific hypotheses" are best viewed as statements of opinion for "purposes of the First Amendment and the laws relating to fair competition." (*ONY*, *supra*, 720 F.3d at pp. 496-97.) These principles are at their zenith in this case. Consistent with these principles, the government may not condemn as "presumptively untruthful or misleading" reasonably debatable scientific claims about the safety or effectiveness of a medical product. (*Friedman*, *supra*, 13 F.Supp.2d at p. 67.)

C. The trial court erred by imposing liability on Defendants without considering the First Amendment.

First Amendment concerns are entitled to "special solicitude" from California courts. (*Bailey v. City of Nat'l City* (1991) 226 Cal.App.3d 1319, 1331.) And this Court has squarely held that "expressions of opinion about an issue of genuine scientific debate" are "fully protected under the First

Amendment" and "not actionable under either the UCL or FAL." (*Bernado*, *supra*, 115 Cal.App.4th at p. 342.) Defendants pressed such concerns, repeatedly, in the trial court. (3.RA.0516-0520; 4.RA.0733.) They were ignored.

In awarding the People a $344 million penalty—an amount greater than all other reported UCL and FAL awards combined—the trial court found that *every* communication Defendants made about Ethicon's pelvic-mesh products violated California law. Of course, the typical UCL/FAL case raises no First Amendment concerns because the speech at issue is cut and dry—it is "inherently misleading," purely commercial speech. (See, e.g., *People v. Dollar Rent-A-Car Sys.* (1989) 211 Cal.App.3d 119 [misrepresenting rental-car insurance charges].)

Not so for scientific speech. As the People conceded on the first day of trial, the "scientific propositions" about pelvic mesh are "very much in dispute" here. (20.RT.2200:3-4.) Yet as the basis for thousands of individual violations (penalized at $1,250 apiece), the trial judge indiscriminately relied on

materials in which Ethicon's allegedly 'deceptive' statements did no more than accurately describe the results of scientific studies on matters of genuine scientific debate. Indeed, much of Defendants' liability was bottomed on the People's claims that Ethicon somehow cherry-picked from the scientific literature and "deceptively" relied on published, peer-reviewed scientific articles. (26.AA.5629, 5599–5600.)

For example, the trial court found Defendants liable for sharing a brochure that reported a finding that Prolene mesh causes "no tissue reactions." (26.AA.5624, 5705.) But that brochure accurately cited the results of a peer-reviewed study that "did not find a single case of tape erosion, tissue reactions, or other adverse effects." (11.AA.2910, 2914; 28.RT.3856:4–3859:21.) And after citing that study, the brochure goes on, in the next paragraph, to state that "multiple clinical studies" show only a low risk of "erosion." (11.AA.2910.) "Erosion" arises from tissue reactions, so the brochure's full context would have confirmed for a physician

that the "no tissue reactions" statement was merely summarizing (accurately) one of several studies.

Likewise, the trial court found Defendants liable for merely stating that mesh resists infection. (26.AA.5628, 5689.) But ample scientific literature supports that claim. A standard text by a California surgeon explains that Type-1 meshes such as Prolene, with "pores larger than 75 microns," resist infection by "deterr[ing] housing and growth of bacteria." (28.RT.3862:4–3864:12.) The article concludes that "the risk of infection can be avoided by utilization of . . . Type-1 prostheses" like Prolene mesh. (28.RT.3864:18–3865:17.)

Perhaps most offensive to the First Amendment, the trial court held that *every* mention by Ethicon of peer-reviewed studies on tension-free vaginal tape by Drs. Ulmsten and Nilsson "paint[ed a] misleadingly positive picture" and was a separate basis for liability. (26.AA.5629; see also 26.AA.5711.) But those studies speak for themselves, especially when surgeons—who possess the training,

experience, and expertise needed to evaluate the studies' findings—are the target audience.

Under the First Amendment, Defendants cannot be punished for repeating any of these scientific claims—even if the People could provide contrary scientific support. But at no time have the People contended that *any* scientific study Ethicon relied on was based on fraudulent data. That should have foreclosed liability. "[T]o the extent a speaker or author draws conclusions from non-fraudulent data, based on accurate descriptions of the data and methodology . . . those statements are not grounds for a claim of false advertising[.]" (*ONY*, *supra*, 720 F.3d at p. 498; see also *Biolase, Inc. v. Fotona Proizvodnja Optoelektronskih Naprav D.D.* (C.D. Cal. June 4, 2014, No. SACV14-0248 AG(ANx)) 2014 WL 12579802, at *3-5 [rejecting FAL claims based on dentist's advertising statements because they were "accurate restatements of conclusions in scientific journal articles"].)

Such burdens on scientific speech are burdens on scientific inquiry. Drug and device manufacturers regularly

rely on credible (if inconclusive) scientific evidence in developing and marketing new technologies to benefit consumers. If they are hampered in their ability to share scientific findings, they may also be discouraged from pursuing lines of investigation. That is why "[c]laims which are supported by some credible, albeit inconclusive, evidence are not to be prohibited, but rather 'qualified' by the use of disclaimers because they are only potentially misleading." (*All. for Nat'l Health U.S. v. Sebelius* (D.D.C. 2011) 786 F.Supp.2d 1, 17.)

Just as it could not ban Defendants' scientific speech without first showing that disclaimers would not remedy any likelihood of deception, the State may not "exact a cost after the speech occurs." (*Citizens United v. FEC* (2010) 558 U.S. 310, 337.) In such cases, "the First Amendment imposes restraints on lawsuits seeking damages for injurious falsehoods." (*Kasky v. Nike* (2002) 27 Cal.4th 939, 953.) And there is no record evidence that clarifying disclosures could

not cure any alleged misunderstanding or confusion caused by Defendants' scientific speech.

Yet the trial court considered none of that. It made no attempt to separate protected speech from unprotected speech. (See, e.g., *Cent. Hudson Gas & Elec. Corp. v. Pub. Servs. Comm'n of N.Y.* (1980) 447 U.S. 557, 566 ["At the outset, we must determine whether the expression is protected by the First Amendment."].) It simply ignored, without addressing, the First Amendment implications of the People's case. And it did so by adopting, nearly verbatim, the People's proposed statement of decision.

What's worse, the People introduced *no* evidence that Ethicon's statements were 'actually or inherently misleading' to physicians or patients. Indeed, the People called *no* California surgeon who used Ethicon's pelvic mesh, and no California patient who viewed Ethicon's marketing materials before receiving a pelvic-mesh implant, to testify. Nor did the People prove that Prolene suture 'degrades' as that term is defined by FDA and used in Ethicon's labeling.

In contrast, Defendants submitted overwhelming scientific and medical evidence showing that its statements were not 'inherently misleading.' In fact, the consensus scientific evidence establishes that Defendants' statements were *true*. (48.RT.7973:21–7977:13; 7999:5–8002:15; see also 50.RT.8366:8–23.) At most, then, these are matters of legitimate scientific debate and thus shielded from liability under the First Amendment.

These flaws with the trial court's decision cannot be sidestepped on appeal. When a plausible First Amendment defense is raised, this Court has a solemn duty to "make an independent examination of the whole record" to ensure that "the judgment does not constitute a forbidden intrusion on the field of free expression." (*In re George T.* (2004) 33 Cal.4th 620, 1013, quoting *Bose Corp. v. Consumers Union of U.S., Inc.* (1984) 466 U.S. 485, 499, internal quotation marks omitted.)

The California Supreme Court requires this rigorous appellate review "precisely to make certain that what the government characterizes as speech falling within an

unprotected class actually does so." (*In re George T.*, supra, at p. 1014.) This obligation on appeal is a "constitutional responsibility that cannot be delegated to the trier of fact," no matter if the facts are found "by a jury or by a trial judge." (*Id.*)

* * *

WLF is aware of no case, apart from the trial court's decision below, in which a California court has awarded UCL and FAL penalties for scientifically disputed health claims. Yet the trial court imposed a $344 million penalty without even acknowledging, much less evaluating, Defendants' repeated and well-founded First Amendment objections. Under this Court's own precedent, that award cannot stand.

II. AFFIRMING THE DECISION BELOW WOULD IRREPARABLY CHILL SCIENTIFIC SPEECH ON VITAL MATTERS OF PUBLIC HEALTH.

The First Amendment secures an "unfettered interchange of ideas" (*Roth v. United States* (1957) 354 U.S. 476, 484), giving the public "access to discussion, debate, and the dissemination of information" (*First Nat'l Bank of Bos. v.*

Belotti (1978) 435 U.S. 765, 783 [plur. opn.]). The decision below, if allowed to stand, will upend those cherished goals. By failing even to consider the First Amendment import of imposing blanket liability on *every* communication Ethicon made about its pelvic-mesh products, the trial court's decision poses disastrous consequences far beyond the confines of this case.

The chilling effect an affirmance would have on drug and device manufacturers' constitutionally protected speech cannot be overstated. Under the trial court's view, even if manufacturers distribute nothing but peer-reviewed journal articles or FDA-cleared information—which is fully protected speech—they still can face crushing civil penalties under the UCL and the FAL. If legitimate First Amendment concerns no longer need be fairly considered by trial courts, drug and device manufacturers will be forced to weigh both their duty to educate physicians and their need to market their products against the risk of ruinous liability. That could prove calamitous.

Chilling the vital role of drug and device manufacturers in the informational marketplace is not only impermissibly discriminatory but also degrades the quality and quantity of information available to doctors and their patients. That result is far more likely to harm, than to improve, the public health. Manufacturers should not be hamstrung in keeping helpful—and potentially life-saving—products on the market. This is especially unfair when the target audience for the speech—California physicians—and federal regulators agree that the products are labeled and marketed appropriately for the very use promoted.

Indeed, the decision below is even more troubling given that all speech at issue is on-label. Under federal law, on-label speech is always speech about a "government-approved use" and therefore "permitted." (*Caronia*, *supra*, 703 F.3d at p. 165.) Even under a narrow view of the First Amendment, a manufacturer should be able, at a minimum, to enjoy a safe harbor when repeating FDA-cleared information about on-label uses.

This Court's decision thus will reverberate far beyond California's borders. To restrict drug and device manufacturers' ability to provide scientific research findings to those who prescribe those drugs and devices runs counter not only to public health but also to the First Amendment. Freedom of speech on scientific matters is a hallmark of modern medicine. To avoid the chilling of scientific discourse, such speech must enjoy ample breathing room so that scientific debate thrives.

But drug and device manufacturers are not the only ones affected by the trial court's approach to scientific speech. Nationwide businesses from every industry routinely advertise their products in California using claims—including safety- or health-related claims—backed by scientific evidence. The trial court's ruling stands to limit the ability of a wide swath of American innovators to rely on credible scientific evidence in developing and marketing new and highly beneficial products.

Imposing a 'speech tax' in the form of unpredictable and unwarranted liability creates massive uncertainty in the cost-benefit analysis of developing a product. As that uncertainty about costs and benefits rises, the incentive to produce products in the first place falls. If the risk of unforeseeable liability becomes too high, manufacturers are likely to throw up their hands and leave the market altogether. (See, e.g., Jones, *Another Big Company Departs California—Will Last One To Leave Shut The Lights?* (Feb. 3, 2017) Inv'rs Bus. Daily < https://bit.ly/3eJSZk9> [as of Sept. 20, 2021].)

The trial court's holding that *every* communication Defendants made about Ethicon's pelvic-mesh product violated California law cannot withstand First Amendment scrutiny. To prevent the chilling of constitutionally protected speech, this Court should take seriously Defendants' First Amendment arguments, clarify the line separating protected from unprotected speech, and reverse the decision below.

CONCLUSION

The Court should reverse or, at minimum, vacate and remand.

September 20, 2021 Respectfully submitted,

/S/ *Mollie F. Benedict*
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CERTIFICATE OF WORD COUNT
(Cal. Rules of Court, rule 8.204(c)(1).)

The text of this brief consists of 3,998 words.

Dated: September 20, 2021

/S/ *Mollie F. Benedict*
Mollie F. Benedict

Counsel for Amicus Curiae Washington Legal Foundation

CERTIFICATE OF SERVICE

I, Estella Licon, declare:

I am employee of the law firm of Tucker Ellis LLP, a resident of California, a citizen of the United States, over the age of eighteen, and not a party to the within action. My business address is 515 South Flower Street, 42nd Floor, Los Angeles, CA 90071.

On September 20, 2021, I served the following documents:

APPLICATION OF WASHINGTON LEGAL FOUNDATION FOR LEAVE TO FILE *AMICUS* BRIEF AND *AMICUS* BRIEF IN SUPPORT OF DEFENDANTS AND APPELLANTS

(√) **ELECTRONIC:** By serving an electronic version of the documents listed above via TrueFiling EFS on the recipients designated below, who are registered TrueFiling EFS users.

(√) **BY MAIL:** By placing the documents listed above in a sealed envelope with postage thereon fully prepaid, in the United States mail at Los Angeles, California, addressed as set forth below. I am readily familiar with the firm's practice of collecting and processing correspondence for mailing. Under that practice it would be deposited with the U.S. Postal Service on the same day with postage thereon fully prepaid in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if the postal cancellation date or postage meter date is more than one day after date of deposit for mailing in affidavit.

(√) **WEBSITE UPLOAD:** By causing to be uploaded to the Attorney General's official website for service of papers under Cal. Bus. & Prof. Code §§ 17209 and 17536.5, https://oag.ca.gov/services-info/17209-brief/add.

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I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed at Los Angeles, California on September 20, 2021.

/s/Estella Licon
Estella Licon