No. 20-1149

In the Supreme Court of the United States

BRISTOL-MYERS SQUIBB CO., ET AL., PETITIONERS

v.

CLARE E. CONNORS, ATTORNEY GENERAL OF HAWAII

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS AMICI CURIAE IN SUPPORT OF PETITIONERS

JAMES C. STANSEL
MELISSA B. KIMMEL
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
950 F Street, NW
Suite 300
Washington, DC 20004

DOUGLAS HALLWARD-DRIEMEIER
Counsel of Record
CHIMSO OKOJI
ROPES & GRAY LLP
2099 Pennsylvania Avenue, NW
Washington, DC 20006
(202) 508-4600
Douglas.Hallward-Driemeier@ropesgray.com

TARA S. MORRISSEY
JENNIFER B. DICKEY
U.S. CHAMBER LITIGATION CENTER
1615 H Street, NW
Washington, DC 20062

SAMUEL POKROSS
ROPES & GRAY LLP
Prudential Tower
800 Boylston St.
Boston, MA 02199

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases:

Cases—Continued: Page(s)

Cases—Continued: Page(s)

Constitutional provisions and statutes:

Miscellaneous:

In the Supreme Court of the United States

NO. 20-1149

BRISTOL-MYERS SQUIBB CO., ET AL., PETITIONERS

v.

CLARE E. CONNORS, ATTORNEY GENERAL OF HAWAII

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS AMICI CURIAE IN SUPPORT OF PETITIONERS

INTEREST OF AMICI CURIAE[1]

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, non-profit association that represents the nation's leading biopharmaceutical and biotechnology companies. PhRMA's mission is to advocate for public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA's members invest billions of dollars each year to research

[1] Pursuant to Rule 37.2(a), counsel for all parties received timely notice of amici's intent to file this brief, and consented in writing. No counsel for any party authored this brief in any part, and no person or entity other than amici, amici's members, or amici's counsel made a monetary contribution to fund its preparation or submission.

and develop new drugs, more than 500 of which have been approved by the U.S. Food and Drug Administration (FDA) since 2000.

The Chamber of Commerce of the United States of America (Chamber) is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than 3 million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files amicus curiae briefs in cases that raise issues of concern to the nation's business community. The Chamber has an interest in ensuring that its members are afforded a neutral federal tribunal in which to vindicate federal rights that are impinged by state governmental entities.

PhRMA and the Chamber have a strong interest in this case because their members are increasingly the targets of suits by private counsel purporting to act in the name of the state. In addition, PhRMA and the Chamber have a substantial interest in ensuring that the courts fully protect companies' federal rights, including important First Amendment interests regarding scientific information in the healthcare context.

Amici therefore respectfully urge this Court to grant the petition for a writ of certiorari and reverse the ruling of the court of appeals.

SUMMARY OF THE ARGUMENT

This Court has repeatedly recognized that federal courts have a "virtually unflagging" obligation to exercise the jurisdiction Congress has conferred, *Sprint Commc'ns Inc.* v. *Jacobs*, 571 U.S. 69, 77 (2013) (quoting *Colorado River Water Conservation Dist.* v. *United States*, 424 U.S. 800, 817 (1976)), including with respect to challenges to conduct by state actors that would subvert federally protected rights, see *Ex parte Young*, 209 U.S. 123, 160 (1908). In the decision below, the Ninth Circuit adopted just the type of broad view of abstention under *Younger* v. *Harris*, 401 U.S. 37 (1971), that this Court rejected in *Sprint*. If allowed to stand, the decision will undermine critical federal oversight of state conduct that implicates important federal interests, including by infringing federally protected constitutional rights. The court of appeals' opinion would permit private counsel, purportedly acting on behalf of state enforcement authorities, to violate defendants' federal rights with little or no federal judicial oversight—such as, in this case, by imposing staggering liability on speech that is protected by the First Amendment.

The instant case demonstrates the risks of a broad application of *Younger* abstention. Here, private attorneys, with no regulatory authority or expertise, used the name of the state to convince a state court to dictate the content of scientific speech, and to do so in a way that contradicts the expert judgment of federal regulators. Without question, had a state agency issued a regulation purporting to require petitioners to make scientifically unsubstantiated statements about their products, petitioners would have had a right to a federal forum in which to challenge that mandate. The fact that the state

chose instead to impose a similar mandate through litigation by self-interested counsel should not make the state's conduct any *less* subject to federal review. Yet the court of appeals' opinion does just that—providing a contingency-fee lawyer with greater immunity from federal judicial scrutiny for compelled speech than state officials proceeding by regulation would enjoy. The ruling below will only exacerbate the increasing trend in which state attorneys general lend their names to creative private lawyers who bring actions "on behalf of" a state, with little to no oversight by those state actors with true regulatory expertise and authority.

Review is necessary to reaffirm the "primacy of the federal judiciary in deciding questions of federal law," *England* v. *La. State Bd. of Med. Exam'rs*, 375 U.S. 411, 415-416 (1964), and the duty of federal courts to decide cases within their jurisdiction, *Sprint*, 571 U.S. at 77. This Court should grant the writ and reverse, in order to ensure that parties with valid federal claims against state actors have access to a federal forum.

ARGUMENT

I. THE COURT OF APPEALS' OPINION ERODES A DEFENDANT'S RIGHT TO OBTAIN FEDERAL JUDICIAL REVIEW OF IMPORTANT QUESTIONS OF FEDERAL LAW, INCLUDING FEDERAL CONSTITUTIONAL RIGHTS

In *Ex parte Young*, this Court established that federal courts are available to hear challenges to conduct by state actors that would subvert a party's federal rights. 209 U.S. 123, 160 (1908). Since then, this Court's decisions have repeatedly emphasized that the *Ex parte Young* doctrine rests on the need to "vindicat[e] federal

rights" and to "hold state officials responsible to the supreme authority of the United States." *Pennhurst State Sch. & Hosp.* v. *Halderman*, 465 U.S. 89, 105 (1984) (citation omitted); see also *Green* v. *Mansour*, 474 U.S. 64, 68 (1985) (explaining that *Ex parte Young* furthers the federal interest in vindicating federal law). The Ninth Circuit, in adopting an expansive conception of abstention under *Younger* v. *Harris*, 401 U.S. 37 (1971), declined to fulfill its "virtually unflagging" obligation to vindicate federal rights and decide questions of federal law, despite this Court's clear direction in *Sprint Communications Inc.* v. *Jacobs* that "only exceptional circumstances * * * justify a federal court's refusal to decide a case in deference to the States." 571 U.S. 69, 77-78 (2013) (quoting *Colorado River Water Conservation Dist.* v. *United States*, 424 U.S. 800, 817 (1976), *New Orleans Pub. Serv., Inc.* v. *Council of City of New Orleans*, 491 U.S. 350, 368 (1989)). As the Court has recognized, "[t]here are fundamental objections to any conclusion that a litigant who has properly invoked the jurisdiction of a Federal District Court to consider federal constitutional claims can be compelled, without his consent and through no fault of his own, to accept instead a state court's determination of those claims." *England* v. *La. State Bd. of Med. Exam'rs*, 375 U.S. 411, 415 (1964). In the decision below, the court of appeals contravened this established precedent by permitting private, self-interested counsel, acting in the name of the state, to violate petitioners' federal rights without meaningful federal review.

As discussed below, see pp. 6-15, *infra*, this case well demonstrates the dangers of the Ninth Circuit's overbroad application of *Younger* abstention. Not only did the court of appeals abstain from vindicating petitioners'

federal rights, but it ignored other federal interests, including those of FDA. The court's decision allows private attorneys to dictate the content of scientific speech in a way that contradicts the expert judgment of federal regulators and violates federal law.

A. The court of appeals misapplied this Court's precedent regarding *Younger* abstention, and thus foreclosed a federal judicial forum to vindicate a defendant's federal constitutional rights. In *Sprint*, the Court offered a forceful reminder of the long-standing principle that "federal courts ordinarily should entertain and resolve on the merits an action within the scope of a jurisdictional grant, and should not 'refus[e] to decide a case in deference to the States.'" 571 U.S. at 72 (quoting *New Orleans Pub. Serv.*, 491 U.S. at 368). This is because federal courts have an "obligation to hear and decide a case," and "[p]arallel state-court proceedings do not detract from that obligation." *Id.* at 77 (quoting *Colorado River Water Conservation Dist.*, 424 U.S. at 817). The Court in *Sprint* reaffirmed that, pursuant to *Younger* and its progeny, only three "exceptional circumstances * * * justify a federal court's refusal to decide a case in deference to the States": (1) intrusion into ongoing state criminal prosecutions, (2) interference with certain "quasi-criminal" civil enforcement proceedings, and (3) state civil proceedings involving orders in furtherance of state courts' judicial function. *Id.* at 77-78.

As relevant here, the Court in *Sprint* provided that the only "civil enforcement proceedings" that come within *Younger's* scope are those "'akin to a criminal prosecution' in 'important respects.'" *Sprint*, 571 U.S. at 73, 79 (citations omitted). Further, the Court provided

criteria to determine whether particular proceedings were sufficiently akin to criminal prosecution:

> Such enforcement actions are characteristically initiated to sanction the federal plaintiffs, i.e., the party challenging the state action, for some wrongful act. In cases of this genre, a state actor is routinely a party to the state proceeding and often initiates the action. Investigations are commonly involved, often culminating in the filing of a formal complaint or charges.

Id. at 79-80 (citations omitted).

Instead of examining these factors, the court below summarily decreed that "[w]hat matters for *Younger* abstention is whether the state proceeding falls within the general class of quasi-criminal enforcement actions—not whether the proceeding satisfies specific factual criteria." Pet. App. 7a. As detailed in the Petition, that approach is contrary to that of every court of appeals to consider whether to abstain in favor of ongoing civil enforcement proceedings since the *Sprint* decision. Moreover, the court's approach effectively would resuscitate the broad-based exceptions based on *Middlesex County Ethics Committee* v. *Garden State Bar Association*, 457 U.S. 423 (1982), that the Court repudiated in *Sprint*.

The court below failed to apply the factors set forth in *Sprint*, and in so doing, improperly denied federal review of petitioners' claim that the state is infringing their federal rights. The underlying case exemplifies what the Court sought to avoid by reiterating the narrow and exceptional grounds for *Younger* abstention. Applying the factors, it is evident that Hawai`i did not

"initiate" the Unfair or Deceptive Acts or Practices (UDAP) action in the traditional sense; rather, private counsel developed the claims prior to approaching the attorney general to bring the action on behalf of the state. This alone could serve as a sufficient reason to find *Younger* abstention inapplicable. While the court of appeals "s[aw] no reason why the application of *Younger* should turn on the State's choice of lawyers," Pet. App. 5a, a state actor's blessing of a suit conceived by private attorneys seeking a personal payday is a far cry from a considered determination by a state official, based on thorough investigation by the state, to initiate an enforcement action, and does not warrant the "exceptional" step of declining to exercise jurisdiction under *Younger*.

This Court has previously recognized the import of the disparate incentives motivating private counsel. In *Hughes Aircraft Co.* v. *United States ex rel. Schumer*, the Court held, in the context of the False Claims Act, that expanding the class of persons authorized to initiate suit to include private persons acting as *qui tam* relators was "not insignificant," and amounted to "a new cause of action, not just an increased likelihood that an existing cause of action will be pursued." 520 U.S. 939, 949-950 (1997). As the Court explained, "[a]s a class of plaintiffs, *qui tam* relators are different in kind than the Government. *They are motivated primarily by prospects of monetary reward rather than the public good.*" *Id.* at 949 (emphasis added). Just as the monetary incentives rendered *qui tam* relators different in kind, here, the private lawyers hired by the state pursuant to contingency-fee arrangements are different in kind for purposes of assessing whether *Younger* abstention is appropriate.

As for the second *Sprint* factor, there is no dispute that the initial "investigation" was also conducted by private lawyers, not the state. This fact confirms that, from its very origins, the lawsuit diverged in material respects from a criminal proceeding. Prosecutors typically exercise "considerable discretion in matters such as the determination of which persons should be targets of investigation, what methods of investigation should be used, what information will be sought as evidence, [and] which persons should be charged with what offenses." *Young* v. *United States ex rel. Vuitton et Fils S.A.*, 481 U.S. 787, 807 (1987). In criminal cases, "prosecutorial investigation will have been completed prior to the filing of the accusatory instrument." *Michigan* v. *Harvey*, 494 U.S. 344, 365 n.9 (1990) (citing ABA Standards for Criminal Justice 3–3.9(a), 11-43 (2d ed. 1980)). Here, by contrast, the state itself conducted no investigation or inquiry with respect to Plavix, further undermining application of *Younger*'s narrow exception to exercising federal court jurisdiction.

Finally, the alleged "wrongdoing" at issue further removes this case from the type of "quasi-criminal proceeding" to which *Younger* abstention applies. By definition, the prosecution of criminal wrongdoing involves the violation of clear standards of conduct. It is a hallmark of criminal law that "a criminal statute must give fair warning of the conduct that it makes a crime." *Bouie* v. *City of Columbia*, 378 U.S. 347, 350-351 (1964); see also *Liparota* v. *United States*, 471 U.S. 419, 427 (1985) ("[T]he rule of lenity ensures that criminal statutes will provide fair warning concerning conduct rendered illegal."); *United States* v. *Harriss*, 347 U.S. 612, 617 (1954) ("The underlying principle is that no man shall be held criminally responsible for conduct which he could not

reasonably understand to be proscribed."). The same is true of "quasi-criminal" civil penalties; courts have "long recognized that parties subject to * * * administrative sanctions are entitled to . . . clear notice of what conduct is proscribed by a regulation before being subject to monetary penalties for a particular violation." *Consol Buchanan Mining Co.* v. *Sec'y of Lab.*, 841 F.3d 642, 648-649 (4th Cir. 2016) (citation and internal quotation marks omitted), as amended (Nov. 23, 2016). If Hawai`i had provided clear advance notice to petitioners that state law mandated that their product packaging include scientifically dubious self-criticism of their product, petitioners would have been entitled to bring suit in federal court to challenge that mandate. See pp. 13-14, *infra*. Here, by contrast, petitioners are accused only of violating the highly general provisions of a state proscription against "unfair or deceptive acts or practices," which gave petitioners no notice that they were required to provide a warning in their labeling regarding a scientific hypothesis that was the subject of significant scientific debate. *Younger* recognizes the state's important sovereign interest in enforcing its criminal laws against wrongdoing without undue federal interference. Those interests are much diminished and the balance shifts in favor of federal review, however, when the law at issue is a vague civil standard that can be applied in ways that raise serious due process and First Amendment issues, as illustrated by this case.

B. Beyond its failure to follow this Court's guidance in *Sprint*, the Ninth Circuit's decision also more broadly runs counter to this Court's long-standing jurisprudence stressing the importance of a federal judicial forum to hear certain federal claims. The Court has stressed that, "[i]n order to provide a federal forum for plaintiffs who

seek to vindicate federal rights, Congress has conferred on the district courts original jurisdiction in federal-question cases—civil actions that arise under the Constitution, laws, or treaties of the United States." *Exxon Mobil Corp.* v. *Allapattah Servs., Inc.*, 545 U.S. 546, 552 (2005) (citing 28 U.S.C. 1331). And, in order to ensure that parties can fully avail themselves of that federal forum, the Court construed federal question removal to encompass as well supplemental jurisdiction over related state claims to allow "federal courts to hear the whole" case. *United Mine Workers of Am.* v. *Gibbs*, 383 U.S. 715, 725 (1966); see also *Johnson* v. *Mississippi*, 421 U.S. 213, 219 (1975) (allowing for removal of actions to federal court when a defendant cannot enforce civil rights claims in state court); cf. *Knick* v. *Township of Scott*, 139 S. Ct. 2162, 2167 (2019) (reversing precedent that made the statutory "guarantee of a federal forum ring[] hollow" where, in practice, plaintiffs were forced to litigate federal claims in state court). The decision below cuts against this Court's jurisprudence, foreclosing federal judicial review of an important claim of federal law.

1. The decision below would shield from federal review broad categories of state actions that infringe important federal rights, including under the First Amendment, that could otherwise be adjudicated in federal court. The facts of this case are emblematic. This Court has stressed that the "First Amendment requires heightened scrutiny whenever the government creates 'a regulation of speech because of disagreement with the message it conveys.'" *Sorrell* v. *IMS Health Inc.*, 564 U.S. 552, 566 (2011) (quoting *Ward* v. *Rock Against Racism*, 491 U.S. 781, 791 (1989)). Such protection is especially vital "in the fields of medicine and public health,

where information can save lives." *Ibid.* As *Sorrell* and this case both demonstrate, First Amendment interests can be undermined by a state's exercise of authority under the banner of "consumer protection" laws, and a federal forum should be available to vindicate those rights.

In the underlying state proceeding, private counsel, in the name of the State of Hawai`i, brought an action pursuant to the state's UDAP statute. The complaint alleges that petitioners should have warned consumers that the cardiovascular drug Plavix was less effective for individuals with a genetic variation more common among Asians and Pacific Islanders, and should have urged doctors to consider routine genetic testing for that variation before prescribing the drug. In 2010, FDA did require a warning on the labeling stating that Plavix had "diminished effectiveness" in individuals with the relevant genetic variation, and that tests were available to identify whether a patient possessed the relevant genetic variation. At the time, leading cardiologists and medical organizations criticized the warning as premature and unsupported, and subsequent studies by the companies and independent researchers further undercut the findings of diminished effectiveness in individuals with the genetic variation. In 2016, FDA rescinded the language from the label referring to the link between genetic traits and clinical outcomes, and subsequent evidence further indicates that Plavix is effective without regard to genetics, race, or ethnicity. See, *e.g.*, Yukio Ozaki et al., *CVIT Expert Consensus Document on Primary Percutaneous Coronary Intervention (PCI) for Acute Myocardial Infarction (AMI) in 2018*, 33 Cardiovascular Intervention & Therapeutics 178, 182-183 (2018); see also Glenn N. Levine et al., *2016 ACC/AHA*

Guideline Focused Update on Duration of Dual Antiplatelet Therapy in Patients with Coronary Artery Disease, 68 J. Am. Coll. Cardiology 1082 (2016).

Against this backdrop, private lawyers proposed, and the state's attorney general authorized in 2014, a suit against petitioners under UDAP for deceptive marketing, alleging that they should have disclosed before the 2010 labeling revision that Plavix had diminished effectiveness for patients with the relevant genetic variation, particularly for patients of Asian or Pacific Islander descent. In this fashion, the state seeks to impose liability on petitioners for refusing to make self-critical statements about their product that, petitioners contend, conflict with scientific consensus or, at a minimum, remain a disputed scientific issue. Pet. 9, 21.

The Ninth Circuit's opinion shielding this dispute from federal judicial consideration turns logic on its head. The decision makes state action that lacks any of the hallmarks of considered state policy immune from federal judicial review, while far more formalized and considered state action *would* be subject to challenge in federal court. There is no question that, had a state agency issued a regulation purporting to require petitioners to make the same scientifically dubious statements about their products as respondent seeks to mandate under UDAP, petitioners would have had a right to a federal forum in which to challenge that regulatory requirement. Indeed, federal court challenges to state mandated speech are quite common. See, *e.g.*, *Paypal, Inc.* v. *Consumer Fin. Prot. Bureau*, No. 1:19-cv-03700, 2020 WL 7773392 (D.D.C. Dec. 30, 2020) (challenge to mandated short-form disclosure of fees for digital wallets); *National Ass'n of Wheat Growers* v. *Becerra*, No.

17-cv-2401, 2020 WL 3412732 (E.D. Cal. June 22, 2020) (challenge to mandated warning labels for products that contain a particular herbicide); see also *Expressions Hair Design* v. *Schneiderman*, 137 S. Ct. 1144 (2017) (federal challenge to law requiring that price differences between cash and credit be stated in terms of cash discounts rather than credit card surcharges). The court of appeals' decision would afford greater immunity from federal court supervision to a civil claim asserted by private counsel furthering his own pecuniary interests than would be afforded to formal state regulations adopted by state officials charged with acting in the public interest. Nothing in the Constitution's federal structure or this Court's *Younger* decision requires that counterintuitive result.

2. The court of appeals' holding is particularly misguided on the facts of this case, which arises in a context of federal supremacy—regulation of the sale and marketing of pharmaceuticals. The motivating constitutional principles behind *Younger* abstention are "comity and federalism," *Huffman* v. *Pursue, Ltd.*, 420 U.S. 592, 610 (1975), and *Younger* was predicated on "proper respect for [core] functions" of state sovereignty—enforcement of state criminal law, 401 U.S. at 44. Here, however, the court of appeals applied *Younger* abstention to allow the state to encroach upon a core area of *federal* responsibility.

The decision below displaces FDA's expert judgment with that of a private lawyer and single state judge. FDA has exclusive responsibility for reviewing and approving drug labeling as well as enforcing the federal prohibition on false or misleading labeling. See 21 U.S.C. 352(a), 337(a); see also *Wyeth* v. *Levine*, 555 U.S.

555, 608 (2009) ("The FDA has underscored the importance it places on drug labels by promulgating comprehensive regulations—spanning an entire part of the Code of Federal Regulations, * * * that set forth drug manufacturers' labeling obligations."). In the drug approval context, the Court has emphasized that, "[w]here the FDA determines, in accordance with its statutory mandate, that a drug is on balance 'safe,' our conflict preemption cases prohibit any State from countermanding that determination." *Wyeth*, 555 U.S. at 609; see also *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) (after FDA has struck "a somewhat delicate balance of statutory objectives" and determined that petitioner submitted a valid application to manufacture a medical device, a state may not use common law to negate it).

Critically, here, FDA has exercised active supervision of petitioners' labeling for Plavix, but in a way that conflicts with the state's actions under review. FDA has not found that petitioners' prior labeling was false or misleading in any respect, including with regard to petitioners' pre-2010 labeling. Moreover, FDA's removal of the precise language at issue here in 2016 reflects its judgment that the warning for which the state lawsuit would impose civil liability and penalties for omitting was not warranted.

The holding below thus turns the underlying motivation for *Younger* abstention upside down. Rather than shielding a core function of state sovereignty from federal interference, the decision below would shield from federal review state interference in an area of federal preeminence.

II. There Is An Urgent Need For This Court's Review, In Light Of The Increasing Prevalence Of Largely Unsupervised Enforcement Cases Being Brought By Private Lawyers In The Name Of States

The underlying lawsuit in this case—brought by private counsel on behalf of Hawai`i under the UDAP statute—exemplifies a trend in state regulatory enforcement, and underscores why this Court's review of the question presented is urgently needed. State attorneys general are increasingly opting for contingency-fee arrangements with private counsel to bring public enforcement actions in numerous areas of consumer protection law. While a state may generally be free to authorize private counsel to sue on its behalf, that decision remains an important consideration in determining whether a particular civil enforcement proceeding is akin to a criminal prosecution that implicates *Younger* abstention under the *Sprint* factors. That is particularly so because private counsel take no oath to uphold the Constitution. While a given state official's actions may infringe on constitutional rights, those actions are generally taken in light of the official's understanding of the public interest. Private attorneys seeking personal remuneration through litigation are not similarly constrained. As a result, it is all the more likely that private counsel will pursue aggressive theories of liability without regard to defendants' First Amendment or other constitutional rights.

A. The opinion below warrants review by this Court as it broadens *Younger* abstention in a manner that creates a gaping hole in the availability of federal judicial

review at a time when such review is critical. An increasing number of state enforcement actions are being litigated by private counsel. This "new model for state-sponsored litigation that combines the prosecutorial power of the government with private lawyers aggressively pursuing litigation that could generate hundreds of millions in contingent fees" has become commonplace. Richard O. Faulk & John S. Gray, *Alchemy in the Courtroom? The Transmutation of Public Nuisance Litigation*, 2007 Mich. St. L. Rev. 941, 968 (2007); see also Martin H. Redish, *Private Contingent Fee Lawyers and Public Power: Constitutional and Political Implications*, 18 Sup. Ct. Econ. Rev. 77, 80 (2010). In recent years, the number of state enforcement actions litigated by private attorneys has skyrocketed, and has expanded into all corners of state consumer protection enforcement. See, *e.g.*, *County of Santa Clara* v. *Superior Court*, 235 P.3d 21, 25 (Cal. 2010) (using private lawyers to bring tort lawsuits against lead paint manufacturers), cert. denied, 131 S. Ct. 920 (2011); *City of Seattle* v. *Monsanto Co.*, 387 F. Supp. 3d 1141, 1165 (W.D. Wash. 2019) (using private lawyers to bring water-contamination claims); *Nessel* v. *3M Co.*, No. 20-03366-NZ (Mich. Cir. Ct. for 17th Jud. Cir. Jan. 14, 2020) (using private lawyers to sue manufacturers and users of per- and polyfluoroalkyl substances for allegedly contaminating drinking water with carcinogens); Ariel Gilreath, *Greenville County Schools to File Lawsuit Against Juul, Maker of E-Cigarettes*, Greenville News (Dec. 10, 2020), https://tinyurl.com/2npnxa36 (using contingency-fee attorneys to bring claims against the e-cigarette maker Juul for deceptive and improper marketing); *City of Oakland* v. *BP PLC*, 960 F.3d 570, 573 (9th Cir. 2020) (using contingency-fee arrangements in climate-change

lawsuits against companies in the fossil fuel industry), amended by 969 F.3d 895 (9th Cir. 2020); *State* v. *Actavis Pharma, Inc.*, 167 A.3d 1277, 1279 (N.H. 2017) (hiring private lawyers to investigate opioid manufacturers and commence lawsuits on behalf of the state), cert. denied, 138 S. Ct. 1261 (2018).

The proliferation of these lawsuits by private lawyers on behalf of states and localities has resulted in outsourcing public enforcement of state law away from public officials with subject-matter expertise and obligations to serve the public interest. In one particularly striking example, seven district attorneys in Tennessee purported to serve as plaintiffs to authorize a state court suit conceived by contingency-fee lawyers, alleging that several pharmaceutical companies' sale and marketing of prescription opioid medications to DEA-licensed wholesalers and retail pharmacies (in amounts authorized by DEA) violated the Tennessee Drug Dealer Liability Act (Drug Dealer Act), Tenn. Code Ann. § 29-38-101 to -116. See *Effler* v. *Purdue Pharma L.P.*, 614 S.W.3d 681, 684 (Tenn. 2020). Although the district attorneys purported to sue on behalf of the political subdivisions they represented, they neither provided notice to those subdivisions about the lawsuit nor sought their consent to sue. See *id.* at 683, 686, 691. Recognizing that the district attorneys were "not serving as counsel for any governmental entities, but as plaintiffs with retained counsel," the Tennessee Supreme Court held that the district attorneys lacked standing to sue under the Drug Dealer Act. *Id.* at 688-691.

B. This trend heightens the risk that private lawyers, with little to no oversight by state actors, will bring

public enforcement actions that interfere with defendants' federal rights, including their First Amendment rights.

In recent years, states and localities have hired private counsel to bring actions under state UDAP and other consumer protection laws challenging allegedly deceptive or false advertising and marketing. See *American Bankers Mgmt. Co.* v. *Heryford*, 885 F.3d 629, 632 (9th Cir. 2018) (suit against credit card servicing company); see also *Commonwealth* v. *Janssen Pharms., Inc.*, 8 A.3d 267, 268-269 (Pa. 2010) (suit against pharmaceutical company); *State ex rel. Discover Fin. Servs., Inc.* v. *Nibert*, 744 S.E.2d 625, 629 (W. Va. 2013) (suits against credit card servicing company and pharmaceutical companies). Given the First Amendment interests at stake, overreach in these lawsuits raises serious concerns. While state agencies face "legal and practical checks" that guide their enforcement discretion toward false and misleading speech that is particularly egregious and harmful, private lawyers may press the state to bring lawsuits to challenge speech based on purely financial, political, or ideological motives. See, *e.g.*, *Nike, Inc.* v. *Kasky*, 539 U.S. 654, 679-680 (2003) (Breyer, J., dissenting from dismissal of writ of certiorari as improvidently granted) (arguing that a "private false advertising action brought on behalf of the State, by one who has suffered no injury, threatens to impose a serious burden upon speech").

The number of legal or regulatory actions by states that are targeting pharmaceutical manufacturers' speech has increased dramatically in recent years. These regulatory efforts have spanned a range of subjects, including attempts to limit manufacturers' access

to information about doctors' prescribing habits, see *Sorrell*, 564 U.S. at 557; novel legal theories to target pharmaceutical marketing, see, *e.g.*, *State ex rel. Hunter* v. *Purdue Pharma L.P.*, No. CJ-2017-816, 2019 WL 9241510, at *4, *12 (Okla. Dist. Ct. Nov. 15, 2019) (applying public nuisance law to defendants' marketing); *Ortho-McNeil-Janssen Pharms. Inc.* v. *State*, No. CV-12-1058 (Ark. Mar. 20, 2014) (applying Medicaid fraud and unfair trade practices law to promotion of prescription medications); and attempts to mandate self-critical statements concerning drug prices, see, *e.g.*, *Pharmaceutical Rsch. & Mfrs. of Am.* v. *David*, No. 2:17-cv-02573, 2021 WL 22473, at *6-8 (E.D. Cal. Jan. 4, 2021) (challenging a 2017 California statute mandating manufacturer statements regarding price increases beyond a state-specified threshold).

The confluence of these trends—increased targeting by regulators of speech in the healthcare context and increased outsourcing of enforcement decisions to private, self-interested attorneys—heightens the risk that such suits by private counsel in the name of the state will impinge upon the First Amendment rights of pharmaceutical manufacturers and other defendants.

The opinion below increases the likelihood that parties seeking to vindicate their federal constitutional rights will find the doors of the federal courthouse closed to them. Before a federal court closes its doors to federal constitutional claims under *Younger* abstention, it must ensure that the underlying action implicates the sovereign interests of the state in enforcing its criminal or quasi-criminal law against wrongdoing, rather than an effort by private lawyers to commandeer the state's reg-

ulatory authority for personal gain. The court of appeals' decision, which fails to engage in that essential inquiry, warrants this Court's review and correction.

CONCLUSION

For the foregoing reasons, and those stated in the Petition, the Court should grant the writ.

Respectfully submitted,

DOUGLAS HALLWARD-DRIEMEIER
CHIMSO OKOJI
SAMUEL POKROSS
ROPES & GRAY LLP

JAMES C. STANSEL
MELISSA B. KIMMEL
PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA

TARA S. MORRISSEY
JENNIFER B. DICKEY
U.S. CHAMBER LITIGATION CENTER

MARCH 2021