No. 20-1149

In The

Supreme Court of the United States

BRISTOL-MYERS SQUIBB CO., SANOFI-AVENTIS U.S. LLC, SANOFI US SERVICES INC., FKA SANOFIAVENTIS U.S. INC., AND SANOFI-SYNTHELABO LLC,

Petitioners,

v.

CLARE E. CONNORS, IN HER OFFICIAL CAPACITY AS THE ATTORNEY GENERAL OF THE STATE OF HAWAII,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* SUPPORTING PETITIONERS

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QUESTION PRESENTED

Whether federal courts must abstain from hearing any federal case when there is a parallel civil consumer-protection action pending in state court.

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INTRODUCTION AND INTEREST OF *AMICUS CURIAE*[*]

State consumer-protection lawsuits have morphed in recent years. Consumers formerly sued to vindicate their rights under these statutes. Then state attorneys general began taking the lead and suing as *parens patriae* to protect consumers.

Now, however, law firms without clients enforce state consumer-protection laws. The law firms approach attorneys general with a win-win proposal. Permit the firm to pursue *parens patriae* suits for a large cut of any recovery. The attorney general bears no litigation risk. But he or she gets the political accolades if the firm recovers.

The Ninth Circuit held that these lawsuits by contingency-fee attorneys are like criminal prosecutions. Yet they do not resemble criminal cases; they are closer to extortion. This decision allows politically vulnerable state court judges to impose nine figure liability for companies exercising their First Amendment rights.

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It often appears as *amicus* in cases to defend the right to a federal forum. *See, e.g.*,

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[*] No party's counsel authored any part of this brief. No person or entity, other than Washington Legal Foundation and its counsel, paid for the brief's preparation or submission. After timely notice, all parties consented to WLF's filing this brief.

BP plc v. Mayor and City Council of Baltimore, No. 19-1189 (U.S. brief filed Nov. 23, 2020); *Latiolais v. Huntington Ingalls, Inc.*, 951 F.3d 286 (5th Cir. 2020) (*en banc*). It also appears as *amicus* in compelled-speech cases. *See, e.g.*, *United States v. United Foods, Inc.*, 533 U.S. 405 (2001); *Pac. Gas & Elec. Co. v. Pub. Utilities Comm'n of Cal.*, 475 U.S. 1 (1986).

It's no surprise that the Ninth Circuit's decision split from eight courts of appeals. The decision denies Petitioners their right to a federal forum. Making abstention under *Younger v. Harris*, 401 U.S. 37 (1971) the norm—rather than the exception—disobeys the Court's command in *Sprint Commc'ns, Inc. v. Jacobs*, 571 U.S. 69 (2013). The Court should grant the petition and remind the Ninth Circuit, again, that this Court's decisions are binding.

STATEMENT

I. *YOUNGER* ABSTENTION DOCTRINE

The *Younger* abstention doctrine is only fifty years old. In *Younger*, a state criminal defendant asked a federal court to invalidate the criminal statute under which he was charged. The Court held that the federal court must abstain from deciding the case absent bad faith, harassment, or a "patently" invalid state statute. *Younger*, 401 U.S. at 53-54 (quotation omitted). This holding tracked "the basic doctrine of equity jurisprudence that courts of equity should not act * * * to restrain a criminal prosecution, when the moving party has an adequate remedy at law and will not suffer irreparably injury if denied equitable relief." *Id.* at 43-44.

The Court described some benefits of abstention. For example, "restraining equity jurisdiction within narrow limits" helps "avoid a duplication of legal proceedings and legal sanctions." *Younger*, 401 U.S. at 44. It also promotes comity between state and federal courts. *Id.*

Later, the Court extended *Younger* to cases "in aid of and closely related to [a State's] criminal statutes." *Huffman v. Pursue, Ltd.*, 420 U.S. 592, 604 (1975). Abstention is also necessary in proceedings vindicating "the authority of the judicial system, so that its orders and judgments are not" futile. *Juidice v. Vail*, 430 U.S. 327, 336 n.12 (1977) (citation omitted).

Lower courts soon viewed *Younger* abstention as an easy way to avoid deciding hard cases. But the Court reaffirmed "the rule that only exceptional circumstances justify a federal court's refusal to decide a case in deference to the States." *New Orleans Pub. Serv., Inc. v. Council of City of New Orleans*, 491 U.S. 350, 368 (1989) (citations omitted).

In its most recent *Younger* decision, this Court limited *Younger* abstention in civil-enforcement proceedings to "state proceedings 'akin to a criminal prosecution' in 'important respects.'" *Sprint*, 571 U.S. at 79 (quoting *Huffman*, 420 U.S. at 604). Eight courts of appeals have read *Sprint* to require a case-specific analysis when deciding whether to abstain under *Younger*. *See* Pet. 22-28.

II. FACTS AND PROCEDURAL HISTORY

In 1997, the Food and Drug Administration approved Plavix to help prevent heart attacks and strokes. Scientists later learned that some people with a genetic variation had trouble metabolizing Plavix. It was unclear whether this could lead to a higher risk of a stroke or heart attack.

So in 2010, the FDA required Petitioners to add a warning to Plavix's label. The warning advised doctors that those with the genetic variation had trouble metabolizing Plavix which could lead to an increased risk of stroke or heart attack. It also noted that tests were available to see if a patient had the genetic variation.

But scientists continued researching whether Plavix increased the risk of heart attacks and strokes for those with the genetic variation. The new evidence was inconclusive as to whether those with trouble metabolizing Plavix face an increased risk of heart attack or stroke. In 2016, the FDA therefore removed the cardiovascular-risk warning.

Consistent with the latest medical evidence, Hawaii never received a complaint about Plavix. That, however, did not stop Respondent's over-zealous counsel from making Respondent an offer she could not refuse. They offered to sue Petitioners for failing to warn of Plavix's non-existent risk to patients with the genetic variation. Respondent would not bear any of the litigation risks. Rather, she would see only the upside if her counsel prevailed. In return, Respondent's counsel simply wanted a cut of

any recovery. After the unconscionable verdict, that amounts to more than $100 million.

Knowing that a state-court judge would not give them a fair shake, Petitioners sought a declaratory judgment in federal court. But the District Court abstained from hearing the case under *Younger*. Embracing a rule rejected by every other court of appeals to apply *Younger* after *Sprint*, the Ninth Circuit then affirmed. Petitioners now ask this Court to set the record straight and affirm their right to a federal forum.

SUMMARY OF ARGUMENT

I.A. This case presents an important, reoccurring question about applying *Younger*. The rise of contingency-fee counsel enforcing state consumer protection laws is troubling. These attorneys face no political consequences for their decisions and do not advance the public interest. Rather, they seek to pad their bank accounts. Attorneys general embrace these lawsuits because it helps them politically as they receive political contributions and positive press.

B. This Court's recent decisions are clear: *Younger* abstention is appropriate in civil cases only when they are like criminal proceedings. Civil cases filed by contingency-fee counsel are nothing like criminal proceedings. Thus, federal courts should not employ *Younger* abstention when contingency-fee counsel represents an attorney general proceeding as *parens patriae*.

II. This case is important for a second reason. The First Amendment protects the right to speak and the right not to speak. This protection extends to both natural persons and legal entities. Applying Hawaii's unfair and deceptive acts and practices (UDAP) statute here is a content-based regulation. It therefore is presumptively invalid.

A. Petitioners' speech is entitled to First Amendment protection. Statements that track experts' recommendations are not misleading. Similarly, taking a position that the FDA has adopted cannot be misleading. Yet the state court refused to acknowledge that the First Amendment protected Petitioners' speech.

B. Any court reviewing Petitioners' First Amendment argument should apply strict scrutiny. Prescription-drug labels are not commercial speech. If a content-based restriction on non-commercial speech cannot satisfy strict scrutiny, it is unconstitutional.

C. As applied, Hawaii's UDAP statute fails strict scrutiny. It is not narrowly tailored to advance a compelling state interest. Nor does it use the least restrictive means necessary to advance its stated purpose. Any neutral court would therefore grant Petitioners relief on their First Amendment claim.

D. Even if a court applied intermediate scrutiny instead of strict scrutiny, Petitioners would have a right to relief. Compelling drug makers to recite highly misleading and controversial speech cannot advance a substantial governmental interest. Even if it could, Hawaii's restriction here is not narrowly tailored to advance that interest.

ARGUMENT

I. *YOUNGER* DOES NOT APPLY TO LITIGATION BROUGHT BY CONTINGENCY-FEE COUNSEL.

This case raises an important question about the scope of *Younger* abstention. Recently, there has been an explosion of UDAP claims brought by contingency-fee counsel for state attorneys general. This increase in contingency-fee-fueled UDAP litigation has led to a proportional increase in as-applied constitutional challenges in federal courts. Proper application of *Younger* is critical to ensure that federal courts hear cases over which they have jurisdiction.

The Ninth Circuit's decision strays far from this Court's precedent. *Younger* abstention is limited to "particular state civil proceedings that are akin to criminal prosecutions." *Sprint*, 571 U.S. at 72 (citing *Huffman*, 420 U.S. 592). Any case that a private contingency-fee attorney pursues does not resemble a criminal prosecution. Respondent's claims, therefore, cannot prompt abstention under *Younger*.

A. Contingency-Fee Counsel Now Dominate State UDAP Litigation.

Proponents justify contingency-fee arrangements because they grant access to justice for those who cannot afford an attorney. *See* John C. Coffee, Jr., *Class Wars: The Dilemma of the Mass Tort Class Action*, 95 Colum. L. Rev. 1343, 1351 (1995). But this "cannot explain why AGs would choose to hire outside" contingency-fee counsel. David A. Dana, *Public Interest and Private Lawyers: Toward a*

Normative Evaluation of Parens Patriae Litigation by Contingency Fee, 51 DePaul L. Rev. 315, 317 (2001).

So why do attorneys general use contingency-fee lawyers? The answer is simple. They stand to gain political capital (and possibly money for their offices) if a lawsuit succeeds while bearing none of the litigation's risk. What's more, attorneys general can accumulate campaign contributions from hiring contingency-fee attorneys.

"In most jurisdictions, attorneys general have unfettered discretion to dole out these lucrative arrangements." John Beisner, *et al.*, *Bounty Hunters On The Prowl: The Troubling Alliance Of State Attorneys General and Plaintiffs' Lawyers*, 2 (May 25, 2005), https://bit.ly/3veHwzP. This means that attorneys general can award contingency-fee contracts as political favors to their donors. *Id.* In other words, "some plaintiffs' attorneys have used their relationships with state attorneys general as a litigious cash cow." John O'Brien, *AGs in six states put under microscope in ATRA report*, Legal Newsline (Dec. 2, 2010), https://bit.ly/3qlwTaz (cleaned up).

A recent high-profile example shows how state attorneys general award contingency fees as political spoils. Last year, South Carolina received a $600 million settlement over plutonium. *See* Joseph Cranney, *Columbia law firms can keep $75 million state payout for giant nuclear waste settlement*, Charleston Post & Courier (Nov. 10, 2020), https://bit.ly/3bmEilA. The attorney general agreed to give his contingency-fee counsel 12.5% of that settlement—a whopping $75 million. *See id.*

South Carolina's governor soon denounced the attorneys' fee award. *See* Cranney, *supra*. So did ethics groups. *See id.* The groups noted that one of the two law firms that received the money was the attorney general's former firm. In short, the attorney general awarded his former firm with an unconscionably high payment. This was political spoils at its finest.

The plaintiffs' bar is also eager to enter into these deals. Contingency-fee agreements "allow[] private attorneys to capitalize on the government's existing access to the system and privileged status in order to expand their business and enrich themselves." U.S. Chamber Institute for Legal Reform, *Big Bucks and Local Lawyers: The Increasing Use of Contingency Fee Lawyers by Local Governments*, 7 (Oct. 2016), https://bit.ly/30fNulB.

While a consumer must prove injury, under many state UDAP statutes, the attorney general need not show any injury to recover. *Compare White v. Wyeth*, 705 S.E.2d 828, 835 (W. Va. 2010) (requiring consumers to prove injury) *with* W. Va. Code § 46A-7-111(2) (injury not required when suit brought by attorney general). So the contingency-fee attorneys may proceed under a lower burden of proof. They can also pursue civil penalties for any statutory violation statewide. This greatly expands the potential recovery—and attorneys' fee award.

This background explains why, over the past two decades, "private plaintiffs' lawyers have succeeded in persuading state attorneys general to retain them under contingency fee arrangements to bring purported enforcement actions in the

attorney[s] generals' stead." Beisner, *supra* at 1. The agreements are mutually beneficial for both parties. The losers, however, are clear: the public, the State, and the business community.

B. Suits By Contingency-Fee Counsel Are Not Like Criminal Prosecutions.

Criminal prosecutions do not resemble suits like the one Respondent filed in Hawaii state court. Those suits thus cannot justify *Younger* abstention. *See Sprint*, 571 U.S. at 72 (citation omitted); *cf. Mata v. Lynch*, 576 U.S. 143, 150 (2015) ("when a federal court has jurisdiction, it also has a virtually unflagging obligation to exercise that authority" (cleaned up)).

1. The first major distinction between a criminal case and a suit by contingency-fee counsel is neutrality. As this Court has explained, prosecutors do not represent "an ordinary party to a controversy." *Berger v. United States*, 295 U.S. 78, 88 (1935). Rather, they represent "a sovereignty whose obligation to govern impartially is as compelling as its obligation to govern at all; and whose interest, therefore, in a criminal prosecution is not that it shall win a case, but that justice shall be done." *Id.* In other words, "the attorney general has a 'special and enduring duty to seek justice,' a duty that entails more than serving as an advocate for the state." Leah Godesky, *State Attorneys General and Contingency Fee Arrangements: An Affront to the Neutrality Doctrine?*, 42 Colum. J.L. & Soc. Probs. 587, 607 (2009) (quoting *State v. Lead Indus. Ass'n*, 951 A.2d 428, 471 (R.I. 2008)).

Private attorneys, on the other hand, have no duty of neutrality. Andrew Thornton, *The State's Retention of Outside Counsel on Contingency to Prosecute Environmental Laws: Two Common Objections*, 10/19/2015 Geo. Envtl. L. Rev. Online 1 (2015). They are therefore free to pursue their own goal—raking in fees.

So "[t]he interests of contingency-fee litigators and a State government may not fully align." Erin Hawley, *Public Power, Private Gain: Issues In Third-Party Litigation Finance*, (Mar. 21, 2019), https://bit.ly/3ebQ2tf. While States "might prefer a settlement that specifies certain actions that will or will not be taken by the defendant," "[c]ontingency fee litigators are after" monetary recoveries. *Id.*

Several courts have recognized that "[i]t is not consistent with the public interest that a prosecuting officer may receive personal gain as the result either of the conviction or acquittal of one charged." *State v. Hambrick*, 196 P.2d 661, 667 (Wyo. 1948) (quoting *Callahan v. Jones*, 93 P.2d 326, 330 (Wash. 1939)). These cases flowed naturally from the Court's decision in *Tumey v. Ohio*, 273 U.S. 510 (1927). There, the Court held that a defendant was entitled to a judge who received no compensation for a conviction. *Id.* at 523.

Respondent, however, paid her counsel based on the results of this case. The same is true of other contingency-fee lawsuits under state UDAP laws. This is a personal gain. And prosecutors cannot receive a personal gain in a criminal case. The stark difference in attorneys' pay distinguishes cases like this one from criminal prosecutions.

This case also shows why "oversight" by the attorney general cannot ensure neutrality. Neither Respondent nor anyone in her office signed any filing in state court. Nor did she appear as counsel at a single hearing or argument in the case. How can the attorney general ensure neutrality through oversight if she does not enter an appearance in the case?

The answer is simple; she cannot exercise meaningful control. Rather, contingency-fee counsel make the important calls without input from Respondent or her staff. This lack of meaningful oversight eliminates even the appearance of neutrality.

This lack of oversight is not unique to Hawaii. One case out of New Jersey shows that this practice is common. There, a state trial court found that New Jersey's contingency-fee-counsel agreement was invalid because of a lack of oversight by the attorney general. Douglas F. McMeyer, *et al.*, Husch Blackwell, *Contingency Fee Plaintiffs' Counsel and the Public Good?*, 9, https://bit.ly/3ryTYYC (citing *N.J. Soc. for Env't v. Cambell*, No. MERL-343-04). This example shows that when trial courts seriously examine these arrangements, they learn that the attorney general is not meaningfully overseeing contingency-fee counsel. The lack of neutrality by contingency-fee attorneys therefore weighs heavily against applying *Younger* in contingency-fee cases.

2. The second way these suits differ from criminal actions is that defendants can face sequential lawsuits for the same conduct in the same jurisdiction. A sovereign government is the only one that can bring criminal charges. *Cf. Trainor v.*

Hernandez, 431 U.S. 434, 444 (1977) (applying *Younger* in civil proceeding "brought by the State in its sovereign capacity"). A private citizen normally cannot indict a defendant and then prosecute the case. Rather, neutral prosecutors litigate criminal cases.

When a criminal case brought by the sovereign ends, jeopardy attaches and the Sixth Amendment bars future charges. But for consumer-protection actions brought by an attorney general, no such preclusive effect attaches in some jurisdictions. Both the attorney general—through contingency-fee counsel—and consumers can still bring separate lawsuits for the same conduct.

West Virginia is a good example. Under West Virginia Code § 46A-7-111(2), the Attorney General may sue for willfully violating the State's UDAP law. But under West Virginia Code § 46A-7-113, a consumer can also sue under West Virginia Code § 46A-6-106. Unsurprisingly, this has caused problems for companies doing business in West Virginia.

Many plaintiffs have sued under West Virginia's UDAP statute for deceptively advertising pelvic mesh. *See*, *e.g.*, *Mullins v. Ethicon, Inc.*, 2017 WL 345865, *3 (S.D.W. Va. Jan. 20, 2017). Yet the attorney general pursued claims—through contingency-fee counsel—for the same conduct. *See State ex rel. Morrisey v. Johnson & Johnson*, No. 19-C-286 (Cir. Ct. Monongalia Cnty. W. Va.).

This means that defendants had to defend against these claims twice. The second time, when the

attorney general sued using contingency-fee counsel, they threw in the towel and settled. This would never happen in a criminal case. Once the claims were dismissed, the claims would be extinguished. But the contingency-fee case continued precisely because it did *not* resemble a criminal case.

The Ninth Circuit, however, glossed over this key difference between contingency-fee cases and criminal cases. It ignored the ability of consumers and attorney general to recover under UDAP statutes for the same conduct. Rather, it reached for a rule that shielded it from deciding many cases.

3. The third way that cases brought by contingency-fee counsel differ from criminal cases is that there is no right to a jury trial. The Sixth Amendment—as incorporated against the States by the Fourteenth Amendment—gives criminal defendants in state courts the right to a jury trial. *Duncan v. Louisiana*, 391 U.S. 145, 148-50 (1968). But the Seventh Amendment has not been similarly incorporated against the States. *Minneapolis & St. Louis R. Co. v. Bombolis*, 241 U.S. 211, 216-23 (1916).

Many States deny defendants the right to a jury trial in UDAP suits. *See, e.g.*, *Fazio v. Guardian Life Ins. Co. of Am.*, 62 A.3d 396, 402 (Pa. Super. 2012); *State ex rel. Douglas v. Schroeder*, 384 N.W.2d 626, 629 (Neb. 1986). This means that a single state-court judge—who is amenable to political pressure—can impose massive liability. That, of course, is what happened here.

The "right to a jury trial is fundamental to the American scheme of justice." *Ramos v. Louisiana*, 140

S. Ct. 1390, 1397 (2020) (cleaned up). Defendants, however, are often denied this right in UDAP cases. These suits by contingency-fee counsel thus are nothing like criminal cases.

* * *

There are few similarities between an UDAP suit filed by contingency-fee counsel and a criminal case brought by a sovereign. The Ninth Circuit's decision "would extend *Younger* to virtually all parallel state and federal proceedings, at least where a party could identify a plausibly important state interest." *Sprint* 571 U.S. at 81 (citation omitted). This case thus falls well short of the test this Court articulated for applying *Younger* abstention. *See id.* at 79. This important, reoccurring issue deserves the Court's attention.

II. PETITIONERS ARE ENTITLED TO RELIEF ON THEIR FIRST AMENDMENT CLAIM.

This case is also important for another reason. The state court essentially ignored Petitioners' First Amendment argument. It just copied and pasted one paragraph of Respondent's proposed conclusions of law when rejecting Petitioners' argument. *See* Pet. App. 107a-108a.

The lack of analysis by a state-court judge shows why an Article III judge should decide the issue. A jurist not facing political pressure could faithfully apply this Court's free-speech precedent when deciding whether Hawaii may compel Petitioners to repeat controversial speech. Allowing the Ninth Circuit's decision to stand, however, would

invite state-court judges to ignore serious First Amendment concerns in the name of political expediency.

A. Petitioners' Speech Is Protected By The First Amendment.

The First Amendment—as incorporated against the States by the Fourteenth Amendment—protects both freedom of speech and the freedom not to speak. *See Wooley v. Maynard*, 430 U.S. 705, 713-15 (1977); *W. Va. Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943). And this protection is not limited to natural persons. The First Amendment also protects businesses. *See generally Citizens United v. FEC*, 558 U.S. 310 (2010).

The state court's First Amendment "analysis" is lacking. In a single paragraph that it did not draft, the state court glossed over Petitioners' First Amendment argument. Pet. App. 107a-108a. This shows that federal intervention is necessary to ensure fair adjudication of Petitioners' arguments.

The First Amendment does not protect commercial speech that is misleading or that encourages illegal behavior. *Greater New Orleans Broad. Ass'n, Inc. v. United States*, 527 U.S. 173, 183 (1999) (citation omitted). The state court apparently held that Plavix's label was misleading and thus not entitled to First Amendment protection. *See* Pet. App. 107a-108a. If left to stand, the Ninth Circuit's decision means that Hawaii can ignore the First Amendment.

Contrary to the state court's holding, the speech Respondent seeks to compel is misleading. There is nothing about Petitioners' silence on Plavix's alleged risks that misleads doctors or the public. The label does not claim that all individuals with the genetic variation can metabolize Plavix as well as those without the genetic variation. Nor does the label suggest that those of a specific race with high rates of the genetic variation show better clinical outcomes than others.

If the label made one of those claims, then Respondent could argue that the label was misleading. But that is not the theory that Respondent's for-hire counsel concocted. The complaint alleged—and the state court found—that the label was misleading because it failed to disclose a non-existent risk.

When the FDA first required the warning, a leading cardiologist said that it "warn[ed] people about a harm that ha[d] yet to be established." Pet. App. 40a (quoting Larry Husten, *Plavix Label Gets Black Box Warning About Poor Metabolizers*, Cardio Brief (Mar. 12, 2010), https://bit.ly/3kknr5X). The American College of Cardiology and American Heart Association similarly thought that the warning was premature. *See id.* at 41a (citing David R. Holmes Jr. *et al.*, *ACCF/AHA Clopidogrel Clinical Alert: Approaches to the FDA "Boxed Warning": A Report of the American College of Cardiology Foundation Task Force on Clinical Expert Consensus Documents and the American Heart Association*, 56 J. Am. C. Cardiology 321, 334 (2010)).

Scientific research on the issue continued after the FDA added the warning to Plavix's label. The evidence showed no increased risk of stroke or heart attack for those with the genetic variation. *See* Stephan Fihn *et al.*, *2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease*, 60 J. Am. College of Cardiology e44, e95-e96 (2012); *see generally* Adnan M. Bhopalwala, *et al.*, *Routine screening for CYP2C19 polymorphisms for patients being treated with clopidogrel is not recommended*, 74 Haw. J. Med. & Pub. Health 16 (2015).

These additional findings—combined with the lack of any reliable scientific evidence supporting the state court's finding—led the FDA to remove the cardiovascular-risk warning from Plavix's label. So if Petitioners' failure to include a warning was misleading, then the FDA misled consumers by removing the cardiovascular-risk warning from the label. This, of course, is absurd. Just as there was nothing misleading about the FDA's actions, there was nothing misleading about Petitioners' decision not to include a warning. Thus, Petitioners' speech is entitled to First Amendment protection.

B. Courts Should Apply Strict Scrutiny When Analyzing Petitioners' First Amendment Arguments.

As with individual speech, courts evaluate corporate speech under different standards depending on the context. Generally, content-based restrictions "are presumptively unconstitutional and may be justified only if the government proves that

they are narrowly tailored to serve compelling state interests." *Reed v. Town of Gilbert*, 576 U.S. 155, 163 (2015) (citations omitted). This test is better known as strict scrutiny.

Although strict scrutiny normally applies to content-based speech restrictions, sometimes a lesser version of scrutiny applies. Relevant here, "commercial speech" regulations are "subject to" at least the scrutiny "outlined in *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980)." *Matal v. Tam*, 137 S. Ct. 1744, 1763-64 (2017).

Hawaii's restriction on Petitioners' speech must satisfy strict scrutiny. *Central Hudson* applies only when a speaker "propose[s] a commercial transaction." *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 760 (1976).

The state court ordered Petitioners to pay $834 million because it did not parrot the State's speech on Plavix labels. For at least two reasons, prescription-label warnings are not commercial speech.

First, anyone who has received a prescription understands how labels work. Warning labels are intended for prescribing physicians, not consumers. In any event, consumers do not review the labels before purchasing prescriptions. Rather, when they receive a prescription the label and associated warnings are in the bag. Consumers do not stand at the pharmacy counter and read the label before purchasing the drug. The warnings therefore do not

propose a transaction between a drug maker and a consumer.

Second, the FDA prohibits prescription-drug labels from being "promotional." 21 C.F.R. § 201.56(a)(2). This means that a label cannot be a "commercial advertisement for the sale of goods and services." *U.S. Healthcare, Inc. v. Blue Cross of Greater Phila.*, 898 F.2d 914, 933 (3d Cir. 1990) (citations omitted). If it were such a commercial advertisement, it would be promotional and therefore barred by federal law.

There is thus no serious argument about which standard applies here. Hawaii's UDAP statute—as applied to Petitioners—must pass strict scrutiny. It falls woefully short of that demanding standard.

C. As Applied, Hawaii's UDAP Statute Does Not Satisfy Strict Scrutiny.

As applied, Hawaii's statute is not narrowly tailored to advance a compelling governmental interest. Nor is it the least restrictive means of advancing Hawaii's interest. So it flunks strict scrutiny.

1. Hawaii's UDAP statute is not narrowly tailored to advance a compelling governmental interest. Hawaii has an interest in protecting the health and safety of Hawaiians. But the statute is not narrowly tailored to advance this interest.

This Court's decision in *Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018) shows why. There, California sought "to educate low-

income women about the services it provides." *Id.* at 2375. It did so by compelling private entities to speak the State's preferred message. This Court rejected that argument because the compelled speech was "wildly underinclusive." *Id.* (quoting *Brown v. Entm't Merchants Ass'n*, 564 U.S. 786, 802 (2011)).

The Court then described a laundry list of clinics who were exempt from the compelled speech. *See NIFLA*, 138 S. Ct. at 2375-76. Here, there is a similar laundry list of ways that Hawaii could have educated consumers about Plavix's alleged risks. For example, it could have required pharmacists to ask customers prescribed Plavix if they had genetic testing. If the answer were no, Hawaii could then have required a face-to-face warning from the pharmacist.

Hawaii could have also countered the alleged risk on the front end. It could have forced doctors to warn their patients of Plavix's alleged risks before prescribing it. The State could have also required a waiver by patients who did not receive the genetic testing or those who had the genetic variation.

But it did none of those things. Rather, it compelled only Petitioners to repeat the controversial views espoused by Respondent. This singling out of one company shows that Hawaii's UDAP statute is not narrowly tailored to advance a compelling governmental interest.

2. Hawaii's UDAP statute is also not the least restrictive means of advancing its interest. The State could have achieved its goals by speaking for itself. It

chose not to do so. The reason is simple: Hawaii knew that taking Plavix saved its residents' lives.

Hawaii Medicaid regularly sends advisories to doctors and other medical professionals. *See* Pet. 7. These advisories can take any form because it is the State itself that is speaking. Nothing prevented Hawaii Medicaid from advising doctors about Plavix's alleged risk for those with the genetic variation.

Yet from the time that the FDA approved Plavix until now, Hawaii Medicaid did not send a single warning about Plavix's safety. Sending out such a warning would have advanced Hawaii's stated interest. But it would have done so without compelling Petitioners to espouse the State's views.

Speech by the State would be a less-restrictive alternative to compelling Petitioners' speech. Respondent's failure to acknowledge this alternative—much less explain why it would not work—again reveals what everyone knew. There was no chance that the state court would seriously consider Petitioners' First Amendment arguments. Because had it analyzed the arguments, the state court would have found that Hawaii's UDAP statute violated the First Amendment as applied to Petitioners.

D. Hawaii's UDAP Statute Also Cannot Satisfy The *Central Hudson* Test Here.

Even if a court applies only intermediate scrutiny, Petitioners would prevail. Under *Central Hudson*, the government may regulate commercial

speech that is neither inherently misleading nor related to an unlawful activity only if the regulation (1) is narrowly tailored (2) to directly advance (3) a substantial governmental interest. *Central Hudson*, 447 U.S. at 566. Hawaii's regulating Petitioners' speech neither advances a substantial governmental interest nor is it narrowly tailored.

1. The government never has a legitimate reason to force companies to deliver misleading information about their products. *See Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 967 (9th Cir. 2009), *aff'd sub nom.*, *Brown*, 564 U.S. 786. In other words, a compelled disclosure fails First Amendment scrutiny if it "could be misinterpreted by consumers." *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1216 (D.C. Cir. 2012), *overruled on other grounds, Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18 (D.C. Cir. 2014) (*en banc*). Thus, nothing in the First Amendment would allow Hawaii to force a pharmaceutical company to parrot Respondent's views.

Respondent may not require pharmaceutical companies to spread her viewpoint, particularly "where the messages themselves are biased against or are expressly contrary to the corporation's views." *Pac. Gas*, 475 U.S. at 16 n.12. Rather, when "divergent views" exist on an issue of public debate, "'the general rule is that the speaker and the audience, *not the government*, assess the value of the information.'" *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 578-79 (2011) (quoting *Edenfield v. Fane*, 507 U.S. 761, 767 (1993) (emphasis added)).

"If the disclaimer creates confusion, rather than eliminating it, the only possible constitutional justification for [the] speech regulation is defeated." *Borgner v. Fla. Bd. of Dentistry*, 537 U.S. 1080, 1080 (2002) (Thomas, J., dissenting from denial of certiorari). Here, the value of Hawaii's highly misleading and controversial compelled speech is zero.

The compelled speech here is also not "purely factual and uncontroversial." *NIFLA*, 138 S. Ct. at 2372 (quotation omitted). The government may sometimes compel purely factual and uncontroversial speech to correct misleading commercial speech. But because the mandated speech here is neither factual nor uncontroversial, *Central Hudson*'s normal analysis applies.

Hawaii's controversial warning itself thus constitutes a significant constitutional harm. States cannot transform a First Amendment test created to correct false or misleading speech into a justification for pushing false or misleading speech onto the public. But that is precisely what the Ninth Circuit has let Hawaii do.

2. Even if Hawaii's UDAP statute advanced a substantial governmental interest, it is not narrowly tailored. The warning that Respondent advocates is overbroad. It includes truthful information about how those with a genetic variation metabolize Plavix. The warning also correctly notes that testing for the genetic variation is available. If the required warning stopped there, Petitioners' argument would be weaker.

But Hawaii went much further than that. The warning advised doctors to consider alternative treatments for those with the genetic variation because of a higher cardiovascular risk. This information goes well beyond what is necessary to advance Hawaii's substantial governmental interest.

Doctors should be the ones that consider the competing scientific evidence about any alleged risk to those with the genetic variation taking Plavix. There was compelling scientific evidence showing that those communities most susceptible to the genetic variation—Asians—saw better clinical results after taking Plavix. *See* Pet. App. 42a & n.17 (citations omitted). A blanket warning that those with the genetic variation face an increased risk of cardiovascular problems is therefore not narrowly tailored.

* * *

Petitioners' First Amendment claims are not meritless. Rather, any fair assessment would confirm that applying Hawaii's UDAP statute here violates the First Amendment. But a state-court judge did not even analyze the First Amendment argument. An Article III judge should review the claim and decide the case based on this Court's precedent rather than political pressure.

CONCLUSION

This Court should grant the petition.

Respectfully submitted,

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