No. 26-457

In the

Supreme Court of the United States

NOVARTIS PHARMACEUTICALS CORPORATION,

Petitioner,

v.

LYNN FITCH, Attorney General of Mississippi,

Respondent.

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

BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE SUPPORTING PETITIONER

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QUESTION PRESENTED

Whether state laws that impose different and more expansive program terms on drug manufacturers who participate in the federal 340B Program violate the Supremacy Clause.

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INTEREST OF AMICUS CURIAE*

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 curiae in cases involving the 340B Drug Pricing Program, urging adherence to Congress's statutory framework. *See, e.g., Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136 (8th Cir. 2024); *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696 (3d Cir. 2023). WLF also appears as amicus curiae in cases involving the Constitution's limits on state interference with federal policies and operations. *See, e.g., Suncor Energy v. Comm'rs of Boulder Cnty.*, No. 25-170 (filed May 21, 2026); *Charter Consol. Ltd. v. Cape Intermediate Hldgs. Ltd.*, No. 26-328 (filed Oct. 13, 2026).

This case epitomizes both concerns. It asks whether a State may impose its own special burdens on drug manufacturers based solely on their participation in the federal 340B program. Because that question profoundly affects both federal supremacy and federal healthcare policy, the Court should grant review.

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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. Counsel for all parties were timely noticed of WLF's intent to file this brief.

INTRODUCTION

This case raises an exceptionally important question about whether the States may reshape a federal program by targeting and burdening the very entities that help to carry it out. Mississippi's H.B. 728 singles out and burdens only drug manufacturers that agree to participate in the federal 340B program. By doing that, it conflicts with the Supremacy Clause's bar against States interfering with a federal operation. And by forbidding what federal law permits, H.B. 728 overrides federal policy judgments, expands manufacturers' federal obligations, and shifts billions in costs throughout the federal healthcare system. This Court should grant review to stop the States from advancing local interests at the expense of federal program participants.

To participate in Medicaid and Medicare Part B, drug manufacturers must participate in 340B by entering into Pharmaceutical Pricing Agreements with the Department of Health & Human Services. Under the PPAs, manufacturers must offer steep discounts on drugs to qualifying healthcare providers known as "covered entities." 42 U.S.C. § 256b(a); 42 U.S.C. § 1396r-8(a)(1). Around 340B's start in 1992, roughly 1,000 covered entities participated in the program. *See* Karen Mulligan, *The 340B Drug Pricing Program: Background, Ongoing Challenges, and Recent Developments*, at 5 (USC Schaeffer Ctr. For Health Pol'y & Econ., White Paper Oct. 2021), https://tinyurl.com/mpdbv2ec. But the program has since evolved far beyond the modest safety-net operation that Congress had originally intended. *See* Aiden Lee et al., *Mission vs. Margin: Misaligned Incentives in the 340B Drug Pricing Program*, at 1

(Off. of the Assistant Sec'y for Plan. & Evaluation, HHS Oct. 2026), https://tinyurl.com/3mznswz6.

Indeed, despite Congress's expectation that covered entities would use 340B discounts to help "low-income" patients, H.R. Rep. No. 102-384, pt. 2, at 10 (1992), today they regularly buy drugs at the 340B price, bill insurers or patients at full price, and then pocket the difference. Such "spread pricing" isn't prohibited by the text of the 340B statute, but its widespread use has prompted some courts to conclude that 340B has transformed from a program designed to help needy patients into a "windfall for hospital[s]." *See, e.g., AbbVie Inc. v. Wrigley*, 832 F. Supp. 3d 920, 928-29 (D.N.D. 2026), appeal docketed, No. 26-1863 (8th Cir. May 5, 2026).

The numbers tell that story. Today, 340B spans nearly 60,000 covered entity sites. *See* U.S. Gov't Acct. Office, *340B Drug Discount Program*, GAO-26-108784, at 5 (Oct. 23, 2025). In 2025 alone, 340B purchases exceeded $100 billion and generated over $140 billion in spread-pricing revenue for covered entities. *See* Eleanor Blalock & Carlee Launsbach, *The Size of the 340B Program: Patient and Payer Spending on Drugs Purchased Through the 340B Program Reached $244 Billion in 2025*, at 2 (BRG Oct. 2026), https://tinyurl.com/3znd6te5.

The contract-pharmacy arrangements at the heart of this case have fueled this growth. Under these arrangements, pharmacies dispense 340B drugs for covered entities and share in the revenue. *See* Lee, *Mission vs. Margin* at 5. This practice allows covered entities to order even more 340B discounted drugs, far beyond their own facilities, increasing their

spread revenue. *See* Ryan Long et al., *Cui Bono? Misaligned Incentives in the 340B Program*, at 2-3 (USC Schaeffer Ctr. for Health Pol'y & Econ., White Paper Sept. 2025), https://tinyurl.com/45z47887. Widespread contract-pharmacy use has also increased program-integrity concerns about drugs being dispensed to people who don't qualify under federal law as patients of a covered entity—a practice known as "diversion" that the 340B statute prohibits. *See* 42 U.S.C. § 256b(a)(5).

To address these concerns, some drug manufacturers have conditioned 340B sales on covered entities' acceptance of reasonable limits to contract-pharmacy use. The Third and D.C. Circuits have upheld such conditions under federal law, concluding that Congress "preserve[d]—rather than abrogate[d]"—manufacturers' ability to limit the number of contract pharmacies a covered entity may use for program discounts. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 464 (D.C. Cir. 2024); *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 703 (3d Cir. 2023).

But covered entities, unhappy with these results, have turned to their state legislatures. And Mississippi, like a growing number of States, has enacted a statute forbidding manufacturers from requesting contract-pharmacy limits with their 340B offers. *See* Miss. H.B. 728, codified at Miss. Code Ann. § 41-149-7. The law's effect is to expand beyond federal requirements the circumstances in which manufacturers must offer 340B pricing, resulting in substantial revenue for in-state hospitals.

The Fifth Circuit below upheld H.B. 728 on the theory that it regulates drug distribution rather than drug pricing. Because 340B left drug distribution "unaddressed," the Fifth Circuit said, States can regulate it. Pet. App. 5a, 19a (internal citation omitted). But that distinction obscures what the law does. H.B. 728 doesn't regulate drug distribution generally. It regulates *only* distribution of 340B drugs, *only* by manufacturers participating in 340B, and *only* because those manufacturers agreed to meet obligations created by federal law. And while the petition ably shows why that renders the law's validity doubtful under various preemption precedents, Pet. 20-25, WLF writes separately to emphasize two additional points further supporting review.

First, H.B. 728 raises serious constitutional doubts under this Court's preemption-adjacent cases that follow the *McCulloch* principle, also known as the "intergovernmental immunity doctrine." *United States v. Washington*, 596 U.S. 832, 838 (2022). A State has no power to interfere with a federal program by "discriminat[ing] against the Federal Government or those with whom it deals." *Id.* Yet that's precisely what H.B. 728 does. Its prohibitions apply against only those manufacturers agreeing to perform 340B's discount function. And because of H.B. 728's additional requirements, the law undermines a federal operation by deterring further participation in it.

Second, the decision below has consequences that extend beyond the parties and even 340B itself. To date, 22 States have enacted contract-pharmacy laws targeted at 340B. Pet. 2, 17. By compelling

broader distribution of 340B drugs, these laws expand the number of 340B transactions, which result in billions of dollars in collateral costs that hit Medicaid, Medicare, and the Affordable Care Act.

If allowed to stand, the decision below will invite States to impose their own requirements on entities carrying out a federal program and reshape federal healthcare policy through state law. Only this Court can stop it. Review should be granted.

ARGUMENT

This case is about a federal program. Congress created 340B by statute, placed HHS in charge of it, and vested enforcement authority exclusively in HHS, including a federally prescribed dispute-resolution process. *See* 42 U.S.C. §§ 256b(a), 256b(d)(3); *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 114 (2011) ("Congress placed [HHS] in control of § 340B's drug-price prescriptions."). Unlike Congress's approach to many other Spending Clause programs, neither the U.S. Code nor the Code of Federal Regulations contemplates any role for the States in setting or enforcing manufacturers' 340B obligations. Pet. 3, 17.

The Court underscored 340B's exclusively federal character in *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011). There, the Court emphasized Congress's decision to centralize administration of 340B in HHS and to ensure its operation on a "uniform, nationwide basis." *Astra*, 563 U.S. at 120. Those structural features are no accident. Because 340B is "interdependent" with Medicaid, the Court explained, Congress has entrusted its

administration to a national agency capable of considering the federal healthcare programs together. *Id*.

Relying on its decision in *AbbVie Inc. v. Fitch*, 152 F.4th 635 (5th Cir. 2025), however, the Fifth Circuit brushed aside these principles and rejected Novartis's challenge by applying the "presumption against preemption." Pet. App. 5a. As the petition explains, that decision conflicts with several of this Court's preemption precedents. *See* Pet. 20-25 (collecting cases). And if anything, the opposite presumption applies under the Supremacy Clause, *see* U.S. Const. art. VI, cl. 2, where, as here, a State interferes with a federal program by imposing obligations beyond those that Congress set for program participation.

Indeed, when a State tries to assert control over operators of a federal program, there's no presumption favoring the State. Quite the opposite: the "activities of federal [actors] are shielded by the Supremacy Clause from direct state regulation unless Congress provides clear and unambiguous authorization." *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 180 (1988) (internal citations and quotation marks omitted). This holds true even if "the federal function is carried out by a private contractor." *Id.* at 181.

The Court's review is needed to address application of this principle to 340B—the "second-largest drug-purchasing program in the U.S." Long, *Cui Bono?* at 1.

I. H.B. 728 RAISES AN EXCEPTIONALLY IMPORTANT QUESTION ABOUT WHETHER STATES MAY SINGLE OUT PARTICIPANTS IN A FEDERAL PROGRAM FOR SPECIAL BURDENS.

As Chief Justice Marshall wrote in *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316 (1819), a State has no power "to retard, impede, burden, or in any manner control, the operations of the constitutional laws enacted by [C]ongress." *McCulloch*, 17 U.S. at 436. And so, under this *McCulloch* principle, a State can't interfere with a federal project by "discriminating against the federal government or those with whom it deals." *Washington*, 596 U.S. at 838 (cleaned up). The decision below sits at odds with this "intergovernmental immunity doctrine." *Id.*

A. The Supremacy Clause prohibits States from singling out those who deal with the federal government on terms that Congress has set.

A "regulation imposed on one *who deals with the Government* has as much potential to obstruct governmental functions as a regulation imposed on the Government itself." *North Dakota v. United States*, 495 U.S. 423, 438 (1990) (plurality opinion) (emphasis added).

Consistent with this principle, a State may not condition performance of a federal operation on its own approval, even through a generally applicable state law. *See, e.g., Hancock v. Train*, 426 U.S. 167, 174 n.23, 179-80 (1976) (holding that federal installations—including a federally owned nuclear facility "operated under contract by the Union

Carbide Corp."—need not obtain state operating permits absent "a clear congressional mandate" authorizing state regulation); *Pub. Utils. Comm'n v. United States,* 355 U.S. 534, 543-44 (1958) (holding that California could not require state approval of rates a carrier negotiated with the federal government); *Leslie Miller, Inc. v. Arkansas*, 352 U.S. 187, 190 (1956) (per curiam) (holding that Arkansas could not require a state contractor's license of a contractor the Air Force had selected). A law like H.B. 728, which singles out manufacturers for undertaking obligations of a federal program, is weaker still.

The governing rule is straightforward. Although the intergovernmental immunity doctrine doesn't prohibit every state law that incidentally burdens federal operations, *see North Dakota*, 495 U.S. at 434-35 (plurality opinion), a State may not single out those "with whom [the federal government] deals" and target them with extra burdens. *Washington*, 596 U.S. at 838 (internal citation and quotation marks omitted).

The Court's unanimous decision in *United States v. Washington*, 596 U.S. 832 (2022) aptly applied the rule. There, Washington State created a special workers-comp regime that applied only to federal contract workers performing cleanup work at a federal site. *Id.* at 836. The Court held the law unconstitutional because it targeted the contractor based on its role in the project, resulting in increased costs for both the contractor and the federal government, which was ultimately responsible for covering the workers-comp claims. *Id.* at 836, 839. That was impermissible, and for good reason. Intergovernmental immunity, the Court explained,

prevents States from yielding to political pressures that burden federal operations "for the benefit of the State's own citizens." *Id.* at 841.

This isn't some new judicial innovation. Burdening a federal operation for "the benefit a State's own citizens" was the story in *McCulloch*, where Maryland taxed the Second Bank of the United States to disadvantage federal operations in favor of the State's banks. That's also the story here. H.B. 728's effect is to benefit in-state hospitals and for-profit pharmacies like CVS and Walgreens (Pet. 12-13) at the expense of the very drug makers participating in a federal program on Congress's terms. The Court's review is needed to prevent this new brand of economic localism from burdening participants in a federal program.

B. Under 340B, participating drug manufacturers agree to a specific bargain with the federal government.

Whether drug manufacturers resemble traditional procurement contractors is beside the point. The intergovernmental immunity doctrine is not limited to contractors; it protects "those with whom [the federal government] deals," whoever they are. *Washington*, 596 U.S. at 838. The Court has applied it to a lessee of federal land, *Phillips Chem. Co. v. Dumas Indep. Sch. Dist.*, 361 U.S. 376, 387 (1960); to federal retirees, *Dawson v. Steager*, 586 U.S. 171, 175 (2019); and even to the workers of federal contractors, *Washington*, 596 U.S. at 839. What unites those cases is not the label on the relationship but the State's reason for regulating: in each, the State singled out a private party *because of*

its dealings with the United States. *See id.* at 838–839. The same is true of drug manufacturers that sign a PPA. Their relationship with HHS "originates from, is governed by, and terminates according to federal law," *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001), and H.B. 728 regulates them for no reason other than that relationship.

Acting under its spending power, Congress made a bargain that allows manufacturers to access Medicaid and Medicare Part B reimbursement by signing federally prescribed Pharmaceutical Pricing Agreements with HHS. *See Medina v. Planned Parenthood S. Atl.*, 606 U.S. 357, 365 (2025) (explaining that the "spending power" allows Congress to offer funds on "certain conditions"). By signing a PPA, manufacturers undertake program duties defined by the 340B statute. *See Astra*, 563 U.S. at 115. Congress uses participating manufacturers to "subsidize" covered entities with the expectation that they will use the "subsidy" to benefit low-income patients. *See*, e.g., *AbbVie Inc. v. Drummond*, 808 F. Supp. 3d 1266, 1277 (W.D. Okla. 2025) (referring to the 340B discount as an effective "subsidy" from manufacturers).

340B thus isn't a regulation of general applicability that happens to reach drug makers. It's a bargain struck under the Spending Clause between the United States and the drug makers that accept its terms. U.S. Const. art. I, § 8, cl. 1. The question for the Court is whether Mississippi may impose obligations on a drug maker for no reason other than because the company has signed an agreement with the federal government.

C. H.B. 728 is triggered only by a manufacturer's agreement to 340B's program obligations.

Mississippi seeks to regulate conduct only by those who sign a federal agreement. H.B. 728 bars a "manufacturer" from "restrict[ing]" or "otherwise interfer[ing] with" . . . the "acquisition" or "delivery" of a "340B drug" through a contract pharmacy. Miss. Code Ann. § 41-149-7. Not any "drug"— only "*340B* drug[s]," which are drugs "that ha[ve] been subject to any offer for reduced prices" under the federal program's terms. *See* Miss. Code Ann. § 41-149-3(a). A manufacturer that doesn't agree to Congress's bargain owes no discount on any drugs dispensed by a covered entity or its contract pharmacies, without violating H.B. 728 at all.

Far from imposing state obligations "unrelated to the [manufacturers'] status as a Government contractor or supplier," *North Dakota*, 495 U.S. at 438 (plurality opinion), H.B. 728 "singles them out" and "regulates them" for that very reason, *Washington*, 596 U.S. at 839 (cleaned up). That is discrimination in the constitutional sense.

The Fifth Circuit's reasoning overlooks all this. The court held that because the 340B statute doesn't address distribution, Mississippi was free to regulate it. Pet. App. 5a-6a. But when a State regulates those carrying out a federal program, "[n]o artificial presumption" favors the State. *United States v. Locke*, 529 U.S. 89, 108 (2000). The opposite presumption applies: the State must point to "clear and unambiguous" congressional authorization for its regulation. *Goodyear Atomic*, 486 U.S. at 180; *see*

Washington, 596 U.S. at 842-44 (finding no such authorization in a statute that spoke generally to state workers' compensation laws). Statutory silence is the antithesis of a clear waiver. The Fifth Circuit never asked whether Congress authorized Mississippi to rewrite the terms of a manufacturer's federal-program obligations; it asked only whether Congress forbade it. That is the wrong question, and it produced the wrong answer.

And the consequences for both manufacturers and 340B are severe. Federal law doesn't require manufacturers to deliver 340B drugs through an unlimited number of pharmacies, *see, e.g., Novartis*, 102 F.4th at 464, but contract pharmacies remain a "major source" of 340B discount "expansion," Long, *Cui Bono?* at 2. H.B. 728 is designed to sustain that expansion.

By barring 340B offers that limit contract-pharmacy use, H.B. 728 vastly expands manufacturers' discount obligations, imposing costs beyond those contemplated by the federal program. *See Drummond*, 808 F. Supp. 3d at 1273 (explaining that similar Oklahoma law "expands drug manufacturer's obligations under the federal 340B program"). Those costs must be felt somewhere—either through higher prices on the company's other products, reduced corporate expenditure on research and development of the next big thing, or shrinking staff count.

And greater discount costs aren't the only state-created burden. H.B. 728 also increases litigation exposure. For instance, a New Hampshire hospital is currently relying on state 340B laws

"including those of Arkansas, *Mississippi*, Louisiana and Vermont" to support a state consumer protection claim challenging manufacturer conditions on 340B pricing. *See* Compl. ¶ 227, *Mary Hitchcock Mem'l Hosp. v. Eli Lilly and Co.*, No. 1:26-cv-00616 (D.N.H. July 27, 2026), ECF No. 1 (emphasis added). That's exactly the decentralized-enforcement mess that *Astra* foreclosed nearly fifteen years ago. *See Astra*, 563 U.S. at 120-21.

Predictably, these state-added burdens discourage 340B participation, cannibalizing not just that federal program, but the Nation's medical safety-net for the poor and elderly altogether. The United States recently warned the Fourth Circuit that increasing the costs of 340B participation may cause "rational manufacturers" to withdraw from the program altogether, which would necessarily entail withdrawal from Medicaid and Medicare Part B. *See* Br. of the United States at 21, *AbbVie Inc. v. Brown*, No. 24-1939 (4th Cir. July 10, 2026). At least one manufacturer, Bausch Health, has already taken that step, attributing its decision to withdraw to "legislative changes." *Id.* (quoting Bausch Health Cos., Quarterly Report (Form 10-Q), at 53 (Oct. 30, 2025)). Now dozens of its drugs are no longer available to Medicaid patients nationwide. *Id.*

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The decision below authorizes precisely the type of state interference with federal operations that this Court has prohibited under the Supremacy Clause since the early days of the Republic. Absent review, States will continue to enact their own requirements governing participant duties in 340B. This significant issue—which cuts to foundational

limits on state authority—warrants the Court's review.

II. REVIEW IS ESPECIALLY NEEDED BECAUSE H.B. 728 INCREASES COSTS THROUGHOUT THE FEDERAL HEALTHCARE SYSTEM.

On top of the serious federalism concerns, review is especially warranted because the consequences of the decision below extend well beyond 340B itself.

Between 2020 and 2025, annual 340B purchases grew from $39.7 billion to more than $100 billion, while provider margins from those purchases increased from $63.6 billion to more than $142 billion. *See* Blalock & Launsbach, *The Size of the 340B Program* at 1 n.2. Contract-pharmacy arrangements have been the principal driver of this growth. *See* Cong. Budget Off., *Growth in the 340B Drug Pricing Program*, at 19 (Sept. 2025), https://tinyurl.com/mr3k4ree. Those arrangements are the very practice that H.B. 728 is designed to preserve and expand. Because 340B operates within a broader network of federal healthcare programs, state laws like H.B. 728 shift billions in costs to Medicaid, Medicare, and the federal treasury.

Medicaid: Start with Medicaid. Federal law prohibits "duplicate discounts," meaning a drug purchase can't receive both a 340B discount and a Medicaid rebate. *See* 42 U.S.C. § 256b(a)(5). This means that every prescription routed through 340B is one that doesn't generate a Medicaid rebate. As 340B utilization increases, Medicaid rebate collections decline and Medicaid costs correspondingly increase.

See Sayeh Nikpay et al., *Policy Insight—When Safety-Net Programs Compete: Medicaid, 340B, and the Battle Over Drug Discounts,* Health Aff., at 56 (Jan. 2026).

These costs are substantial. One study estimates that Medicaid loses approximately $6.5 billion annually in foregone rebate revenue because of drugs purchased through 340B that don't generate corresponding Medicaid rebates. *See* Eleanor Blalock & Carlee Launsbach, *The Financial Impact to Medicaid from the 340B Drug Pricing Program*, at 2 (BRG July 2025), https://tinyurl.com/mp7e3k2j. Approximately $4.2 billion is borne by the federal government. *Id*.

Medicare: Similar forces affect Medicare. HHS recently concluded that increased 340B activity is associated with higher Medicare spending and greater costs to the federal government. *See* Lee, *Mission vs. Margin* at 8. Outside of HHS, research shows that increased contract-pharmacy use contributes to higher Medicare Part D premiums. *See* Sayeh Nikpay & Claire McGlave, *Association Between 340B Contract Pharmacy Growth and Payer-Specific Drug Coverage*, Am. J. Managed Care (Feb. 27, 2026), https://perma.cc/X3UM-FURH. This means greater Medicare spending not only by the federal government but also by Medicare beneficiaries. *See* Long, *Cui Bono?* at 8.

Affordable Care Act. The Affordable Care Act, too, suffers higher costs. One recent study found that increased 340B activity is associated with higher premiums in ACA Marketplace plans. *See* Neal Masia, *The Association of the 340B Program with*

Affordable Care Act (ACA) Premiums: A Longitudinal Analysis from 2018 to 2022, SAGE Publications, at 1, 4 (Sept. 4, 2025), https://tinyurl.com/y3hmpd4m. And because ACA subsidies rise with the cost of coverage, higher premiums result in higher federal expenditures. Indeed, the same study estimates that 340B activity is associated with more than $2 billion annually in additional ACA subsidy payments. *Id.* at 5.

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By preserving and expanding the contract-pharmacy arrangements, laws like Mississippi's increase costs not merely for participating manufacturers, but for Medicaid, Medicare, and the Affordable Care Act programs. The decision below affects not only Novartis, Mississippi, or 340B, but the federal healthcare system at large. This national question cries out for certiorari.

CONCLUSION

Congress created 340B, but Mississippi seeks to commandeer it for the economic benefit of its in-state concerns. The Fifth Circuit's decision permits States to impose special burdens on participants in a federal program while increasing costs throughout the federal healthcare system. These are issues of significant consequence. The petition should be granted.

Respectfully submitted,

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