No. 24-737

IN THE

Supreme Court of the United States

SPROUT FOODS, INC.,

Petitioner,

v.

GILLIAN DAVIDSON, *et al.*,

Respondents.

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

BRIEF OF ATLANTIC LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF THE *AMICUS CURIAE* [1]

Established in 1977, the Atlantic Legal Foundation (ALF) is a national, nonprofit, nonpartisan, public interest law firm. ALF's mission is to advance the rule of law and civil justice by advocating for individual liberty, free enterprise, property rights, limited and responsible government, sound science in judicial and regulatory proceedings, and effective education, including parental rights and school choice. With the benefit of guidance from the distinguished legal scholars, corporate legal officers, private practitioners, business executives, and prominent scientists who serve on its Board of Directors and Advisory Council, ALF pursues its mission by participating *as amicus curiae* in carefully selected appeals before the Supreme Court, federal courts of appeals, and state supreme courts. See atlanticlegal.org.

* * *

ALF has a long-standing commitment to promoting limited and responsible government, sound science, free enterprise, and the rule of law—all principles implicated by this case. As a public-interest law firm, ALF often appears as *amicus curiae* before the Supreme Court and other appellate courts to ensure that federal statutes like the Federal Food, Drug, and Cosmetic Act ("FDCA") are interpreted and

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[1] Petitioner's and Respondents' counsel were provided timely notice in accordance with Supreme Court Rule 37.2 No counsel for a party authored this brief in whole or part, and no party or counsel other than the *amicus curiae* and its counsel made a monetary contribution intended to fund preparation or submission of this brief.

enforced consistent with Congress's intent and constitutional design.

ALF's particular interest here stems from its belief that piecemeal, state-by-state, enforcement litigation—especially private enforcement suits—undermine not only the congressional objective of establishing and maintaining uniform national food labeling standards, but also the scientifically guided policymaking that Congress vested in the U.S. Food & Drug Administration (FDA). Allowing state-by-state enforcement of FDA's standards not only would supplant and undermine FDA's enforcement expertise and discretion but also would force consumers and businesses to bear the cost in the form of confusing labels, burdensome compliance, and diminished product innovation. ALF champions clear and consistent regulatory frameworks, especially those informed by reliable science. ALF urges the Court to reinforce the FDCA's express and implied preemptive scope and ensure that state-level enforcement, including through private suits such as this, does not subvert the FDCA's uniform national scheme.

SUMMARY OF ARGUMENT

Congress enacted the Federal Food, Drug, and Cosmetic Act (FDCA), as amended by the Nutrition Labeling and Education Act of 1990 (NLEA), to promote uniform, nationwide standards for food labeling, enforced by a national, expert agency—the FDA. The relevant FDCA express preemption clause, 21 U.S.C. § 343-1(a), bars States from imposing any labeling requirement "not identical" to federal law.

Here, though, the more important provision is the FDCA's exclusivity provision, 21 U.S.C. § 337(a).

Subject to certain exceptions not relevant here, *see id.* at § 337(b), Section 337(a) vests sole enforcement of FDCA-based requirements in the FDA and other authorized public officials, not private litigants. This exclusivity scheme is no accident. Congress centralized enforcement authority in the FDA exclusively because food labeling often involves complex, science-based determinations—the kind of technical judgment best made by an expert agency that can balance competing public-health and economic considerations. By impliedly preempting private rights of action, Congress prevented a patchwork of suits that could fragment the uniformity crucial to a nationwide labeling regime.

Before the Ninth Circuit's opinion here, the First, Second, and Sixth Circuits all consistently held that § 337(a) bars private litigants from bringing FDCA-violation claims disguised as state-law causes of action. *See DiCroce v. McNeil Nutritionals, LLC*, 82 F.4th 35 (1st Cir. 2023); *Loreto v. Procter & Gamble Co.*, 515 F. App'x 576 (6th Cir. 2013); *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105 (2d Cir. 1997). But now, the door is open for enterprising plaintiffs' attorneys and their wealthy financiers, and other interested groups, to bypass FDA control over food labeling.

In the decision below, the Ninth Circuit allowed private litigants to use California's state-law "mirror" provisions to circumvent the FDCA's no-private-enforcement prohibition. The court of appeals reasoned that because these state requirements were "identical" to federal law, they not only escaped the FDCA's express preemption clause, § 343-1(a), but also the statute's exclusivity provision, § 337(a).

That analysis ignores implied preemption under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Plaintiffs cannot engage in an "end run" around the FDA's exclusive enforcement authority simply by invoking state law. Such suits strip the FDA of its congressionally mandated role, subjecting manufacturers to 50 different private enforcement regimes and ensuring that labeling standards, though "identical" on paper, are interpreted and applied in divergent ways across state courts.

Allowing private parties to enforce FDCA-based standards (here, state standards that are identical to FDA's standards) fosters inconsistency, forum-shopping, and over-warning, ultimately contradicting Congress's intent that the FDA alone decide how, when, and whether to bring actions for alleged misbranding. The Court should grant certiorari to reaffirm that 21 U.S.C. § 337(a) impliedly preempts private suits seeking to enforce FDCA rules under state-law and thus preserve the uniform labeling that Congress explicitly sought when it passed these laws.

ARGUMENT

I. The Ninth Circuit's opinion undercuts FDCA food labeling uniformity

The FDCA, enacted in 1938, grants the FDA power to ensure that "foods are safe, wholesome, sanitary, and properly labeled," and prohibits the misbranding of food in interstate commerce. 21 U.S.C. §§ 331(a)-(c); 393(b)(2)(A). In 1990, Congress amended the FDCA with NLEA "to clarify and to strengthen the Food and Drug Administration's legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made

about nutrients in foods." Pub. L. No. 101-535, 104 Stat. 2353 (1990) (codified at 21 U.S.C. § 343, *et seq*.); *see also* H.R. Rep. No. 101-538 (1990).

Respondents Gillian and Samuel Davidson filed suit in federal district court, alleging that Sprout Foods, Inc. had mislabeled its baby-food products in violation of California's Sherman Food, Drug, and Cosmetic Law ("Sherman Law"). The Sherman Law expressly adopts and incorporates federal regulations promulgated under the FDCA, stating that "[a]ll food labeling regulations and any amendments to those regulations adopted pursuant to the federal act . . . shall be the food labeling regulations of this state." Cal. Health & Safety Code § 110100(a).

Because Respondents' claims rely solely on Sprout Foods' alleged violation of these FDCA-based standards—simply repackaged as a violation of the Sherman Law—the district court dismissed their First Amended Complaint in its entirety under Federal Rule of Civil Procedure 12(b)(6). *See* Pet. App. 51a–52a. The district court reasoned that the Sherman Law claim was "entirely dependent upon the FDCA" and thus impliedly preempted. *Id.* 60a.

On appeal, however, the Ninth Circuit reversed. It held that Respondents can sue for Sherman Law—in reality, FDCA—food labeling violations, in the name of California's unfair competition law. Under the Sherman Law, California food labeling regulations are identical to FDCA regulations. Despite the clear directive of Congress that only the FDA can sue violators to enforce these regulations, the lower court held that private litigants can do so in the name of unfair competition. Private enforcement is expressly barred under the FDCA, but the majority reasoned

that the FDCA "places no limitations on enforcement of these state parallels," so the Sherman Law claim is outside the FDCA's preemptive reach. Pet. App. 16a.

This is not the law—and it circumvents the preemption and exclusive enforcement provisions of both the FDCA and the California Sherman Law. This invades and usurps the exclusive enforcement powers of the FDA and the California Department of Public Health. Other circuits consistently and correctly hold that state statutes mirroring the FDCA cannot license a private right of action that Congress expressly withheld in the federal statute. *See* Pet. App. 13a, 16a–20a; *DiCroce v. McNeil Nutritionals, LLC*, 82 F.4th 35 (1st Cir. 2023); *Loreto v. Procter & Gamble Co.*, 515 F. App'x 576 (6th Cir. 2013); *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105 (2d Cir. 1997).

According to the Ninth Circuit majority, however, "[t]here is no reason why Congress would permit states to enact particular legislation and then deny enforcement by their citizens." Pet. App. 13a. By this logic, the Ninth Circuit concluded that private suits under the Sherman Law—though derived wholly from FDCA-based standards—are allowed under the FDCA.

II. Express preemption under the FDCA prevents States from creating "a patchwork of inconsistent requirements"

FDCA's express preemption provision for food labeling is codified at 21 U.S.C. § 343-1. It provides that "no State or political subdivision of a State may directly or indirectly establish … any requirement for the labeling of food … that is not identical" to FDA's requirements. Because this provision requires that any state food labeling laws impose requirements that

are "identical" to federal law, States have no leeway to deviate from—or to reinterpret—federal standards. Any state law requiring information to be listed on a food label is preempted *if* the state-required information is *also not* required under the FCDA.

"Without uniform standards, food manufacturers are forced to label differently in different states, raising costs and confusing consumers." House Report No. 101-538, at 10 (1990); *see also Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 459–60 (2012) (discussing the dangers of state laws invading federally preempted regulatory territory); *cf. Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 452 (2005) ("In the main, [the statute] pre-empts competing state labeling standards—imagine 50 different labeling regimes prescribing the color, font size, and wording of warnings—that would create significant inefficiencies for manufacturers.") (interpreting the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U. S. C. § 136, *et seq.*).

California's Sherman Law does not create an independent state-law basis for private enforcement of food labeling requirements. Rather, it wholesale incorporates the FDCA's labeling requirements—and in so doing, it does not empower private litigants to sue for violations for what in substance, and even in form, are FDCA requirements.

The Ninth Circuit's reading—treating verbatim adoption of FDCA rules as a basis for private suits even in the case of a California statute which itself bars private suits—sharply contravenes FDCA's unique statutory scheme and the express prohibition of private enforcement set forth in 21 U.S.C. § 337(a).

III. By barring private enforcement suits, the FDCA's exclusivity provision impliedly preempts state-law claims that seek to enforce federal food labeling standards, even if in the form of identical state standards

While the claimed violation here may appear straightforward—front-of-package nutrition label disclaimers—opening the door to private enforcement on this basis empowers countless future suits on more complicated or less clear-cut labeling issues.

Congress did not merely bar States from imposing labeling requirements "not identical" to federal law; it also chose to centralize all FDCA enforcement in the FDA. While express preemption under 21 U.S.C. § 343-1(a) bars States from imposing non-identical labeling requirements, implied preemption under 21 U.S.C. § 337(a) ensures that only the FDA may enforce FDCA-based standards—even if a State has simply copied those standards verbatim. Even when a state statute purports to mirror FDCA regulations, private lawsuits predicated solely on those "identical" standards run afoul of a separate, equally important principle: implied preemption under *Buckman*.

While express preemption under 21 U.S.C. § 343-1(a) prohibits a patchwork of varying labeling requirements, implied preemption under 21 U.S.C. § 337(a) bars private litigants from suing to enforce those requirements in the first instance. In other words, States cannot circumvent the FDCA's no-private-enforcement rule simply by adopting federal standards as their own. The Ninth Circuit's decision addressed express preemption only, ignoring this second, equally important and independent

preemption ground. This collides with FDA's exclusive enforcement authority under the FDCA.

From its inception, the FDCA vested enforcement powers in the FDA to protect public health through uniform, science-based regulation of food, drugs, and cosmetics. *See* 21 U.S.C. § 337(a). Congress recognized that food labeling requires specialized expertise and national oversight. By including no private right of action, Congress sought to avoid private litigants—in various jurisdictions—second guessing, for different reasons, FDA judgments about labeling. *See Buckman* 531 U.S. at 349–50) (finding implied preemption where private plaintiffs asserted medical device-related claims intruding on the FDA's exclusive enforcement).

Although Congress allowed States to enforce certain FDCA provisions under 21 U.S.C. § 337(b), § 337(b) does not create or authorize private suits; it provides a narrow pathway for state officials to bring an enforcement action under federal law to enforce a few of the FDCA food labeling statutes, subject to strict procedural requirements such as notice to the FDA and an opportunity for the FDA to intervene. *See* 21 U.S.C. § 337(b)(2). Far from permitting the "fragmentation" that private suits cause, these conditions preserve the FDA's supervisory role, thereby helping maintain uniformity. In contrast, purely private suits—like Respondents'—circumvent these safeguards and invite the very patchwork of ad hoc enforcement Congress sought to avoid.

Congress intended the FDA—armed with deep scientific and regulatory expertise and experience—to be the final arbiter of food-labeling standards. By empowering the FDA with broad authority under the

FDCA, Congress recognized that food labeling often involves complex, science-driven determinations about nutrition, health impacts, and consumer understanding, including in connection with baby food. These issues require specialized judgment and the balancing of policy considerations.

The Ninth Circuit's decision, however, supplants the FDA's centralized role with a patchwork of private jury verdicts and judicial rulings across fifty States. This effectively displaces the agency's interpretive authority and undercuts Congress's choice to channel labeling disputes into a uniform national system. If private litigants can enforce FDCA requirements through state mirror statutes, courts—not the FDA—will dictate labeling rules. Such decentralization eviscerates the very agency deference that ensures consistency, scientific rigor, and predictable labeling standards. *See Buckman*, 531 U.S. at 349.

Allowing a multitude of private enforcers to second-guess the FDA's policy calls or regulatory interpretations produces the same discord Congress sought to avoid, and it relegates the agency's expert-driven determinations to near irrelevance. Indeed, nowhere in the FDCA did Congress authorize state-by-state reinterpretations of FDA regulations under the guise of "identical" labeling laws. Instead, FDCA's prohibition against non-identical state labeling requirements embodies a congressionally mandated deference to FDA's labeling determinations and related enforcement decisions.

When private plaintiffs invoke state laws that merely copy FDCA standards, they effectively attempt to enforce those federal standards. On their face, such "identical" state-law provisions do not violate the

FDCA's express preemption clause, 21 U.S.C. § 343-1(a). But they run headlong into implied preemption under § 337(a), which reserves FDCA enforcement power to the government alone. As the Court explained in *Buckman*, permitting private litigants to sue over alleged FDCA violations under state law undermines the agency's authority and disrupts uniformity. *See* 531 U.S. at 349–51.

Here, Respondents rely on the California Sherman Law—incorporating FDCA standards—to prosecute what is, in reality, an FDCA misbranding action. Yet the Sherman Law itself does not permit such private suits, reflecting the same policy choice Congress made in § 337(a). By endorsing an "end run" via the State's Unfair Competition Law, the Ninth Circuit essentially overrides the FDCA's exclusivity regime and sets the stage for inconsistent interpretations of identical FDA regulations across multiple States.

The Ninth Circuit's ruling, allowing such private enforcement of FDCA provisions under California law, cannot be reconciled with *Buckman*'s holding that state-law suits seeking to police FDA-related misconduct are impliedly preempted. 531 U.S. at 349–51. Multiple circuits have likewise enforced § 337(a) to dismiss claims that simply repackage FDCA violations under state law. *See, e.g., Loreto v. Procter & Gamble Co.*, 515 F. App'x 576, 579–80 (6th Cir. 2013); *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997).

By contrast, the decision below endorses a patchwork of private enforcement. That "end run" around FDCA exclusivity invites the very confusion and balkanization of labeling requirements Congress sought to avert. Exclusivity under § 337(a) stands at

the core of Congress's decision to centralize FDCA enforcement and preempt inconsistent or duplicative state-level regulation. Private litigants have no authority to sue for misbranding under the FDCA, nor can they do so by grafting FDCA rules onto state statutes. Private litigation should not function as a backdoor to "above-and-beyond" regulation.

IV. Divergent state-by-state interpretation and enforcement promote forum-shopping, encourage frivolous lawsuits, and make regulatory compliance unpredictable and costly

The Ninth Circuit's expansive reading of "identical" state statutes opens the door to forum-shopping, inviting plaintiffs' attorneys to cherry-pick jurisdictions most sympathetic to consumer class actions or known for plaintiff-friendly jurisprudence. Although such private suits nominally enforce federal standards, the practical effect is the proliferation of divergent interpretations in different courts. *See De Buono v. NYSA-ILA Med. & Clinical Servs.* Fund, 520 U.S. 806, 814 n.8 (1997) (recognizing that inconsistent state rulings frustrate Congress's goal of uniform administration); *Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985) (acknowledging the importance of uniform federal schemes to avoid inconsistent state regulation).

The Ninth Circuit's endorsement of private FDCA enforcement through state-law "mirror" provisions threatens a host of adverse policy outcomes. These policy considerations show why the FDCA exclusivity provision impliedly preempts private enforcement.

A. Over-warning

One predictable consequence of this litigation-driven approach is information overload otherwise known as over-warning. Fearful of unpredictable suits and potential liability, manufacturers will load labels with excessive disclaimers—burying important safety or nutritional details in fine print. This clutter not only confuses consumers but also undermines the FDCA's goal of clear, science-based labels that highlight genuinely important information.

A product deemed fully compliant in one State may be forced to carry unique disclaimers or face litigation in another. Faced with a rising tide of private enforcement actions under "identical" but state-driven rules, manufacturers naturally respond by adopting "defensive labeling." Defensive labeling clutters packages with disclaimers that obscure details. *See Wyeth v. Levine*, 555 U.S. 555, 578 (2009) (noting the risks of over-warning and its tendency to dilute crucial cautionary information). Rather than providing consumers with clear, concise, and scientifically grounded labeling as intended under federal law, companies under siege by state-level lawsuits will overload labels with fine print, legalese, disclaimers, and qualifiers, and do so without any benefit to or advancement of public health.

The result is an escalation of compliance costs that can be especially crippling for small and mid-sized companies, which lack the resources of national conglomerates. In practical terms, such businesses may find it easier to exit certain markets or adopt burdensome disclaimers that obscure otherwise valuable product information. This phenomenon not only inflates production and design expenses (such as

frequent label revisions and special runs for certain States), but also undermines consumer understanding. *See Wyeth*, 555 U.S. at 578 (noting the perils of "over-warning" and its potential to diminish the effectiveness of warnings). When every potential risk or claim is highlighted, vital information can be lost in a blur of redundant, legally mandated verbiage.

Over-warning does not serve the public interest and is at odds with the FDA's goal of providing useful, science-based product information. Rather, it promotes consumer confusion and increases costs—with little demonstrable benefit to health or safety. The Ninth Circuit's decision therefore impedes Congress's aim of uniform, streamlined regulations by putting manufacturers in the impossible position of second-guessing the next wave of state-level lawsuits, rather than relying on the FDA's measured judgment. This mismatch between self-selected plaintiffs with litigation motivations, and federal policy, supports the conclusion that § 337(a) impliedly preempts claims like those at issue here.

B. Consumer confusion

The decision below risks fragmenting national labeling rules through multijurisdictional variations. Divergent rulings from multiple state courts interpreting the same FDCA provisions will yield inconsistent label requirements, sowing consumer confusion. The uniformity that Congress envisioned—and that helps consumers make informed choices—will erode under the weight of conflicting or duplicative label mandates.

This will cause consumer confusion as products labeled lawfully under one State's interpretation may

be deemed deceptive and unlawful elsewhere, contributing to public mistrust of food labeling overall. Left unaddressed, these conflicting rulings will only multiply, further compounding the inconsistencies and undermining the uniformity essential to a coherent federal regulatory scheme.

C. Chill on innovation

The risk of state-level enforcement, especially by private enforcement actions, stifles innovation, and frustrates interstate commerce and federal objectives. The threat of private suits for even minor deviations from perceived labeling norms deters companies from developing new products or improving existing ones. Small and mid-sized firms especially lack the resources to navigate multi-state litigation, stifling the healthy competition and innovation that federal labeling standards were designed to foster.

The Ninth Circuit's ruling threatens innovation in food product development, contrary to the purpose of the FDCA's uniform standards. Innovators that aspire to create healthier or more specialized products often rely on well-defined labeling guidelines to accurately communicate nutritional benefits or unique formulation attributes. *See In re Farm Raised Salmon Cases*, 42 Cal. 4th 1077, 1086 (2008) (recognizing the FDCA's objective of balancing accurate labeling with promotion of industry innovation); *see also Nat'l Meat Ass'n*, 565 U.S. at 457–58 (explaining how uniform federal rules promote both clarity and innovation).

When each State can enforce its own spin on labeling requirements, food manufacturers must anticipate and guard against the strictest or most

idiosyncratic interpretation, increasing the risk and cost of any novel product launch. These risks multiply when States permit private lawsuits that seek monetary awards or drastic labeling changes based on alleged noncompliance with "identical" rules. Manufacturers with cutting-edge formulations—such as plant-based proteins, functional foods, or reduced-sugar alternatives—often find themselves in uncharted territory regarding labeling language. The fear that one or more States may judicially outlaw or criminalize a new labeling claim can dissuade these companies from expanding into broader markets or even developing the product in the first place.

Companies that lack the legal and financial capacity for multi-state litigation may exit the market or forgo innovative ideas altogether. This outcome runs counter to Congress's intent for the FDCA to require safe, clear, and innovative labeling on a national scale. By sanctioning parallel enforcement that deviates from uniform federal rules, the Ninth Circuit's approach disincentivizes innovation to the detriment of both industry and the consumers who might benefit from new and improved food products.

D. Balkanization of interstate commerce

Allowing private enforcement on a state-by-state basis robs the FDA of the centralized authority Congress granted it—authority that depends on scientific expertise and uniform rulemaking, not piecemeal judicial interpretations. *See Buckman*, 531 U.S. at 349–50. Indeed, by replacing the FDA's measured policymaking with varying judicial decrees, the Ninth Circuit's approach effectively displaces the unified national framework envisioned by Congress. Without the FDA's exclusive oversight,

manufacturers are forced to navigate a shifting array of local pronouncements on what is "misleading" or "accurate" under the same federal regulation—an unsustainable jerry-rig that denies both consumers and businesses the consistency and predictability on which they rely.

Because food producers often distribute nationwide, the most aggressive or idiosyncratic state-level enforcement effectively sets a de facto national standard. Congress designed the FDCA to avert such balkanization, ensuring consistent and predictable labeling rules in all fifty States. The Ninth Circuit's ruling contravenes that goal, thereby fragmenting interstate commerce in the food industry. A claim that succeeds in one State—perhaps because of a novel reading of a "misleading" label—can be rejected elsewhere, yielding a litany of de facto labeling requirements. Such disparity undermines the FDCA's nationally uniform standards in two distinct but related ways.

By filing suit in specific venues with favorable procedural rules or pro-plaintiff stances, private litigants can force settlements even where the labeling complies with FDA regulations. The risk of a runaway verdict or massive class-wide liability places intense settlement pressure on companies whose food labeling would otherwise pass muster under a single, uniform federal regime (or in another State).

And as multiple courts inevitably reach conflicting conclusions, manufacturers trying to market and distribute products nationwide will be whipsawed by inconsistent rules. Complying with state-level injunctions or settlement agreements in one State will likely prompt precisely the type of over-labeling or

excessive disclaimers Congress sought to prevent. Instead of simply complying with the FDA's carefully calibrated regulations, businesses must anticipate the strictest or most aggressive state interpretation—lest they be forced to defend against multiple, costly lawsuits. *See, e.g., Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 475 (2013) (fear of liability can compel manufacturers to modify product labeling).

E. Additional burden on taxpayers

Private enforcement of FDCA-based requirements also imposes hidden costs on taxpayers and state governments. When multiple courts in different jurisdictions take up duplicative suits over the same alleged food labeling violations, state judicial systems and enforcement agencies must expend additional resources, doing so alongside the federal regime. Local taxpayers effectively subsidize these extra proceedings both in terms of courtroom administration and potential regulatory offshoots even though Congress intended the FDA's expert oversight to streamline national enforcement. By vesting exclusive enforcement authority in the FDA, Congress chose to avoid foisting these needless litigation costs onto the public. The Ninth Circuit's approach contravenes that design, amplifying the burden on taxpayers who must fund the fragmented machinery of redundant litigation in multiple venues.

V. This Court should grant certiorari and reverse the Ninth Circuit so that the "California Effect" does not force the entire nation to follow one State's agenda

The Ninth Circuit's decision also invites the so-called "California Effect," whereby one particularly

assertive regulator wields its market size and legal framework to dictate the practical national standard for food labeling. As the largest consumer market in the country, California exerts outsized influence on any product sold nationwide. Faced with the enforcement risk and litigation costs of a single State's aggressive approach, manufacturers frequently default to California's requirements—whether officially more stringent or merely interpreted as such in the courts—to avoid exposure to crushing liability. *See Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 249 (2004) (recognizing that California's unique laws and regulations can, by mere market necessity, effectively become the de facto standard for other States). The same dynamic occurs here, as companies look beyond FDA requirements and brace for California's private class actions under its "identical" Sherman Law.

This phenomenon not only thwarts Congress's intent for a uniform, nationwide labeling regime under the FDCA, but it also allows a single jurisdiction to impose broader or different enforcement interpretations on products sold coast to coast. As a result, national food labeling—purportedly governed by federal standards—becomes dominated by the legal climate of just one State. Small and mid-sized companies could find it especially hard to bear the compliance cost of separate formulations or labels for California alone, forcing them instead to over-label or withdraw from markets altogether.

In short, the "California Effect" undercuts the uniform federal standards that Congress established through the FDCA's express preemption provisions. By sanctioning divergent, state-driven enforcement

practices, the Ninth Circuit's ruling effectively cedes de facto national regulatory authority to whichever State undertakes the most expansive interpretation of "identical" rules. This scenario not only betrays the FDCA's emphasis on expert-driven, centralized oversight by the FDA but also contravenes the very federal uniformity that Congress insisted upon when it enacted the Nutrition Labeling and Education Act. The resulting balkanized environment further heightens legal uncertainty and chills innovation, thus warranting this Court's intervention to reaffirm the primacy of federal standards and restore the national consistency vital to food labeling.

CONCLUSION

The petition for a writ of certiorari should be granted and the decision of the Ninth Circuit reversed.

Respectfully submitted,

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