No. 2022-1411

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

PACIRA BIOSCIENCES, INC.,

Appellant

v.

AMERICAN SOCIETY OF ANESTHESIOLOGISTS, INC., ET AL.,

Appellees

Appeal from the United States District Court for the
District of New Jersey
Case No. 2:21-cv-09264(MCA)

AMICUS CURIAE BRIEF OF THE COUNCIL OF MEDICAL SPECIALTY SOCIETIES, SUPPORTED BY 28 OF ITS MEMBER SOCIETIES, IN SUPPORT OF AFFIRMANCE

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CORPORATE DISCLOSURE STATEMENT AND STATEMENT OF FINANCIAL INTEREST

Pursuant to Rule 26.1 and Third Circuit Local Appellate Rule 26.1, the Council of Medical Specialty Societies makes the following disclosure:

The Council of Medical Specialty Societies has no parent corporation and is not publicly traded. The Council is not aware of any publicly owned corporation not a party to the appeal that has a financial interest in the outcome of the litigation.

s/ Aaron D. Lindstrom

Dated: September 30, 2022

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STATEMENT OF AMICUS CURIAE

Founded more than 50 years ago, the Council of Medical Specialty Societies provides an independent forum for medical specialty societies to discuss issues of national interest and mutual concern. Over the years, it has grown to now include 48 specialty societies that represent more than 800,000 physicians. A full list of its member societies is available at https://cmss.org/membership/societies/.

The Council is interested in this appeal because of the critical importance of peer-reviewed scholarly journals to the dissemination and advancement of medical science. Scholarly journals support the research ecosystem, disseminate knowledge and discoveries, stimulate innovation, and serve as records of scientific discourse. Https://cmss.org/value-of-scholarly-publishers/. Indeed, medical journals are the primary medium through which physicians around the world exchange ideas. As a result, the Council is interested in protecting the free exchange of ideas through medical journals so that its members can continue to pursue the advancement of safe and effective medicine.

Given this interest and the fact that scientific journals rest on the premise that science advances through continuous testing and revision,

the Council supports the holding of the district court—that "a scientific conclusion based on nonfraudulent data in an academy publication is not a 'fact' that can be proven false through litigation." JA5. Further, the Council believes that the independent peer-review process itself, which examines scientific conclusions before they are published to ensure they are methodologically supported, greatly reduces the threat that a medical journal would make a false statement with the type of malice necessary to remove the protections of the First Amendment—that it spoke either knowing of falsity or with reckless disregard for the truth.

The Council has moved for leave to file this brief. Only its counsel authored any part of the brief. Only the Council and its members—i.e., no party, party's counsel, other individual, or other organization—contributed financial support intended to fund the preparation or submission of this brief. Fed. R. App. P. 29(a)(4)(D–E). Specifically, the following 28 Council member societies provided financial support for this brief:

1. American Academy of Allergy, Asthma & Immunology
2. American Academy of Dermatology
3. American Academy of Hospice and Palliative Medicine

4. American Academy of Neurology
5. American Academy of Ophthalmology
6. American Academy of Pediatrics
7. American Academy of Physical Medicine & Rehabilitation
8. American Association of Clinical Endocrinology
9. American College of Chest Physicians
10. American College of Emergency Physicians
11. American College of Physicians
12. American College of Radiology
13. American College of Rheumatology
14. American College of Surgeons
15. American Epilepsy Society
16. American Gastroenterological Association
17. American Geriatrics Society
18. American Psychiatric Association
19. American Society for Clinical Pathology
20. American Society of Clinical Oncology
21. American Society for Radiation Oncology
22. American Society of Nephrology
23. American Thoracic Society
24. American Urological Association
25. Infectious Diseases Society of America
26. North American Spine Society
27. Society of Hospital Medicine
28. Society of Vascular Surgery

ARGUMENT

I. The district court's rule correctly advances First Amendment principles.

A. The standard of review is de novo.

This Court "review[s] de novo the grant of a motion to dismiss for failure to state a claim." *Thompson v. State of Delaware Dep't of Servs. for Child., Youth & Their Fams.*, 44 F.4th 188, 194 (3d Cir. 2022).

B. First Amendment protection for debate about scientific conclusions is essential to the development of safe and effective medicine.

Our country has "a profound national commitment to the principle that debate on public issues should be uninhibited, robust, and wide-open . . . ." *New York Times Co. v. Sullivan*, 376 U.S. 254, 270 (1964). Indeed, "[t]he theory of our Constitution is 'that the best test of truth is the power of the thought to get itself accepted in the competition of the market[.]'" *United States v. Alvarez*, 567 U.S. 709, 728 (2012) (quoting *Abrams v. United States*, 250 U.S. 616, 630 (1919) (Holmes, J., dissenting)).

This principle of promoting open debate in a marketplace of ideas is not limited to discussion of governmental affairs. *Abood v. Detroit Bd. of Ed.*, 431 U.S. 209, 231 (1977) ("[O]ur cases have never suggested that

expression about philosophical, social, artistic, economic, literary, or ethical matters to take a nonexhaustive list of labels is not entitled to full First Amendment protection."), rev'd on other grounds by *Janus v. Am. Fed'n of State, Cnty., & Mun. Emps., Council 31*, 138 S. Ct. 2448 (2018). Rather, it extends to debates about issues of public concern, and in the First Amendment context, "public concern is something that is a subject of legitimate news interest; that is, a subject of general interest and of value and concern to the public at the time of publication." *City of San Diego, Cal. v. Roe*, 543 U.S. 77, 83–84 (2004).

The debates and discussions about medical science that occur in scholarly journals are matters of public concern. *E.g.*, *TMJ Implants, Inc. v. Aetna, Inc.*, 498 F.3d 1175, 1185–86 (10th Cir. 2007) (holding that the effectiveness of prosthetic implants was a matter of public concern because "thousands of people . . . have a legitimate interest in the utility of [the] devices"); *Urofsky v. Gilmore*, 216 F.3d 401, 430 (4th Cir. 2000) (Wilkinson, C.J., concurring in judgment) ("Speech in the social and physical sciences, the learned professions, and the humanities is central to our democratic discourse and social progress."). Indeed, "academic freedom" is "a special concern of the First

Amendment." *Keyishian v. Bd. of Regents of Univ. of State of N. Y.*, 385 U.S. 589, 603 (1967).

Articles in peer-reviewed medical journals are the modern equivalent of the public square; they are the central forum where the debate about medical science occurs. Part of the debate occurs before publication, between the authors who submit an article and the external peer reviewers who review the submission to see if it follows the scientific process and reaches scientifically sound conclusions (more about the importance of this process later). And part of the debate occurs after publication, when other interested scientists and doctors read the articles and test the theories and conclusions advanced in the articles. This creates "a global scientific discourse that is played out on the pages of the published scientific journals." E. Chan, *The "Brave New World" of Daubert: True Peer Review, Editorial Peer Review, and Scientific Validity*, 70 N.Y.U. L. Rev. 100, 113 (1995). "The body of published scientific literature is the most visible and prevalent forum through which modern-day scientific claims are communicated to the global audience of scientists." *Id.* The published articles fuel the cycle of scientific discourse: "once a claim is disseminated through publication

in journals, another scientist will test the published scientific claim and then publish the results of this testing," which in turn generates further testing and publication. *Id.* As a result, "[t]he closest approximation to a repository of scientific progress is the collective body of published scientific literature." *Id.* at 115.

Pacira asserts that this context for statements about scientific conclusions in scientific journals does not matter; in its view, there is no difference between statements made in advertisements and statements made in an academic journal. (Pacira Br. 24 (citing *Rhone-Poulenc Rorer Pharms., Inc. v. Marion Merrell Dow, Inc.*, 93 F.3d 511, 513 (8th Cir. 1996), which addressed advertisements for a drug, and *FTC v. NPB Advert., Inc.*, 218 F. Supp. 3d 1352, 1357 (M.D. Fla. 2016), which addressed email advertisements for a dietary supplement)); Pacira Br. 24, 25 (asserting that it is "immaterial" whether statements were "presented in an academic journal" or "in a magazine").) But this context affects how the reader understands the statements at issue, and it affects the type of supporting data that is included with the statement (i.e., data that allows the reader to test the conclusions).

Indeed, these contextual differences are precisely what led to different outcomes between *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490 (2d Cir. 2013), and *Eastman Chemical Co. v. Plastipure, Inc.*, 775 F.3d 230 (5th Cir. 2014), two important cases discussed by Pacira and the district court.

In *ONY*, the Second Circuit considered a falsity claim in the context of "[s]cientific academic discourse" occurring in an article "in a peer-reviewed journal." 720 F.3d at 496, 494. The Second Circuit noted that such articles are "directed to the relevant scientific community" "as part of an ongoing scientific discourse," and so are "understood by the relevant scientific communities" as being statements of "contestable scientific hypotheses" that are "more closely akin to matters of opinion" than of fact. *Id.* at 496–97. In the context of journals engaging in the scientific method, the readers understand that "the conclusions of empirical research are tentative and subject to revision, because they represent inferences about the nature of reality based on the results of experimentation and observation." *Id.* at 496; *accord Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993) ("Scientific conclusions are subject to perpetual revision."). Further, statements in scientific

journals (unlike statements in other contexts, such as magazines) are supported by "data presented in the article" itself. *Id.* at 497. As a result, the Second Circuit held "that, as a matter of law, statements of scientific conclusions about unsettled matters of scientific debate cannot give rise to liability for damages sounding in defamation." *Id.* at 492.

In contrast, when confronted with a commercial advertisement, the Fifth Circuit reached a different outcome precisely because the context was different. In *Eastman*, the Fifth Circuit distinguished *ONY* because *ONY* involved "statements made within the academic literature and directed at the scientific community," and observed that "[i]n that context, the Second Circuit concluded that the defendants' statements should be treated as opinions, else the prospect of defamation liability would stifle academic debate and trench upon First Amendment values." 775 F.3d at 236. In contrast, in the case before the Fifth Circuit, "Eastman did not sue Appellants for publishing an article in a scientific journal," but rather "sought to enjoin statements made in commercial advertisements and directed at customers." *Id.* In short, context was the dispositive difference.

Consistent with the reasoning of both circuits, a number of other courts have also concluded that statements made in the specific context of scientific journals should be treated as matters of opinion, not fact. *E.g.*, *Biolase, Inc. v. Fotona Proizvodnja Optoelektronskih Naprav D. D.*, No. SACV140248AGANX, 2014 WL 12579802, at *4 (C.D. Cal. June 4, 2014) ("attacking the validity of experiments and conclusions published in peer-reviewed scientific journal articles is better done in the scientific, not legal, realm"); *Saad v. Am. Diabetes Ass'n*, 123 F. Supp. 3d 175, 179 (D. Mass. 2015) (concluding that "the ADA's Expression of Concern, which was published in a medical journal 'to alert readers to questions about the reliability of data' in four specific articles" was not actionable given "the context in which it was issued: ongoing scientific discourse"); *Ezrailson v. Rohrich*, 65 S.W.3d 373, 375 (Tex. App. 2001) (concluding that "the medical science research article is not reasonably capable of a defamatory meaning" because "opinions" on "a matter of public health and medicine" "must be protected"). Indeed, as the *Ezrailson* court observed, "in the area of medical science research, criticism of the creative research ideas of other medical scientists should not be restrained by fear of a defamation claim in the event the

criticism itself also ultimately fails for lack of merit," and "calling the medical science research article here defamatory would serve to unduly restrict the free flow of ideas essential to medical science discourse." 65 S.W.3d at 382.

As these courts understood, in the context of an article in a medical journal, the reader understands that scientific conclusions are matters of opinion, not of fact, because scientific conclusions are always subject to revision and are based on inferences drawn from the supporting data that readers may examine themselves.

Pacira tries to argue that the First Amendment is on its side by suggesting that "singling out 'scientific' statements in academic journals" would amount to a "content-based regulation of speech." (Pacira Br. 36.) But Pacira is conflating the *context* of the statement with its *content*. This can be easily seen by examining one of Pacira's own examples. Pacira complains that the rule would treat "identical statement[s]"—i.e., statements with the *same content*—differently if they appeared in *different contexts*—i.e., in a magazine versus in a scientific journal. (Pacira Br. 25.) That is a complaint that the rule is *not* content based, as it produces different results for the same content

when it appears in different contexts. Pacira's argument that the district court's rule is "constitutionally problematic" because it is "content-based" (Pacira Br. 17) is therefore misplaced.

In fact, far from being constitutionally problematic, the district court's rule furthers First Amendment principles by protecting against a chilling effect on scientific discourse. Specifically, if allegations "that some methodological flaw led to a scientifically 'incorrect' answer" can be the basis for a trade-libel claim, JA5, then scientists will be less likely to come forward with their scientific conclusions. Not only would this chilling effect impede scientific discourse and scientific progress, it could also cause real-world harms, such as making it less likely that doctors or scientists might publicly raise safety issues with drugs.

For example, a recent study examined threats and intimidation efforts that 26 clinicians or scientists received for communicating safety, efficacy, or data integrity concerns publicly, including in scientific journals. C. Bennett et al., *Davids versus Goliaths: Pharma and Academia Threats to Individual Scientists and Clinicians*, Journal of Scientific Practice and Integrity 1, 2, 3, & 5 (June 24, 2022). The threats that the individuals received, mostly from employees of

pharmaceutical companies, included not just threats of litigation (which is the most relevant threat here), but also threats of professional harm (such as losing employment). *Id.* at 2–6. The individuals threatened nonetheless went forward in communicating their concerns about drugs and medical devices, and for good reason. The study observed that "[a]n estimated one million persons developed serious toxicities or died from adverse drug reactions from drugs and devices" about which the 26 scientists and clinicians expressed public concerns. *Id.* at 6. But if a methodological flaw in an article published in a medical journal could lead to liability for the authors and the journal, then there is a real risk that fewer safety concerns will be brought to light. *See* N. Persaud et al., *How Can Journals Respond to Threats of Libel Litigation*, 11(3) Public Library of Science – Medicine 1, 1 (March 2014) (quoting the Canadian Supreme Court as observing that "[t]here is concern that matters of public interest go unreported because publishers fear the ballooning cost and disruption of defending a defamation action."); *Simpson v. Mair*, 2008 SCC 40, 2008 CarswellBC 1311 (Can.).

In light of these First Amendment considerations about the importance of open debate in scientific journals, the district court's rule

draws the proper balance in concluding that "a scientific conclusion based on nonfraudulent data in an academic publication is not a 'fact' that can be proven false through litigation." JA5.

C. The peer-review process for medical journals protects against the possibility of malice.

Pacira also attacks the district court's rule as unnecessary on the theory that "[t]he generally applicable elements of defamation law—including the broader leeway given to statements of opinion and the requirement of actual malice—are sufficient to weed out and protect non-defamatory scientific statements." (Pacira Br. 37.) But Pacira discounts the weeding out process that scientific journals implement even *before* those elements could be applied in litigation: specifically, the pre-publication process of independent peer review that acts to weed out the possibility of malice.

In the context of the First Amendment and defamation or trade libel, the requirement that a statement be made with "actual malice" means that the statement was made either with knowledge that it was false or with reckless disregard as to whether it was false. *See New York Times Co. v. Sullivan*, 376 U.S. at 280; *Mayflower Transit, LLC v. Prince*, 314 F. Supp. 2d 362, 376 (D.N.J. 2004). Given this intent

requirement, it is significant that scientific journals use independent, external peer reviewers for the specific purpose of reducing the likelihood that a journal article will include unsound scientific conclusions and that authors voluntarily submit to this vetting process.

Pre-publication peer review dates back to at least 1752, when "the Royal Society of London required all submissions to be reviewed by a council of experts prior to publication." P.R. Farrell et al., *Ancient Texts to PubMed: A Brief History of the Peer-Review Process*, 37 Journal of Perinatology 13, 14 (2017). Over time, more journals began using external peer review. For example, "the British Medical Journal sent every noneditorial submission to a recognized expert as early as 1893." L. Manchikanti et al., *Medical Journal Peer Review: Process and Bias*, 18 Pain Physician Journal E1, E2 (2015). But "peer review did not become fully ingrained until the latter half of the twentieth century." Farrell, *Ancient Texts*, at 14. For example, leading journals such as "*Science* and *JAMA* [*Journal of the American Medical Association*] did not use external reviewers until the 1940s," and "*The Lancet* and *Nature* did not consistently invite external reviewers until the 1970s." *Id.* Today, though, independent peer review is the standard:

"[f]ormalized, invited external peer review is now considered a fundamental tenet of modern scientific literature," *id.* at 13.

Scientific journals turn to external reviewers to weed out bad science. Journals "are under considerable pressure to ensure the integrity and accuracy of material they publish in order to maintain the quality and probity of the research." Manchikanti, *Medical Journal Peer Review*, at E3. And peer review also gives submitting authors "a strong incentive to ensure their conclusions are supported by the data," as they know "their articles will be evaluated by peers . . . ." J.B. Ruhl & James Salzman, *In Defense of Regulatory Peer Review*, 84 Wash. U.L. Rev. 1, 14 (2006). "When peer review is used in the context of journal publication," the journal "acts as a 'middleman' to find independent reviewers with relevant expertise who will review the science, not the scientists, and evaluate the merits of publication." *Id.* at 12. Another marker of this independence from journals is that the reviewers are "usually unpaid" and participate out of a "sense of professional duty." L. Tite, *Why Do Peer Reviewers Decline to Review? A Survey*, 61(1) Journal of Epidemiology & Community Health 9, 9 (Jan. 2007).

To be sure, peer review does not require reviewers to "engage in independent testing and data analysis." *Id.* Substantively, the peer review process is not a 'de novo' review, to borrow from a legal model, but rather more like appellate review." *Id.* Thus, the reviewer assesses the "scientific soundness" of the article, by examining "the methods, data presentation, and statistical design and analyses of the paper . . . ." *Id.* As the Sixth Circuit recently observed, "[p]eer review contains its own independence, as it involves 'anonymously reviewing a given experimenter's methods, data, and conclusions on paper.'" *United States v. Gissantaner*, 990 F.3d 457, 465 (6th Cir. 2021). Anonymity is often a feature of peer review, sometimes by a single-blind review (where the reviewers know who the authors are, but the authors do not know the identity of the reviewers, so that the reviewers may be more direct in their critiques) or by a double-blind review (where neither the author nor the reviewers are aware of each other's identities). A. Gregory et al., *Everything You Need to Know about Peer Review—The Good, The Bad and The Ugly*, 28 Heart, Lung and Circulation 1148, 1149 (2019).

These efforts by scientific journals to ensure the soundness of scientific claims made in articles (and the willingness of authors to

submit to this process) cut directly against the intent necessary for a defamation claim to fall outside the protections of the First Amendment—a reckless disregard for the truth of a statement or actual knowledge of its falsity. Put simply, the fact that journals and authors collectively use independent peer reviewers to evaluate the scientific soundness of articles before publishing them tends to negate the claim that the articles are published with knowledge of false statements or with reckless disregard for the truth or falsity of statements.

Courts have applied similar reasoning to questions of knowledge or reckless disregard in other contexts. For example, in the context of determining whether a taxpayer had "either (1) *actual knowledge* that the trust-fund taxes were not paid and the ability to pay the taxes, or (2) *recklessly disregarded* known risks that the trust-fund taxes were not paid," the Sixth Circuit concluded that reliance on an external reviewer—"an independent, professional accounting firm"—to review the taxes showed the taxpayer did not have the requisite intent—willfulness—to violate the statute. *Byrne v. United States*, 857 F.3d 319, 327, 332 (6th Cir. 2017) (emphasis added). Thus, while Pacira asserts that the district court's rule "threaten[s] to inoculate from legal scrutiny

even *purposefully inaccurate claims* about important facts" (Pacira Br. 1), it overlooks the fact that the use of external peer review by scientific journals and authors demonstrates their *purposeful intent* to weed out inaccurate claims.

Perhaps aware that the presence of peer review addresses many of its concerns that the district court's rule might be abused, Pacira points out that peer review has flaws, such as that it may be insufficient at detecting instances of actual fraud, and it illustrates this by referring to "the Theranos debacle." (Pacira Br. 30.) But the story of Theranos is a story about a company that used "fraudulent data" to build its blood-testing business, B. Golder, *Book Review: Bad Blood: Secrets and Lies in a Silicon Valley Startup*, 87(2) Lineacre Quarterly 233, 234 (2020), and so the district court's rule would not affect a situation like Theranos's. After all, the district court's rule is that "a scientific conclusion *based on nonfraudulent data* in an academic publication is not a 'fact' that can be proven false through litigation." JA5 (emphasis added). In other words, while the use of falsified data is a concern that scientific journals take very seriously, *see, e.g.*, H. Bauchner, *Scientific Misconduct and Medical Journals*, 320 J. Am. Med. Ass'n 1985 (Nov.

20, 2018) (addressing how JAMA responds to allegations of falsified data), and while it is an issue that peer review cannot fully eliminate, the district court's rule already allows trade-disparagement claims to be brought in instances of falsified data. It simply bars claims that allege, as here, "that some methodological flaw led to a scientifically 'incorrect' answer." JA 5.

Further, the examples Pacira provides about researchers submitting fake articles "in high-profile journals in fields including gender studies, queer studies, and fat studies," Y. Mounk, *What An Audacious Hoax Reveals About Academia*, The Atlantic (Oct. 5, 2018) (cited in Pacira Br. 31), are instances where researchers have fooled disciplines outside of the natural and physical sciences by using "fashionable jargon." *Id.* In fact, this article from *The Atlantic* specifically notes that "[w]hile the hoaxers did manage to place articles in some of the most influential academic journals in the cluster of fields that focus on dealing with issues of race, gender, and identity, they have not penetrated the leading journals of more traditional disciplines." *Id.* But even aside from this recognition that the peer-review process may be more effective in the areas of the natural and

physical sciences, the basic underlying point remains: the use of the peer-view process by journals tends to show that journals lack malice—that their intent is to weed out bad science (and hoaxes), not to publish it.

CONCLUSION

In the end, the district court was correct when it observed that "[t]he peer-review process—not a courtroom—thus provides the best mechanism for resolving scientific uncertainties." JA5.

For these reasons, this Court should affirm the district court's ruling.

Respectfully submitted,

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I certify that the filed electronic and paper copies of this amicus brief are identical and that a virus detection program, namely Windows Security, which is updated continuously, has been run on the PDF and that no virus was detected. 3d Cir. Local App. R. 31.1(c).

I certify that I am a member of the bar of the United States Court of Appeals for the Third Circuit. 3d Cir. Local App. R. 28.3(d).

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CERTIFICATE OF SERVICE

I hereby certify that on September 30, 2022, I electronically filed the foregoing **Amicus Curiae Brief** with the Clerk of the Court for the United States Court of Appeals for the Third Circuit using the appellate CM/ECF system.

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/s/ Aaron D. Lindstrom