No. 22-1411

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Pacira BioSciences, Inc.,
Appellant,
v.
American Society of Anesthesiologists, Inc.; Evan D. Kharasch; Nasir Hussain; Richard Brull; Brendan Sheehy; Michael K. Essendoh; David L. Stahl; Tristan E. Weaver; Faraj W. Abdallah; Brian M. Ilfeld; James C. Eisenach; Rodney A. Gabriel; Mary Ellen McCann,
Appellees.

On Appeal from the United States District Court
for the District of New Jersey
The Honorable Madeline Cox Arleo
Case No. 2:21-cv-09264 (MCA)

BRIEF OF *AMICUS CURIAE* FOUNDATION FOR INDIVIDUAL RIGHTS AND EXPRESSION (FIRE) IN SUPPORT OF APPELLEES AND AFFIRMANCE

Eugene Volokh*
First Amendment Clinic
UCLA School of Law
385 Charles E. Young Dr. E
Los Angeles, CA 90095
(310) 206-3926
volokh@law.ucla.edu

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Rule 26.1 Disclosure Statement

Amicus Curiae Foundation for Individual Rights and Expression, a nonprofit corporation organized under the laws of Massachusetts, has no parent companies, subsidiaries, or affiliates and does not issue shares to the public.

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Interest of *Amicus Curiae*[1]

The Foundation for Individual Rights and Expression (FIRE) is a nonpartisan, nonprofit organization dedicated to defending the individual rights of all Americans to the freedoms of speech, expression, and conscience. FIRE is particularly concerned about defending the rights of scholars to freely do research. Since 1999, FIRE has successfully defended First Amendment rights on campuses nationwide through public advocacy, targeted litigation, and *amicus curiae* filings in cases, like this one, that implicate professors' rights. *See, e.g.*, Brief for FIRE, et al. as *Amici Curiae* Supporting Plaintiff-Appellant, *Adams v. Trustees of Univ. of N.C.-Wilmington*, 640 F.3d 550 (4th Cir. 2011); Brief for FIRE as *Amicus Curiae* Supporting Plaintiff-Appellant-Petitioner, *McAdams v. Marquette Univ.*, 383 Wis. 2d 358 (2018). To protect the rights of researchers

[1] No party or party's counsel has authored this brief in whole or in part, or contributed money that was intended to fund preparing or submitting the brief. No person has contributed money that was intended to fund preparing or submitting the brief, except that UCLA School of Law paid the expenses involved in filing this brief. All parties have consented to the filing of this *amicus* brief.

generally, including academics, FIRE urges this Court to affirm the District Court's ruling.

Summary of Argument

The District Court correctly ruled that scientific conclusions in academic journals are protected speech, and should not be subject to liability imposed by lay judges and juries. The Supreme Court's pronouncements on scientific speech support this conclusion. So do the lower court cases on the fact/opinion distinction. And so do the realities of the medical field, where pharmaceutical companies have ample resources to defend themselves through counterspeech—but should not be allowed to deploy those resources to intimidate academics and other researchers into silence.

I. A. Five Supreme Court Justices made clear in *United States v. Alvarez* that even false statements about "the social sciences, the arts, and the like" are protected, 567 U.S. 709, 731-32 (2012) (Breyer, J., concurring, joined by Kagan, J.); *id.* at 749 (Alito, J., dissenting, joined by Scalia, J. and Thomas, J.). This is so because "it is perilous to permit the state to be the arbiter of truth," *id.* at 752 (Alito, J., dissenting), and because in these areas "'any attempt by the state to penalize purportedly false

speech would present a grave and unacceptable danger of suppressing truthful speech,'" *id.* at 731 (Breyer, J., concurring) (quoting *id.* at 751 (Alito, J., dissenting)). This same principle also applies to the life sciences.

Indeed, it fits the life sciences and other physical sciences especially well. Scientific studies, such as ones examining how effective various chemicals are at managing pain, are part of how scientists seek to constantly expand knowledge. Scientists and doctors (the audience for defendants' statements) understand that scientific claims are constantly subject to revision—that they are opinions about the authors' current understandings of the world.

B. To be sure, courts may sometimes need to deal with scientific questions, for instance in medical malpractice cases—but these involve inquiries sharply different from determining the truth or falsity of scientific conclusions in academic journals. Medical malpractice suits or hospital investigations of a doctor's performance consider what a particular doctor did to a particular patient on a particular occasion. Articles in academic journals involve researchers opining on the best inferences to draw from complex medical studies.

C. Likewise, courts may need to consider whether commercial advertisements contain incorrect medical claims. But commercial advertising has long been viewed as less protected, under the "commercial speech" doctrine, than scientific speech outside the context of advertising.

II. Scientific questions should be debated using counterspeech, not litigation. Pacira has ample resources to respond to defendants' claims—and to address defendants' target audience of doctors and researchers—whether through its employees' own articles, press releases, or advertisements. Academics and experts, rather than lay judges and juries, should resolve scientific questions such as the one in this case.

III. Reversing the District Court's decision would chill academics and other scientists from engaging in scientific research. The threat of trade libel litigation would discourage journals from publishing research that criticizes medical products and would discourage researchers from engaging in such research. Researchers must be able to advance science by evaluating—and sometimes criticizing—scientific claims without facing litigation costs that they cannot afford. Otherwise, public commentary about medical products would be skewed in favor of positive evaluations,

which cannot lead to trade libel liability, while negative evaluations sit unpublished in academics' drawers.

Argument

I. Scientific Conclusions in Academic Journals Are Protected Speech.

A. Scientific Conclusions Are Tentative and Subject to Revision.

As noted in the Summary of Argument, five Justices in *Alvarez* made clear that even false statements about "the social sciences, the arts, and the like" are categorically protected. *See supra* p. 2. (The remaining four Justices had no occasion to discuss this, because they would have implemented an even more speech-protective test as to false statements generally, *see Alvarez*, 567 U.S. at 723 (plurality opin.).) This same principle also applies to the life sciences. "[T]he First Amendment protects scientific expression and debate just as it protects political and artistic expression." *Bd. of Trustees of Leland Stanford Jr. Univ. v. Sullivan*, 773 F. Supp. 472, 474 (D.D.C. 1991) (speaking specifically about medical research). Thus, the District Court was correct in holding that scientific conclusions in academic journals should be protected from second-guessing by lay judges and juries.

"Scientific conclusions are subject to perpetual revision." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993). "[T]he hallmarks of scientific research are continuous inquiry, testing, debate, disagreement, and revision." *HipSaver, Inc. v. Kiel*, 464 Mass. 517, 533 (2013). The history of science is the history of formerly widely accepted theories being replaced with new ones, which are then later replaced in turn. The goal is to constantly come closer to the truth, but scientists understand that any particular study is just one more step in the process, not the final step.

Scientific conclusions in an academic journal are thus not confident assertions of fact, but "more closely akin to matters of opinion, and are so understood by the relevant scientific communities." *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490, 497 (2d Cir. 2013). Other researchers are expected to "respond by attempting to replicate the described experiments, conducting their own experiments, or analyzing or refuting the soundness of the experimental design or the validity of the inferences drawn." *Id.*

"When the defendant's statements, read in context, are readily understood as conjecture, hypothesis, or speculation, this signals [to] the reader that what is said is opinion, and not fact." *Levin v. McPhee*, 119 F.3d 189, 197 (2d Cir. 1997). Thus, articles in academic journals are generally shielded from defamation liability. *See, e.g.*, *Gordon & Breach Sci. Publishers S.A. v. Am. Inst. of Physics*, 859 F. Supp. 1521, 1542 (S.D.N.Y. 1994); *HipSaver*, 464 Mass. at 532-33; *ONY*, 720 F.3d at 496-97; *Neurotron, Inc. v. Am. Ass'n of Electrodiagnostic Med.*, 189 F. Supp. 2d 271, 277 (D. Md. 2001), *aff'd*, 48 F. App'x 42 (4th Cir. 2002).

And this fits well the general libel law principle that, "if the disclosed facts are true and the opinion is defamatory, a listener may choose to accept or reject it on the basis of an independent evaluation of the facts." *Redco Corp. v. CBS, Inc.*, 758 F.2d 970, 972 (3rd Cir. 1985). That is especially true for readers of academic journals, who understand the way scientific research and debate works.

Of course, a statement based on fraudulent data can indeed be actionable. "[T]here is no constitutional value in false statements of fact," *Gertz*

v. Robert Welch, Inc., 418 U.S. 323, 340 (1974), and that includes scientific fraud—for instance, fraudulent statements (which are not alleged in this case) that authors performed a test that they did not perform, or that a test yielded one quantitative result when the authors knew it yielded a different result. This is entirely consistent with the District Court's conclusion that "scientific conclusions are protected speech to the extent they are 'draw[n] . . . from non-fraudulent data [and] based on accurate descriptions of the data and methodology underlying those conclusions . . . .'" Appellants' Br. App. 28-29 (quoting *ONY*, 720 F.3d at 498). But in the absence of such fraudulent data, "we depend for [the] correction" of scientific studies "not on the conscience of judges and juries but on the competition of other ideas," *Gertz*, 418 U.S. at 339-40, including competition in scientific debate.

B. The District Court's Position Is Consistent With Courts' Power to Adjudicate Specific Claims of Past Professional Misconduct.

While courts do decide claims that involve science and medicine, such as medical malpractice lawsuits or libel lawsuits stemming from mal-

practice allegations, those kinds of claims examine specific physician behaviors on a specific occasion, rather than adjudicating the truth or falsity of scientific studies. For example, in *Patel v. Soriano*, a surgeon successfully sued for trade libel based on defamatory statements about his morbidity records made by another surgeon. 369 N.J. Super. 192, 211-12 (App. Div. 2004). But *Patel* did not consider statements in scientific debate; rather, it examined how the defendant's statements "essentially charged [the] plaintiff with negligence." *Id.* at 249.

Unlike claims of medical malpractice, which stem from a closed set of facts related to a specific incident, scientific debate involves large datasets, complicated systems, and constant openness to revision. Medical malpractice claims are for courts; claims about the efficacy of various chemicals are for scientific debate.

C. Discussion of Medical Products in Academic Journals Is Not Commercial Speech.

Whatever latitude there is for lawsuits or enforcement actions based on allegedly false advertising on medical matters, that latitude stems from false advertising being false commercial speech. The Supreme Court's "precedents define commercial speech as 'speech that does no

more than propose a commercial transaction,'" *Harris v. Quinn*, 573 U.S. 616, 648 (2014) (quoting *United States v. United Foods, Inc.*, 533 U.S. 405, 409 (2001)), and such speech has long been held to be less constitutionally protected. "[C]ommercial speech, in a libel suit, would receive some, albeit less than heightened, constitutional protection." *U.S. Healthcare, Inc. v. Blue Cross of Greater Philadelphia*, 898 F.2d 914, 932-33 (3d Cir. 1990).

But academic speech in scientific journals is not commercial speech, because it does not propose a commercial transaction. *Gordon & Breach*, 859 F. Supp. at 1542. Indeed, even product reviews in lay publications, such as *Consumer Reports*, are treated as fully protected speech, not commercial speech. *See, e.g.*, *Bose Corp. v. Consumers Union of U.S., Inc.*, 466 U.S. 485 (1984). The special rules related to commercial speech are thus irrelevant to this case.

II. Disagreements over Scientific Studies Are Best Settled Through Counterspeech as Opposed to Litigation.

For scientific speech, even more than for other speech, "[t]he first remedy of any victim of defamation" should be "self-help—using available opportunities to contradict the lie or correct the error and thereby to min-

imize its adverse impact on reputation." *Gertz*, 418 U.S. at 344. Pharmaceutical companies like Pacira enjoy the resources to rebut the ASA's conclusions outside of litigation. They can publish articles of their own in other scientific journals. They can buy advertising. They can send mass mailings. Through this they can easily reach the professional and academic audiences that they are most concerned about persuading.

And these channels of counterspeech are also the ones that are best suited to scientific debate. Scientific controversies should be settled "by the methods of science rather than by methods of litigation." *Underwager v. Salter*, 22 F.3d 730, 736 (7th Cir. 1994). Academic journals and advertisements provide an established and effective forum of counterspeech, through which scientists can "analyz[e] or refut[e] the soundness of the experimental design or the validity of the inferences drawn" through their own research. *ONY*, 720 F.3d at 497.

Reaching a better understanding of such complex subject matter requires the free flow of theories, conclusions, and counterarguments, among people who (unlike judges and juries) have the professional expertise to evaluate the disputes. "More paper, more discussion, better data,

and more satisfactory models—not larger awards of damages—mark the path towards superior understanding of the world around us." *Underwager*, 22 F.3d at 736.

III. Reversing the District Court's Decision Would Chill Academic Debate and Scientific Progress.

If academics and other scientists know that their academic articles can lead to lawsuits by deep-pocketed pharmaceutical companies, they may often be deterred from writing articles that cast doubt on those companies' products. Universities and publishers are not obligated to pay for researchers' legal fees—and, even if they do pay, the prospect of such payments may lead them to pressure their employees and authors not to write things that risk litigation. *See* Amy Gajda, *The Trials of Academe: The New Era of Campus Litigation* 176 (2009); *Take Science off the Stand*, 23 Nature Med. 265, 265 (2017). It appears that the ASA is supporting its authors in this lawsuit, *see* ASA, *Pacira Withdraws Motion to Seek Retraction of Anesthesiology Studies* (May 13, 2021), https://perma.cc/P39V-H4HC; but not all publishers would be able to afford to do that.

Hi-Tech Pharmaceuticals, Inc. v. Cohen, 208 F. Supp. 3d 350 (D. Mass. 2016), offers a helpful illustration. In *Hi-Tech*, a pharmaceutical supplements company sued Harvard Medical School Professor Pieter Cohen for defamation after he published a peer-reviewed article that replicated the results of an FDA study. The FDA took enforcement actions against the pharmaceutical company, and the jury eventually ruled in Cohen's favor.

But as Cohen observed after the lawsuit, the goal of litigating scientific conclusions in academic journals "is to intimidate." Nicolas Bagley, Aaron E. Carroll, & Pieter A. Cohen, *Scientific Trials—In the Laboratories, Not the Courts*, 178 JAMA Internal Med. 7, 7 (2018). To quote Cohen's co-author, also a professor of medicine, "We have a dispiriting shortage of high-quality health research for many reasons, including the fact that it's expensive, difficult and time-intensive. But one reason is more insidious: Sometimes groups seek to intimidate and threaten scientists, scaring them off promising work." Aaron E. Carroll, *Why a Lot of Important Research Is Not Being Done: Lawsuits Have an Intimidating Effect on an Already Difficult Enterprise*, N.Y. Times, Dec. 4, 2017. The

news of a libel trial over scientific research, even one that leads to a defense verdict, can easily deter other scientists from publishing—or even undertaking—work that may cast doubt on the efficacy of commercially available products.

"[A] rule requiring scientists and authors to guarantee the 'truth' of their hypotheses would inevitably lead to self-censorship and would stifle the very debate that leads to scientific knowledge." *Freyd v. Whitfield*, 972 F. Supp. 940, 945 (D. Md. 1997). The District Court's ruling wisely aims to avoid such a chilling effect on scientific research.

Conclusion

Scientific conclusions in academic journals are protected speech, which should not be second-guessed by lay judges and jurors. Science is a continuous, iterative process, yielding opinions that readers understand to be tentative and subject to revision. Disputes about the soundness of academic work should be resolved through counterspeech and scientific debate; otherwise, a wide range of research that may criticize products distributed by deep-pocketed pharmaceutical corporations will

be chilled. For these reasons, the District Court's ruling should be affirmed.

Respectfully Submitted,

s/ Eugene Volokh

Attorney for *Amicus Curiae*
First Amendment Clinic
UCLA School of Law
385 Charles E. Young Dr. E
Los Angeles, CA 90095
(310) 206-3926
volokh@law.ucla.edu

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This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 2,547 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

s/ Eugene Volokh

Attorney for *Amicus Curiae*

Certificate of Service

I hereby certify that I electronically filed this brief with the Clerk of the Court for the United States Court of Appeals for the Third Circuit by using the appellate CM/ECF system today, September 28, 2022. All participants in the case are registered CM/ECF users, and will be served by the appellate CM/ECF system.

s/ Eugene Volokh

Attorney for *Amicus Curiae*