No. 25-

IN THE

Supreme Court of the United States

COUNCIL FOR RESPONSIBLE NUTRITION,

Petitioner,

v.

LETITIA JAMES, IN HER OFFICIAL CAPACITY AS NEW YORK ATTORNEY GENERAL,

Respondent.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

In 2023, the New York Legislature passed N.Y. Gen. Bus. Law §391-oo (the "**Law**"), which bans the sale to minors of dietary supplements that are "labeled, marketed, or otherwise represented" for "weight loss" or "muscle building." To justify this content-based infringement on commercial speech, the government had to satisfy the intermediate scrutiny test set forth in *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980), which requires the government to demonstrate with empirical evidence that the specific regulation will actually and materially advance an important government interest, and that the infringement on commercial speech was a "last resort" among other potential, non-speech-infringing alternatives. *Thompson v. W. States Med. Center*, 535 U.S. 357, 371 (2002).

The questions presented are:

1. Did the Second Circuit err in holding—contrary to the Fourth, Fifth, Sixth, Ninth and Tenth Circuits—that the third prong of the *Central Hudson* test can be satisfied without an evidentiary showing demonstrating that the specific manner of speech restriction will actually, and materially, ameliorate harm?

2. Did the Second Circuit err in watering down the fourth prong of the *Central Hudson* analysis by deferring to the New York legislature's manner of regulating without any meaningful consideration of less-intrusive, alternative means, contrary to the analysis conducted by the majority of circuits?

PARTIES TO THE PROCEEDING

Petitioner Council for Responsible Nutrition was the Plaintiff-Appellant in the courts below.

Respondent Letitia James, in her official capacity as New York Attorney General, was Defendant-Appellee in the courts below.

CORPORATE DISCLOSURE STATEMENT

Petitioner Council for Responsible Nutrition is a non-governmental entity with no parent corporation. No publicly held company owns 10% or more of its stock.

STATEMENT OF RELATED PROCEEDINGS

The following proceedings are directly related to this case:

- *Council for Responsible Nutrition v. James*, No. 24-cv-1881 (ALC), U. S. District Court for the Southern District of New York. Motion for Preliminary Injunction denied Apr. 19, 2024.

- *Council for Responsible Nutrition v. James*, No. 24-1343, U. S. Court of Appeals for the Second Circuit. Judgment entered Nov. 13, 2025.

TABLE OF CONTENTS

Table of Contents

Table of Contents

TABLE OF APPENDICES

TABLE OF CITED AUTHORITIES

Page

Cases

Page

Page

Page

Page

Constitutional Provisions

Statutes and Other Authorities

Cited Authorities

OPINIONS BELOW

The Second Circuit's opinion is reported at 159 F.4th 155 and reprinted in the Appendix to the Petition ("Pet. App.") at 1a. The district court's opinion denying preliminary injunction is reported at 2024 WL 1700036 and reprinted at Pet. App. 31a.

JURISDICTION

The Second Circuit issued its opinion on November 13, 2025, and denied CRN's petition for rehearing *en banc* on December 30, 2025. Pet. App. 61a. CRN timely filed this petition for writ of certiorari on March 30, 2026. *See* 28 U.S.C. § 2101(c); S. Ct. R. 13(3).

This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS INVOLVED

This case involves U.S. Const. amend. I, "Congress shall make no law . . . abridging the freedom of speech. . . ."

The law at issue, N.Y. Gen. Bus. Law § 391-oo, provides in relevant part:

"'Dietary supplements for weight loss or muscle building' means a class of dietary supplement . . . that is labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building. . . ." *Id.* § 391-oo(1)(a).

"No person, firm, corporation, partnership, association, limited liability company, or other entity shall sell or offer to sell or give away, as either a retail or wholesale promotion, an over-the-counter diet pill or dietary supplement for weight loss or muscle building within this state to any person under eighteen years of age." *Id.* § 391-oo(2).

STATEMENT OF THE CASE

Nearly half a century ago, this Court required the government to satisfy a form of intermediate scrutiny to justify restrictions on commercial speech. *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980). To satisfy *Central Hudson*, the government must show with empirical evidence that the infringement will directly and materially advance a substantial interest, and it must show that it carefully considered non-speech-infringing alternatives. But over the past several decades, confusion has arisen in the district and circuit courts about multiple aspects of the *Central Hudson* test. This case presents this Court with the opportunity to stop the erosion of First Amendment protections for commercial speech and to clarify the government's burden for justifying content-based infringements.

The decision below deepens an existing circuit split on the government's burden under the *Central Hudson* test. The Second Circuit diluted the appropriate level of scrutiny and instead applied what more closely resembles rational basis review. The Law at issue restricts the sale of dietary supplements to minors when the dietary supplements are "marketed" or "labeled" for the purposes of "weight loss" and "muscle building." This is plainly

a content-based speech restriction because the law's restrictions are triggered solely by speech—not by the ingredients in any particular product or whether a particular product is dangerous. While Petitioner shares the goal of protecting the health and safety of minors (the government's stated purpose in passing this legislation), this goal can be addressed without infringing on constitutionally-protected speech.

The Second Circuit's holding did not require New York to demonstrate, *through empirical evidence*, that regulating dietary supplements based on speech (marketing), rather than based on a product's ingredients, will directly advance the goal of protecting minors from dangerous ingredients. Instead, rather than finding the lack of evidence to be a failure under *Central Hudson*, the Second Circuit allowed the government to meet its burden by relying on "simple common sense" and two studies that, by the panel's own acknowledgment, do not link products "marketed" or "labeled" for "weight loss" or "muscle building" with any actual harm to minors. The Circuit's failure to require evidentiary substantiation of this link—as at least five other circuits require—has excused the government of one of its critical burdens under *Central Hudson*. In *Greater New Orleans Broadcasting Ass'n, Inc. v. United States*, this Court, concerned about the absence of evidence connecting a specific harm (casino gambling) with a specific regulation (broadcast advertising for certain commercial casinos), deferred for another day "the question whether any lack of evidence in the record fails to satisfy the standard of proof under *Central Hudson*." 527 U.S. 173, 190 (1999). This case presents a perfect vehicle for addressing that question and providing much-needed guidance to the lower courts.

Even more concerning is the Second Circuit's determination that the New York regulation was narrowly tailored—indeed, the court conducted no inquiry at all, stating that it "must" "defer to [the government's] reasonable judgment" in how it chooses to regulate speech. Pet App. at 15a. That completely eliminates the rigor of the fourth prong of the *Central Hudson* test. Unsurprisingly, this unqualified deference is in direct conflict with most other circuits, which engage in a careful inquiry about whether the legislature considered other non-speech alternatives to ensure that the infringement on commercial speech was a "last resort." *Thompson*, 535 U.S. at 371. The Second Circuit's rubber-stamp of the government's "say-so" is barely even rational-basis review—a far cry from the higher scrutiny that *Central Hudson* prescribed.

The decision below removes critical guardrails that this Court erected in *Central Hudson* to ensure that restrictions on commercial speech are rare and only permissible if accompanied by a significant government demonstration that they are necessary. Indeed, following this Court's decision in *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011), there has been discussion that the *Central Hudson* intermediate scrutiny is not even rigorous enough where, as here, the regulation is content-based. *See*, *e.g.*, *Matal v. Tam*, 582 U.S. 218, 253 (2017) (Thomas, J., concurring in part and concurring in judgment) ("I continue to believe that when the government seeks to restrict truthful speech in order to suppress the ideas it conveys, strict scrutiny is appropriate, whether or not the speech in question may be characterized as 'commercial.'" (quoting *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 572 (2001) (Thomas, J., concurring in part and concurring in

judgment))). The Second Circuit's analysis goes against this tide, suggesting a much weaker burden on the government than *Central Hudson* requires.

This Court should grant *certiorari* to preserve constitutional protections for commercial speech and to ensure that the government must satisfy a meaningful burden to justify enacting a content-based infringement on commercial speech.

A. The Law Regulates Dietary Supplements Based on their Marketing

In October 2023, the New York legislature passed Gen. Bus. Law § 391-oo (the "**Law**"), and it went into effect on April 22, 2024. The Law restricts the sale to minors of dietary supplements that are "*labeled, marketed, or otherwise represented* for the purpose of achieving weight loss or muscle building." *Id.* § 391-oo(1)(a) (emphasis added). The Law's prohibition is triggered solely by speech about products. It is a content-based infringement on commercial speech—speech that is otherwise lawful and truthful for legal products that are extensively regulated by the Food and Drug Administration under the Food, Drug, and Cosmetic Act. *See generally* 21 U.S.C. § 301 *et seq.*

The Law's history is worth noting. In 2022, the New York legislature sought to address its concern that weight loss and muscle-building dietary supplements may "contain unlisted, illegal pharmaceutical ingredients that pose serious risks" to consumer health, and a more general concern about the prevalence of eating disorders among minors. C.A. App. 98. To address these concerns, it

passed Assembly Bill No. 431-C (the "**Predecessor Bill**"), which age-restricted dietary supplements based on a list of dangerous ingredients that the New York Department of Health ("**DOH**") would identify. Dist. Ct. ECF No. 25-2 at 2. But on December 23, 2022, New York Governor Hochul vetoed the Predecessor Bill, explaining that DOH apparently "does not have the expertise necessary to analyze ingredients used in countless products, a role that is traditionally played by the FDA." *Id.*

After the Governor's veto, the bill's sponsors pivoted. Bill A5610D, which became the Law, purported to address the same concern as the Predecessor Bill, *i.e.*, that certain dietary supplements "often contain unlisted, illegal pharmaceutical ingredients that pose serious risks," and a more general concern with eating disorders. C.A. App. 94. But instead of identifying those potentially dangerous ingredients (or particular products), the new legislation regulated dietary supplements based on speech associated with products. As the legislature explained:

> This legislation takes a new approach, focused on the way products are marketed, *regardless of their ingredients*. . . . This approach will target drugs [sic] based on their marketing rather than relying on a list of covered ingredients that the industry will soon work around.

Id. (emphasis added).

The Law does not explain how restricting dietary supplements based on their marketing has any connection to the consumption of dangerous ingredients or how it would reduce eating disorders in minors. The Law's

"Justification" section includes just four citations. C.A. App. 93-95. But these cited authorities relate to the consumption of products laced with illegal or dangerous pharmaceutical ingredients—a harm that could have been squarely addressed by prohibiting the sale of products with those ingredients. Nothing in the "Justification" connected the *marketing* of products to any danger for minors. *Id.* This is particularly troubling because the Law, on its face, would allow the sale of potentially dangerous products to minors as long as the manufacturer did not advertise the product as being for "weight loss." Indeed, a manufacturer would be allowed to sell *Product A* to minors but not *Product B*, an identical substance, so long as Product B claimed it aided in "weight loss."

B. The Council for Responsible Nutrition

Petitioner, the Council for Responsible Nutrition ("**CRN**"), is a national trade association for the dietary supplement industry. CRN is comprised of more than 160 companies that manufacture dietary ingredients and/or dietary supplements, or provide services to those suppliers and manufacturers. CRN's members produce a significant portion of the dietary supplements marketed in the United States and around the world. In deciding CRN's motion for a preliminarily injunction, the District Court held that CRN alleged sufficient facts to establish Article III standing on the basis of associational standing. *See* Pet. App. 41a. Specifically, the District Court found that CRN adequately pled that at least one of its members "has suffered an injury in fact related to the prospect of the State's enforcement of the [Law]." *Id.* at 39a.

The Law's use of speech as the trigger for its age-gating requirements directly burdens the communications CRN's members rely on to convey truthful information to consumers about their products, and thus directly implicates protected First Amendment speech.

C. Procedural History

On March 13, 2024, Petitioner filed its initial Complaint in the United States District Court for the Southern District of New York. Through 42 U.S.C. § 1983, the Complaint alleged violations of the First Amendment, among other claims, and sought declarative and injunctive relief. Petitioner filed an Amended Complaint on April 11, 2024.

1. The District Court Proceedings

On April 3, 2024, Petitioner filed an emergency motion for a temporary restraining order and preliminary injunction. The District Court denied the Motion on April 19, 2024, concluding that Petitioner was not likely to succeed on the merits. *See* Pet. App. 31a. The District Court first determined that the Law did not implicate the First Amendment, but instead regulated "conduct." *See id.* at 47a. But the District Court nevertheless went on to analyze the statute under *Central Hudson* and held that the Law would survive intermediate scrutiny. *See id.* With regard to *Central Hudson's* third prong, the court cited a letter from Dr. Jason Nagata, a pediatrician, who submitted testimony to the legislature in support of the Predecessor Bill. *See id.* at 49a; C.A. App. 108-09. But that letter, which was submitted in connection with an *ingredient-based* proposed legislation, does not link a product's marketing to any harm to minors.

With regard to *Central Hudson's* fourth prong, the District Court found that the Law was narrowly-tailored because it was not "a complete ban" on the sale of dietary supplements, it "carves out protein powders, protein drinks and foods marketed as containing protein" (which are not actually dietary supplements), and it "leaves open alternate avenues" to convey product information. *See* Pet. App. 51a-52a. The District Court also noted that the Governor had vetoed the Predecessor Bill. *See id.* at 51a.

After the District Court ruled on Petitioner's motion for preliminary injunctive relief (but before the Second Circuit's review of that order), the District Court ruled on Respondent's Motion to Dismiss. The District Court allowed Petitioner's First Amendment challenge to survive, noting the differences between the standards of review for preliminary injunctive relief and a motion to dismiss on the pleadings.

2. Appellate Proceedings

Respondents filed a timely Notice of Interlocutory Appeal to the United States Court of Appeals for the Second Circuit on May 14, 2024.

On November 13, 2025, the Second Circuit affirmed the District Court's decision denying a preliminary injunction, rejecting Petitioner's argument that the Law was an unconstitutional infringement on commercial speech. *See* Pet. App. 9a-15a. The panel rooted its decision on the likelihood of success of the First Amendment claim exclusively in the *Central Hudson* analysis.

The panel held that the Law would further the State's goal of protecting minors. *See id.* at 12a-14a. Specifically, the panel wrote that, "[w]hen a product's marketed purpose is an indicator of its risks, restricting sales of a product on that same basis—its marketed purpose—will directly advance the goal of reducing those risks." *Id.* at 14a. But the panel did not make a finding on any empirical evidence that regulating dietary supplements marketed for weight loss or muscle building will materially address a known harm to minors. In reaching its conclusion, the court cited "simple common sense" and two studies that were plainly inadequate for connecting the Law's specific content-based speech restriction to alleviating harm to minors. Still, the panel concluded that a product's marketing is a sufficient proxy for harm. *See id.* at 13a.

The panel then determined that the Law was no more restrictive than necessary to achieve its objective. *See id.* at 14a-15a. The Court rejected Petitioner's argument that there were alternatives available that did not implicate speech, specifically the ingredient-based approach of the Predecessor Bill. *See id.* at 15a. The panel did not analyze the Predecessor Bill or any other alternative that would not be triggered by a product's marketing. *See id.* Instead, the panel rested only on the premise that the Governor (but not the New York Legislature) vetoed the Predecessor Bill, and stated that it "must defer to [the Legislature's] reasonable judgment" as to the means to advance its interest. *Id.*

By Order dated December 30, 2025, the Second Circuit declined to grant rehearing *en banc*. *See id.* at 61a.

REASONS FOR GRANTING THE PETITION

I. THE *CENTRAL HUDSON* ANALYSIS PROVIDES THE MINIMUM SAFEGUARDS FOR PROTECTING COMMERCIAL SPEECH

Nearly fifty years ago, this Court held that commercial speech warrants First Amendment protection. *See Bigelow v. Virginia*, 421 U.S. 809, 818 (1975) (rejecting the Virginia Supreme Court's holding that "First Amendment guarantees . . . are inapplicable to paid commercial advertisements."). This holding recognized the important role that commercial speech has historically played in a free and democratic society, and, in particular, the ability of manufacturers to make truthful advertising and marketing claims about their products. As the Court later stated in *Va. State Bd. of Pharm. v. Va. Citizens Consumer Council, Inc.*,

> So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable.

425 U.S. 748, 764-65 (1976); *see also Central Hudson*, 447 U.S. at 561-62 ("Commercial expression not only serves the economic interest of the speaker, but also assists consumers and furthers the societal interest in the fullest possible dissemination of information."); *Edenfield v. Fane*, 507 U.S. 761, 767 (1993) ("The commercial marketplace,

like other spheres of our social and cultural life, provides a forum where ideas and information flourish. Some of the ideas and information are vital, some of slight worth. *But the general rule is that the speaker and the audience, not the government, assess the value of the information presented*." (emphasis added)).

In *Central Hudson*, this Court set forth the framework for assessing governmental intrusions on commercial speech. The *Central Hudson* "test," characterized as a variation of "intermediate" scrutiny, *see Edenfield*, 507 U.S. at 767, requires a court to consider four factors in determining whether a law that infringes commercial speech is constitutional:

(1) whether the speech is not misleading and "concern[s] lawful activity";

(2) "whether the asserted governmental interest is substantial";

(3) "whether the regulation directly advances the governmental interest asserted"; and

(4) "whether [the regulation] is not more extensive than necessary to serve that interest."

Central Hudson, 447 U.S. at 566. The government bears the burden to justify its restrictions. *See Edenfield*, 507 U.S. at 770 (citing *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 71 n.20 (1983)). If the government is unable to meet its burden on all four factors, the infringement violates the First Amendment.

Over the past several decades, members of the Court have periodically cast doubt on whether *Central Hudson* provides *adequate* First Amendment protection. *See Matal*, 582 U.S. at 253 (Thomas, J., concurring) (quoting *Lorillard*, 533 U.S. at 572 (Thomas, J., concurring)); *Greater New Orleans*, 527 U.S. at 197 (Thomas, J., concurring); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 518-28 (1996) (Thomas, J., concurring in part and concurring in judgment); *Thompson*, 535 U.S. at 377 (Thomas, J., concurring); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 492 (1995) (Stevens, J., concurring in judgment) (characterizing the *Central Hudson* approach as "misguided"); *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 431 (1993) (Blackmun, J., concurring) ("I write separately because I continue to believe that the analysis set forth in *Central Hudson* and refined in [*Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469 (1989)] affords insufficient protection for truthful, noncoercive commercial speech concerning lawful activities.").

The appetite for more stringent Constitutional protection for commercial speech became apparent following this Court's decision in *Sorrell*, 564 U.S. 552. In examining the constitutionality of a law restricting commercial speech relating to pharmacy records, this Court stated that "[t]he First Amendment requires heightened scrutiny whenever the government creates 'a regulation of speech because of disagreement with the message it conveys.'" *Id.* at 566. This allusion to heightened scrutiny for content-based commercial speech restrictions left an open question as to when, and whether, a heightened standard of scrutiny should be used. *See Vugo, Inc. v. City of New York*, 931 F.3d 42, 50 (2d Cir. 2019) (noting lack of uniformity among Circuits about *Central Hudson*'s

viability where commercial speech regulation is content-based); *Junior Sports Magazines Inc. v. Bonta*, 80 F.4th 1109, 1115 n.1 (9th Cir. 2023) (declining to answer whether heightened scrutiny applies to content-based commercial speech restrictions); *see also Int'l Outdoor, Inc. v. City of Troy, Mich.*, 974 F.3d 690, 702-03 (6th Cir. 2020) (concluding that content-based commercial speech restrictions warrant heightened scrutiny).

To be clear, this Petition does not ask this Court to discard the *Central Hudson* framework. Instead, it asks the Court to enforce that test with the rigor it has historically been afforded. The Court should reaffirm that the government must prove *with evidence* that its regulation materially advances its interests and that it has carefully tailored its approach in light of non-speech alternatives.

II. THE SECOND CIRCUIT'S APPROACH CONFLICTS WITH OTHER CIRCUITS BY REDUCING THE GOVERNMENT'S BURDEN TO EMPIRICALLY JUSTIFY COMMERCIAL SPEECH RESTRICTIONS.

A. The Third Prong of *Central Hudson* Requires the Government to Demonstrate that the Regulation will Advance its Goals in a Direct and Material Way.

The third *Central Hudson* prong requires the government to "demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Greater New Orleans*, 527 U.S. at 188 (quoting *Edenfield*, 507 U.S. at 770-71). The government

cannot rest on "mere speculation or conjecture" to show the relationship between the regulation and the harm it seeks to prevent. *See Edenfield*, 507 U.S. at 770. Instead, the government must make this showing in a "direct and material way," *id.* at 767, as "ineffective or remote support for the government's purpose" will not suffice. *Id.* at 770. This demanding threshold is a "critical" part of the *Central Hudson* framework. *Rubin*, 514 U.S. at 487. That is because, "[w]ithout this requirement, a state could with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression." *Edenfield*, 507 U.S. at 771.

In *Edenfield*, the Court struck down a Florida statute banning in-person solicitations by certified public accountants. 507 U.S. at 763. Specifically, the Court relied on the government's failure to "present[] studies" suggesting that in-person solicitation "creates the dangers of fraud, overreaching, or compromised independence that the [government] claims to fear." *Id.* at 771. Given that all the government submitted to justify the ban was an affidavit "contain[ing] nothing more than a series of conclusory statements," the Court held that the government failed to meet its burden to show that the ban "will" "in fact" "alleviate [a specific harm] to a material degree." *Id.*[1]

1. A version of this evidentiary requirement even predates *Central Hudson*. The Court invalidated an ordinance that prohibited "For Sale" signs on the front lawns where, *inter alia*, there was no record evidence showing that specific restriction would advance the government's goal of "promoting stable, racially integrated housing." *See Linmark Assocs. Inc. v. Willingboro Twp.*, 431 U.S. 85, 94-95 (1977).

Since *Edenfield*, this Court has rigorously held the government to this burden to justify restrictions on commercial speech with empirical data, such as relevant and "convincing" studies. For example, this Court found that the commercial speech restriction in *Rubin*—a federal prohibition on displaying alcohol content on beer labels—failed where the government tried to meet its third prong burden on the basis of "anecdotal evidence and educated guesses" to support its assertion that the labeling ban prevented its feared alcohol "strength wars." 514 U.S. at 490. This Court held that, in the absence of "convincing evidence" that the burden on commercial speech (restricting the information a manufacturer was allowed to put on beer labels) would actually result in increased alcohol content, the regulation was unconstitutional. *Id.*

In perhaps the strongest articulation of the government's burden on prong three, a plurality of this Court in *44 Liquormart, Inc. v. Rhode Island*, held that a Rhode Island statute that banned references to prices in alcohol advertising was unconstitutional where, *inter alia*, "the State has presented no evidence to suggest that its speech prohibition will *significantly* reduce marketwide consumption." 517 U.S. 484, 506 (1996) (emphasis added). The Court concluded that, "without any findings of fact, or indeed any evidentiary support whatsoever," *id.* at 505, "any conclusion that elimination of the ban would significantly increase alcohol consumption would require us to engage in the sort of 'speculation or conjecture' that is an unacceptable means of demonstrating that a restriction on commercial speech directly advances the State's asserted interest." *Id.* at 507 (quoting *Edenfield*, 507 U.S. at 770).

Where this Court has found that the third prong of *Central Hudson* is satisfied, it is only where the government demonstrated *with evidence* that the commercial speech restriction actually and materially advanced the government's asserted interest. For example, in *Florida Bar v. Went For It, Inc.*, 515 U.S. 618 (1995), this Court upheld a bar association rule banning personal injury attorneys from direct outreach to victims for thirty days—but only after considering the Bar's submission of a 106-page summary of a two-year study that supported, with data, the Bar's suggestion that this specific type of ban will directly protect the integrity of the profession and the privacy of accident victims. *See id.* at 626-28. The summary "contain[ed] data—both statistical and anecdotal—supporting the Bar's contentions that the Florida public views direct-mail solicitations in the immediate wake of accidents as an intrusion on privacy that reflects poorly upon the profession." *Id.* at 626. The Court held, "in light of this showing," that the Bar satisfied the third prong of *Central Hudson*. *Id.* at 628; *see also Lorillard*, 533 U.S. at 557, 561 (finding third prong met where there were "numerous studies" that advertising tobacco products stimulates demand for tobacco products and disputing suggestion that the government failed to submit "evidence that preventing targeted campaigns and limiting youth exposure to advertising will decrease underage use"). The Court expressly contrasted this showing with the absence of evidence in *Edenfield*. *See Florida Bar*, 515 U.S. at 628.

B. The Second Circuit Erred by Relying on "Common Sense" Rather Than Any Proof of "Direct Advancement."

The Second Circuit's analysis of *Central Hudson's* third prong failed to hold the government to its substantial burden. Indeed, the Second Circuit misstated the government's burden by relying on an out-of-context quote from *Lorillard*, *see* Pet. App. 12a, suggesting that the burden of showing "direct advancement" could be met by pointing not only to studies, but also to anecdotes, as well as to "history, consensus, and 'simple common sense.'" *Lorillard*, 533 U.S. at 555 (quoting *Florida Bar*, 515 U.S. at 628). This line from *Florida Bar* was dicta. It followed the Court's conclusion in that case that, "in light of [the government's] showing" involving a substantial study demonstrating the direct link between the speech restriction and the alleviation of harm, *Central Hudson*'s third prong was satisfied. *See Florida Bar*, 515 U.S. at 628-29. The *Florida Bar* opinion went on to rebut the dissent's argument that the summary did not suffice. *See id.* at 640 (Kennedy, J., dissenting). In response, the Court argued that the summary was "sufficient to meet the standard elaborated in *Edenfield*." *Id.* at 628. In making this point, the Court noted that "*in other First Amendment contexts*," such as cases involving conflicting constitutional rights, speech restrictions have been justified by reference to, "history, consensus, and common sense." *Id.* (emphasis added). This statement did not create a new standard; it reinforced that the evidentiary burden set forth in *Edenfield* was still the operative standard.

The *Florida Bar* Court's passing reference to "common sense" is clearly *dicta* and not an annunciation of a new

rule allowing "common sense" to satisfy *Central Hudson's* third-prong in the absence of "evidence." Neither *Florida Bar*, nor *Lorillard*, which cited the same language, stand for the proposition that the government can demonstrate direct advancement on the basis of "common sense." Indeed, in both cases, the Court found the third *Central Hudson* prong satisfied by substantial studies showing a direct link between the speech infringement and the alleviation of the perceived harm. *See Lorillard*, 533 U.S. at 557-61 (proper evidentiary link established between advertising restrictions and use of tobacco products, which are known to be unsafe); *Florida Bar*, 515 U.S. at 625-29. And this Court has never found this prong satisfied by reference to "common sense." Relying on this flawed read, the Second Circuit held that the government had satisfied *Central Hudson's* third prong based solely on a series of weak premises: *first*, in citing *Lorillard*, the court stated that "it is 'simple common sense' that prohibiting supplement sales to minors will reduce supplement consumption in minors." No other evidence or explanation was offered that prohibiting sales would actually reduce minors' supplement consumption (which is still legal)—this was mere speculation by the court, particularly given other means of access by minors. Then, *second*, the court conceded that there is no evidence for the proposition that the supplements *as specifically defined in the Law* are actually harmful to minors; rather, it noted only "the category of products targeted by [the Law] . . . is *generally* the same category used in the cited literature to identify supplements that are especially harmful." Pet. App. 13a (emphasis added). And *third*, perhaps reflecting the lack of any such direct evidence, the panel concluded that here, the regulated products' "marketed purpose" is merely "an *indicator* of

its risks," *id.* (emphasis added), a tenuous connection that is nowhere close to an *actual reflection* of real risk. But absent evidence that a category of supplements marketed as "weight loss" or "muscle building" is actually harmful to minors, and that (by extension) restricting access to this category of products would directly alleviate harm to minors, any such conclusion rests entirely on pure, unsupported speculation.[2] And it certainly cannot support the requisite standard of an "actual" and "material" advancement of the government's goal. Therefore, unlike in cases restricting access to tobacco products or alcohol, where there is a known, well-documented harm inherent to the product regulated, here, restricting access to products based on their marketing to reduce consumption will not reduce the incidence of a known harm. The Second Circuit's analysis is a significantly watered-down version of this prong of *Central Hudson* that is a far cry from the exacting evidentiary burden this Court has demanded.[3]

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2. In fact, even the Law's own sponsor could not point to specific studies establishing a link between the marketing of supplements and the Legislature's purported harms and rested on "trust[ing] that it's probably out there." Dist. Ct. ECF No. 25-1 at 7.

3. The referenced studies are otherwise problematic and do not provide "convincing" evidence that the Law's content-based restriction would "directly" and "materially" alleviate an actual harm to minors. In dissenting from the denial of a petition for writ of certiorari in *Borgner v. Florida Bd. of Dentistry*, 537 U.S. 1080 (2002), members of this Court suggested that it would be appropriate for the Court "to clarify some oft-recurring issues in the First Amendment treatment of commercial speech," *id.*, noting that prior Court decisions "have not . . . sufficiently clarified the nature and the quality of the evidence a State must present" to satisfy the third *Central Hudson* prong. *Id.* This case presents that opportunity, also as it relates to the quality of the evidence on which the Second Circuit relied for the third prong analysis.

C. The Decision Below Widens a Circuit Split.

The Second Circuit's decision also deepened an existing conflict among the circuits about what level of evidence adequately satisfies *Central Hudson*'s third prong. Further percolation is unnecessary and will not change the positions on either side of the split.

At least five Circuits have demanded that the government support speech-infringing regulations with exacting and supportive data as contemplated in *Edenfield* and *44 Liquormart*. *See*, *e.g.*, *Bailey v. Morales*, 190 F.3d 320, 324 (5th Cir. 1999) (regulation failed third prong where the state "relie[d] on 'common sense,' not data or empirical evidence."); *Pac. Frontier v. Pleasant Grove City*, 414 F.3d 1221, 1235 n.12 (10th Cir. 2005) (rejecting argument that common sense and anecdotal evidence justified the restriction by comparing it to the evidence presented in *Florida Bar* and finding proposed evidence inadequate to satisfy third prong). The Fourth Circuit recently held that a West Virginia regulation of attorney advertising satisfied the third prong of *Central Hudson* because, *inter alia*, the regulation prevented use of the ***specific*** phrases that the studies showed were misleading to consumers. *See Recht v. Morrissey*, 32 F.4th 398, 414-15 (4th Cir. 2022) ("To prevent these specific misperceptions by the audience—and the misguided courses of action that might spring from them—the State has prohibited these specific practices by attorneys.").

Just recently, the Ninth Circuit decided *Junior Sports Magazines Inc. v. Bonta*, 80 F.4th 1109 (9th Cir. 2023), and considered whether "common sense" was enough to justify a California law that prohibited a "firearm industry

member" from "advertis[ing], market[ing], or arrang[ing] for" advertising of firearm-related products in a manner "attractive to minors." *Id.* at 1114 (quoting Cal. Bus. & Prof. Code § 22949.80(a)(1)). The Ninth Circuit rejected the government's "common sense" justification for the commercial speech regulation, holding that "a state can invoke 'common sense' only if the connection between the law restricting speech and the government goal is so direct and obvious that offering evidence would seem almost gratuitous." *Id.* at 1118.

The Sixth Circuit, too, has determined that "a standard of 'obviousness' or 'common sense'" does not suffice to satisfy *Central Hudson*'s requirement to substantiate a regulation's direct advancement of a substantial government interest. *Pagan v. Fruchey*, 492 F.3d 766, 774 (6th Cir. 2007) (*en banc*). The Sixth Circuit expressly declined to adopt a standard that would allow "a speech regulation in the absence of evidence of concrete harm so long as common sense clearly indicates that a particular speech regulation will directly advance the government's asserted interest." *Id.* The court held that this would not meet the standard set forth by this Court in *Edenfield*, which "require[d] *some* evidence to establish that a speech regulation addresses actual harms with some basis in fact." *Id.* (emphasis included).

On the other side of the circuit split, the First Circuit (like the Second) has interpreted the third *Central Hudson* prong to require a far less stringent evidentiary standard. In *IMS Health Inc. v. Ayotte*, the court admitted that the government's showing linking its interest and its regulation "was not overwhelming" and that "there was no direct evidence on that point." 550 F.3d 42, 55, 57 (1st

Cir. 2008). But the court concluded that "[a] state need not go beyond the demands of common sense to show that a statute promises directly to advance an identified governmental interest," *id.* at 57, finding the fourth prong adequately demonstrated. *Id*. at 59. And although it more recently relied on an evidentiary showing to support the third *Central Hudson* prong in *Recht*, 32 F.4th at 414-15, the Fourth Circuit has also relied on common sense, as opposed to empirical evidence, in upholding a regulation's constitutionality. *See WV Ass'n of Club Owners & Frat. Svcs, Inc. v. Musgrave*, 553 F.3d 292, 303, 305 (4th Cir 2009).

This split among the circuits warrants clarification by the Court. In *Greater New Orleans*, this Court expressed doubt over whether a federal prohibition on broadcast advertising of lotteries and casino gambling withstood prong three of the *Central Hudson* analysis. 527 U.S. at 189. The Court appeared concerned that evidence was lacking connecting the specific harm (casino gambling) with the specific regulation (regulating advertising for certain casinos). *See id.* But it noted that it "need not resolve the question whether any lack of evidence in the record fails to satisfy the standard of proof under *Central Hudson*" because the regulation failed on the fourth prong (narrow tailoring). *Id.* at 190.

Several years later, this Court was faced with a petition for writ of certiorari in *Borgner v. Florida Bd. of Dentistry*, 537 U.S. 1080 (2002), that could have resolved the question about sufficiency of certain evidence to support the third prong of the *Central Hudson* test. That case involved a challenge to a Florida statute that restricted advertising by dentists, requiring a discussion

of a dental specialty to be accompanied by a disclosure that the specialization was not state-approved. *See id.* The challenger "raise[d] serious questions about the validity of the surveys on which" the courts below found the direct advancement prong satisfied. *Id.* The Court chose not to grant the petition, but a dissent authored by Justice Thomas, joined by Justice Ginsburg, lamented that the case "present[ed] an excellent opportunity to clarify some oft-recurring issues in the First Amendment treatment of commercial speech," *id.*, noting that prior Court decisions "have not . . . sufficiently clarified the nature and the quality of the evidence a State must present" to satisfy the third *Central Hudson* prong. *Id.*

Given this circuit split on a matter of great public importance, this Court should grant *certiorari* and clarify the evidentiary burden required for governmental intrusions on commercial speech with respect to *Central Hudson's* third prong. This case provides an ideal vehicle to address this split and to reaffirm the scope of the constitutional protections for commercial speech.

III. THE SECOND CIRCUIT'S DECISION IMPROPERLY ELIMINATES *CENTRAL HUDSON'S* FOURTH PRONG.

The Second Circuit's application of *Central Hudson*'s fourth prong is even more problematic. *Central Hudson*'s fourth prong considers the "relationship between the [government's] interests and the means chosen to serve them." *Florida Bar*, 515 U.S. at 632. This Court requires the government to demonstrate that the "restriction on speech be no more extensive than necessary," *44 Liquormart, Inc.*, 517 U.S. at 507 (plurality), and that

the "regulation of speech is [] sufficiently tailored to its goal." *Rubin*, 541 U.S. at 490. In addition, "the challenged regulation should indicate that its proponent carefully calculated the costs and benefits associated with the burden on speech imposed by its prohibition." *Greater New Orleans*, 527 U.S. at 188 (internal quotation marks and citation omitted). Under the fourth prong, the government must "affirmatively establish the reasonable fit." *Fox*, 492 U.S. at 480.

In the years after *Central Hudson*, this Court has demanded an increasingly more exacting burden for the government to satisfy this fourth prong.[4] In *44 Liquormart*, a plurality of this Court rejected Rhode Island's argument, in reliance on a prior case, *Posadas de Puerto Rico Assocs v. Tourism Co. of Puerto Rico*, 478 U.S. 328 (1986), that "it merely exercised appropriate 'legislative judgment' in determining" that a ban on alcohol pricing was the best way to achieve its goal of temperance. *44 Liquormart*,

4. In *Posadas de Puerto Rico Assocs v. Tourism Co. of Puerto Rico*, the Court upheld restrictions on casino advertising to Puerto Rico residents. 478 U.S. 328, 344 (1986). The Court reasoned, among other things, that "it is up to the legislature to decide whether or not such a 'counterspeech' policy would be as effective in reducing the demand for casino gambling as a restriction on advertising." *Id.*; *see also Metromedia, Inc. v. City of San Diego*, 453 U.S. 490, 508 (1981) (upholding infringement on commercial speech in billboard regulation, deferring to the reasonable judgment of legislators); *Fox*, 492 U.S. at 481 (noting that *Central Hudson*'s fourth prong "provide[s] the Legislative and Executive Branches needed leeway in a field (commercial speech) 'traditionally subject to governmental regulation'") (citation omitted). But that legislative deference was short-lived and replaced with a more exacting and demanding burden for the government.

517 U.S. at 508. The *44 Liquormart* plurality noted: "we are now persuaded that *Posadas* erroneously performed the First Amendment analysis" and that the *Posadas* Court "clearly erred in concluding that it was 'up to the legislature' to choose suppression over a less speech-restrictive policy." *Id.* at 509. The plurality reasoned that the holding in *Posadas* "cannot be reconciled with the unbroken line of prior cases striking down similarly broad regulations on truthful, nonmisleading advertising when non-speech-related alternatives were available," *see id.* at 509-10, and ultimately "decline[d] to give force to [*Posada*'s] highly deferential approach." *Id.* at 510. The Court struck down the commercial speech restriction because it was "perfectly obvious that alternative forms of regulation that would not involve any restriction on speech would be more likely to achieve" the government's stated goal. *See id.* at 507.

In line with and since the *44 Liquormart* decision, this Court has consistently addressed *Central Hudson*'s fourth prong by considering whether there are available alternative methods to achieve the same policy goals in a manner that does not infringe on speech (or infringes less). And it has consistently declined to defer to legislative judgments, deciding instead to strike down regulations of commercial speech in service of policy goals that could have been accomplished without infringing on speech. *See*, *e.g.*, *Rubin*, 514 U.S. at 490 ("We agree that the availability of these options, all of which could advance the Government's asserted interest in a manner less intrusive to respondent's First Amendment rights, indicates that [the regulation] is more extensive than necessary."); *Greater New Orleans*, 527 U.S. at 193 (finding regulation not narrowly tailored because "the availability of other regulatory options

which could advance the asserted interests in a manner less intrusive to petitioners' First Amendment rights"); *Lorillard*, 533 U.S. at 561 (advertising restrictions failed the fourth-prong of *Central Hudson* because the "broad sweep of the regulations indicates that the [government] did not carefully calculate the costs and benefits associated with the burden on speech imposed by the regulations"); *see also United States v. Am. Library Ass'n, Inc.*, 539 U.S. 194, 218 (2003) (Breyer, J., concurring) (noting the *Central Hudson* approach is "more flexible [than strict scrutiny] but nonetheless provides the legislature with less than ordinary leeway in light of the fact that constitutionally protected expression is at issue.").

In one of this Court's most recent encounters with the fourth *Central Hudson* prong, the Court reiterated that the availability of non-speech-based alternatives is paramount in this analysis: "we have made clear that if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so." *Thompson*, 535 U.S. at 371. "If the First Amendment means anything, it means that regulating speech must be a last—not first—resort." *See id.* at 373. The *Thompson* court struck down a ban on advertising compound drugs where the government did not address why less-speech-restrictive alternatives "would be insufficient" to achieve its goals. *See id.*

Here, the Second Circuit's analysis of *Central Hudson's* fourth prong ignored this Court's clear precedent. The Circuit (again) applied the wrong standard: "We will defer to the Legislature's reasonable judgment about how best to achieve those objectives." Pet. App. 14a (citing *Clear Channel Outdoor, Inc. v. City of New York*, 594 F.3d 94,

104 (2d Cir. 2010)). But *Clear Channel*'s deference to legislative judgment was cabined specifically to the realm of billboards.[5] And *Clear Channel* clearly conflicts with the decades of cases by this Court rejecting blind deference to legislative judgments about fashioning solutions to substantial government interests in favor of "careful[] calculat[ion of] the costs and benefits associated with the burden on speech imposed by its prohibition." *Greater New Orleans*, 527 U.S. at 188 (citation omitted). The Circuit blindly deferred to the legislature, which determined that the governor's veto of an ingredient-based alternative restriction justified a turn to a speech-based legislation as a proxy for addressing the harm. This violates this Court's fourth prong jurisprudence.

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5. *See IMS Health Inc. v. Sorrell*, 630 F.3d 263, 279-80 (2d Cir. 2010), *aff'd* 564 U.S. 552 (2011) ("[R]eliance on *Clear Channel* is misplaced because that decision specifically addresses a regulation of commercial billboards, a distinctive method of speech that poses unique problems such as the potential to distract drivers and is therefore particularly amenable to government regulation."). *Clear Channel* itself framed its deference in narrow terms. *See Clear Channel* 594 F.3d at 104 ("[I]f the City's determination about how to regulate *outdoor commercial advertising* is 'reasonable'—and we find that it is in this case—then we should defer to that determination." (emphasis added)). This Court, and others, have recognized that legislative determinations in the limited space of the aesthetics of outdoor billboards are subject to deference. *See*, *e.g.*, *Metromedia*, 453 U.S. at 508-09 ("We [] hesitate to disagree with the accumulated, common-sense judgments of local lawmakers and the many reviewing courts that billboards are real and substantial hazards to traffic safety."); *see also Interstate Outdoor Advert., L.P. v. Zoning Bd. of Twp. of Mount Laurel*, 706 F.3d 527, 532-33 (3d Cir. 2013).

A. The Decision Below Deepens an Existing Circuit Split.

The decision below conflicts with most other circuits, which refuse to grant deference to legislative judgments and instead require the government to establish that infringements on commercial speech are a last resort in the face of alternatives. *See*, *e.g.*, *Healthy Vision Association v. Abbott*, 138 F.4th 385, 404-05 (5th Cir. 2025) (finding fourth prong not satisfied in the presence of alternative measures that would not infringe on speech); *Yim v. City of Seattle*, 63 F.4th 783, 795-98 (9th Cir. 2023) (same); *Missouri Broad. Ass'n v. Schmitt*, 946 F.3d 453, 461-62 (8th Cir. 2020) ("Missouri contends these alternatives are infeasible for a variety of reasons. But it remains Missouri's burden to establish that the current Statute is narrowly tailored to its interest—and it has not satisfied this burden."); *Bank of Hope v. Miye Chon*, 938 F.3d 389, 396-97 (3d Cir. 2019) (finding fourth prong not satisfied in the presence of potential alternative options); *FF Cosmetics FL, Inc. v. City of Miami Beach*, 866 F.3d 1290, 1299-1301 (11th Cir. 2017) (same); *Nat'l Ass'n of Mfrs. v. S.E.C.*, 800 F.3d 518, 556 (D.C. Cir. 2015) ("Without any evidence that alternatives would be less effective, we still cannot say that the restriction here is narrowly tailored."); *U.S. West, Inc. v. F.C.C.*, 182 F.3d 1224, 1238-39 (10th Cir. 1999) (finding law unconstitutional where government failed to demonstrate narrow tailoring); *Pagan*, 492 F.3d at 778 (6th Cir. 2007) (rejecting district court's holding that "it was not the place of the courts to second-guess [municipality's] decision" in connection with narrow tailoring); *cf. Musgrave*, 553 F.3d at 305-07 (upholding regulation after conducting exacting analysis of usage of less-speech-restrictive means). These other

Circuits have required governments to demonstrate that statutes that infringe on commercial speech are narrowly tailored—they have not deferred to the government's decision to infringe speech.

Indeed, a partial concurrence by a panel in the Fifth Circuit recently raised the concern that deference to the legislature's judgment to infringe on commercial speech is irreconcilable with *Central Hudson's* intermediate scrutiny. In *Reagan Nat'l Advert. of Austin, Inc. v. City of Austin*, a judge criticized the majority's "substantial deference to the City's 'legislative judgment,'" noting that "such deference is inappropriate when applying intermediate scrutiny." 64 F.4th 287, 298 (5th Cir. 2023) (Elrod, J., concurring in part on remand). The judge continued, "in my view, the majority opinion's approach is really just rational-basis review masquerading as intermediate scrutiny." *Id.*; *see also U.S. West, Inc.*, 182 F.3d at 1239 ("The burden under the fourth prong of *Central Hudson* is significantly higher [than rational basis]. The FCC must not only demonstrate that it acted rationally, but that it narrowly tailored its regulations to meet its stated goals."); *F.T.C. v. Trudeau*, 662 F.3d 947, 953 (7th Cir. 2011) (distinguishing *Central Hudson* intermediate scrutiny analysis, which requires tailoring to be "carefully calculated," with the more lenient rational basis standard). The same concerns are relevant here.

Here, and in prior cases, the Second Circuit has excused the government from its burden under the fourth *Central Hudson* prong and essentially eliminated that factor altogether. Several years ago, in *Vugo*, the Second Circuit similarly held that it "must defer to the City's judgment" about the best way to address citizen concerns

with disruptive television ads in taxicabs. 931 F.3d at 58. *Vugo* relied also on the Second Circuit's analysis in *Clear Channel*—a case whose holding this Court has made clear is limited to billboard restrictions—for its proposition that it is appropriate to "defer[] to the city's judgment about 'the appropriate means to further [its] legitimate governmental interest.'" *Id.* (quoting *Clear Channel*, 594 F.3d at 105).

Allowing *Central Hudson's* fourth prong to be "satisfied" based on broad deference to legislative judgment would indeed reduce the burden to a rational basis review. But this Court has made clear that the government must "prove that the regulation directly advances [its] interest and is not more extensive than necessary to serve that interest." *Thompson*, 535 U.S. at 374 (cleaned up); *see also Florida Bar*, 515 U.S. at 632 ("Of course, we do not equate this test with the less rigorous obstacles of rational basis review"). This Court has not suggested that deference to the government's policy preference satisfies the narrow-tailoring requirement. Instead, the fourth prong ensures that an infringement on speech "must be a last—not first—result," *Thompson*, 535 U.S. at 373; *see also 44 Liquormart*, 517 U.S. at 512 ("[S]peech restrictions cannot be treated as simply another means that the government may use to achieve its ends.").

The Second Circuit relieved the government of any burden of "carefully calculat[ing] the costs and benefits associated with the burden on speech imposed by its prohibition." *Greater New Orleans*, 527 U.S. at 188 (internal quotation marks and citation omitted). Indeed, the panel below indicated it was *bound* to afford this deference and failed to scrutinize whether a non-speech

alternative—such as regulating supplements on the basis of their ingredients as the Predecessor Bill had done—was feasible. Instead, the panel held that the Governor's veto of the Predecessor Bill justified the Legislature's subsequent reliance on a speech-based proxy. But neither political convenience nor administrative preference justifies a content-based restriction on speech.

The Second Circuit's decision cannot be reconciled with this Court's approach to commercial speech, which requires evidence-based justifications, careful tailoring, and a meaningful judicial role in evaluating the fit between a regulation and the state's asserted interest. Importing rational-basis-like deference into *Central Hudson's* fourth prong weakens *Central Hudson* into a formality where the government may regulate commercial speech for whatever policy reasons it deems necessary. That is not, and has never been, the law. This Court should grant certiorari and clarify that legislative deference is improper in this context.

IV. THE DECISION BELOW RAISES ISSUES OF RECURRING AND NATIONWIDE IMPORTANCE.

This Court has long warned against even well-intentioned infringements on speech. *See Va. State Bd. of Pharm.*, 425 U.S. at 770 (First Amendment requires courts to "assume that [] information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them."); *Central Hudson*, 447 U.S. at 562 ("[W]e have rejected the 'highly paternalistic' view

that government has the complete power to suppress or regulate commercial speech.").

Here, New York has implemented a type of commercial speech restriction that this Court has not yet encountered: it uses marketing or labeling—*speech*—as the trigger for a sales ban. The Law does not regulate harmful ingredients or any product characteristics that are tied to actual risk. Instead it assumes—with no evidence—that speech can be an adequate proxy for harm. That approach heightens the risk of paternalism that this Court has repeatedly rejected.

Ponder the possible laws and regulations that could be enacted consistent with the reasoning of the decision below. If a legislature can rely on marketing, as opposed to product content or demonstrated harm, to justify regulation, then virtually any public policy concern can justify a speech-triggered restriction. For example, restaurants that describe their offerings as "fast food" or "grab and go" could be barred from serving minors based solely on a legislative assumption that fast food is bad for minors. Manufacturers could likewise be barred from selling minors foods labeled "snacks" because it is common sense that snack foods are bad for minors. All this could be done without any substantiation that items simply marketed as "fast," "quick," or "snacks" always (or even mostly), contain ingredients that are harmful for minors. Car manufacturers could be prohibited from selling vehicles advertised for their "performance" to drivers under twenty-five because that age group statistically causes more accidents—even without any link between

a "performance" claim and evidence the car contains features that lead to accidents by that cohort.[6]

These examples illustrate what makes the weakened form of scrutiny applied below so dangerous. In each scenario, the government would be using marketing or advertising as a proxy for a product's actual potential harm. And in each case, the government could advance its interests through other, non-speech-restrictive means. Treating speech as a proxy for harm—in the absence of convincing, empirical evidence connecting the speech to the harm—is fundamentally incompatible with the First Amendment's protection of truthful commercial speech.

Under the Second Circuit's approach, a legislature could enact any of these hypothetical laws so long as it invokes "common sense" and courts defer to the legislature's chosen means of regulation. This would be true even where non-speech alternatives exist. This case presents an opportunity to prevent that distortion of the commercial-speech doctrine before this speech-as-proxy-for-harm method of regulation spreads.

A. This Case is an Ideal Vehicle to Resolve the Questions Presented.

Finally, this case is a proper vehicle for the Court to clarify the rigor with which the *Central Hudson*

6. Allowing legislators to use speech as a proxy for unsupported harm would likely cause companies to make changes to their marketing to avoid triggering the speech-based regulation, which could eliminate truthful information about products to consumers.

framework must be applied. The panel's opinion squarely and expressly addresses the two legal questions presented.

No additional factual development is necessary, as the panel's reasoning entirely rests on legal standards. The Second Circuit expressly invoked "simple common sense" and "general" evidence (not specific to the manner of regulation in the Law and the harm to be addressed) to satisfy the third *Central Hudson* prong. Pet. App. 13a-14a. Then, with regard to *Central Hudson's* fourth prong, the decision below held that it was required to defer to the New York legislature's chosen means of advancing this goal. *Id.* at 14a-15a. Those holdings present clean questions of law that are suitable for this Court's review.

Further, it is important for the Court to clarify now the proper rigor of the *Central Hudson* analysis to assist courts across the country in evaluating commercial-speech regulations. Providing that guidance will also prevent further divergence among the district and circuit courts. This case presents a viable opportunity for the Court to ensure that *Central Hudson* remains a meaningful First Amendment safeguard.

CONCLUSION

For the foregoing reasons, the Petition for a Writ of Certiorari should be granted.

Respectfully submitted,

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APPENDIX

TABLE OF APPENDICES

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT, FILED NOVEMBER 13, 2025

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

No. 24-1343

COUNCIL FOR RESPONSIBLE NUTRITION,

Plaintiff-Appellant,

v.

LETITIA JAMES, IN HER OFFICIAL CAPACITY AS NEW YORK ATTORNEY GENERAL,

Defendant-Appellee.

August Term 2024
Argued: January 24, 2025
Decided: November 13, 2025

OPINION

Appeal from the United States District Court
for the Southern District of New York
Docket No. 1:24-cv-1881,
Andrew L. Carter, Jr., *District Judge*.

Before: CHIN, PÉREZ, and NATHAN, *Circuit Judges*.

Plaintiff-Appellant Council for Responsible Nutrition ("CRN"), a trade group representing the dietary-

supplement industry, sued the New York Attorney General to enjoin enforcement of Section 391-oo of the New York General Business Law, which prohibits selling dietary supplements to anyone under eighteen years old if the supplement "is labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building." N.Y. Gen. Bus. Law § 391-oo(1)(a). CRN alleges that the statute violates the First Amendment's Free Speech Clause, is unconstitutionally vague, and is preempted by federal law. The District Court denied CRN's motion for a preliminary injunction, finding that it was unlikely to succeed on the merits and had not established irreparable harm or a favorable balance of the equities. This appeal followed.

We affirm, as the District Court did not abuse its direction in finding that CRN failed to show a likelihood of success on the merits, that CRN failed to demonstrate irreparable harm absent relief, and that the public interest weighs against preliminarily enjoining the law.

AFFIRMED.

MYRNA PÉREZ, *Circuit Judge*:

Plaintiff-Appellant Council for Responsible Nutrition ("CRN"), a trade group representing the dietary-supplement industry, sued the New York Attorney General to enjoin enforcement of Section 391-oo of the New York General Business Law, which prohibits selling dietary supplements to anyone under eighteen years old if the supplement "is labeled, marketed, or otherwise

represented for the purpose of achieving weight loss or muscle building." N.Y. Gen. Bus. Law § 391-oo(1)(a). CRN alleges that the statute violates the First Amendment's Free Speech Clause, is unconstitutionally vague, and is preempted by federal law. The District Court denied CRN's motion for a preliminary injunction, finding that it was unlikely to succeed on the merits and had not established irreparable harm or a favorable balance of the equities. This appeal followed.

We affirm, as the District Court did not abuse its direction in finding that CRN failed to show a likelihood of success on the merits, that CRN failed to demonstrate irreparable harm absent relief, and that the public interest weighs against preliminarily enjoining the law.

BACKGROUND

I. Statutory Background

Responding to concerns that dietary supplements marketed for weight loss and muscle building were causing serious medical problems among some youth, the New York State Legislature in 2023 enacted Section 391-oo of the New York General Business Law, which banned the sale of these supplements to minors. Specifically, Section 391-oo provides that

> [n]o person, firm, corporation, partnership, association, limited liability company, or other entity shall sell or offer to sell or give away, as either a retail or wholesale promotion, an over-

> the-counter diet pill or dietary supplement for weight loss or muscle building within this state to any person under eighteen years of age. Retail establishments shall require proof of legal age for purchase of such products.

N.Y. Gen. Bus. Law § 391-oo(2).

"Dietary supplements for weight loss or muscle building" are defined as "a class of dietary supplement," excluding protein supplements, "that is labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building." *Id.* § 391-oo(1)(a).[1]

In the event of a violation of this statute, the Attorney General is authorized to make an application to a state court to enjoin an alleged offender from continuing the

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1. A "dietary supplement," in turn, is defined as

> (1) a product (other than tobacco) that is intended to supplement the diet and that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for the use by a person to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients; (2) intended for ingestion in pill, capsule, tablet, or liquid form; and (3) labeled as a "dietary supplement" pursuant to the federal Dietary Supplement Health and Education Act, 21 U.S.C. 321, as amended.

N.Y. Gen. Bus. Law § 831(2)(a); *see also id.* § 391-oo(1)(a) (incorporating this definition by reference).

violation. *Id.* § 391-oo(5). Courts, in actions filed by the Attorney General, are then tasked with deciding whether a particular supplement "is labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building." *Id.* § 391-oo(6). The statute sets out nonexclusive factors for a court to consider, including how the retailer categorizes the supplement, how it is labeled and marketed more broadly, and whether it contains certain enumerated ingredients. *Id.*

Section 391-oo represents the Legislature's second recent attempt to ban the sale of these supplements to minors. In 2022, it passed Assembly Bill 431-C, which would have charged the state's Department of Health ("DOH") with determining which products were covered by the ban. But the Governor vetoed that bill, finding that "DOH does not have the expertise necessary to analyze ingredients used in countless products, a role that is traditionally played by the FDA." Governor Kathy Hochul, Veto Message No. 122 (Dec. 23, 2022). The Legislature responded to that concern with Section 391-oo by targeting products based on how they are represented and sold, leaving it to the courts to decide on a case-by-case basis whether a particular product meets the statutory definition. *See* Mem. in Support of Legis., A. 5610-D, 2023 State Assemb., Reg. Sess. (N.Y. 2023).

II. Procedural History

On March 13, 2024, CRN sued the Attorney General to enjoin enforcement of the statute, which was set to go into effect on April 22 of that year. CRN moved for a

temporary restraining order and preliminary injunction on April 3, which the District Court denied on April 19. *Council for Responsible Nutrition v. James*, No. 24-CV-1881, 2024 WL 1700036, at *10 (S.D.N.Y. Apr. 19, 2024). CRN timely appealed.

On May 13, 2024, the District Court granted in part and denied in part the Attorney General's motion to dismiss, disposing of all but the First Amendment claim. The court found that, though it had denied a preliminary injunction in part because CRN was unlikely to succeed on its First Amendment claim, that claim was nonetheless plausible and did not warrant dismissal under Rule 12(b)(6). *Council for Responsible Nutrition v. James*, No. 24-CV-1881, 2024 WL 2137834, at *2–4 (S.D.N.Y. May 13, 2024).

STANDARD OF REVIEW

Because CRN seeks to preliminarily enjoin "government action taken in the public interest pursuant to a statutory . . . scheme," it must show (1) irreparable harm, (2) a likelihood of success on the merits, and (3) the injunction would serve the public interest. *Conn. State Police Union v. Rovella*, 36 F.4th 54, 62 (2d Cir. 2022) (quoting *Bronx Household of Faith v. Bd. of Educ.*, 331 F.3d 342, 349 (2d Cir. 2003)).

We review a district court's denial of a preliminary injunction for an abuse of discretion. *N. American Soccer League, LLC v. U.S. Soccer Fed'n, Inc.*, 883 F.3d 32, 36 (2d Cir. 2018). "A district court abuses its discretion when it

rests its decision on a clearly erroneous finding of fact or makes an error of law." *Id.* (quoting *Almontaser v. N.Y.C. Dep't of Educ.*, 519 F.3d 505, 508 (2d Cir. 2008)). We may affirm the denial of a preliminary injunction on any basis supported by the record. *Beal v. Stern*, 184 F.3d 117, 122 (2d Cir. 1999).

DISCUSSION

I. Jurisdiction

As an initial matter, we note that the parties dispute our appellate jurisdiction to review the District Court's denial of a preliminary injunction as to CRN's vagueness and preemption claims, because the District Court dismissed those claims pursuant to Rule 12(b)(6) the day before this appeal was filed. *See Council for Responsible Nutrition*, 2024 WL 2137834, at *3–4. The Attorney General asserts that because those claims have been dismissed, that "portion of CRN's appeal is moot." Appellee's Br. 49. Not so.

We have jurisdiction to review the denial of a preliminary injunction pursuant to 28 U.S.C. § 1292(a)(1). "A case becomes moot only when it is impossible for a court to grant any effectual relief whatever to the prevailing party." *Hassoun v. Searls*, 976 F.3d 121, 128 (2d Cir. 2020) (quoting *Knox v. Serv. Emps. Int'l Union, Local 1000*, 567 U.S. 298, 307, 132 S.Ct. 2277, 183 L.Ed.2d 281 (2012)). Likewise, an appeal from the denial of a preliminary injunction can be mooted by "the occurrence of the action sought to be enjoined." *Fid. Partners, Inc. v. First Tr. Co.*,

142 F.3d 560, 565 (2d Cir. 1998) (quoting *Bank of N.Y. Co. v. Ne. Bancorp, Inc.*, 9 F.3d 1065, 1067 (2d Cir. 1993)); *see also Irish Lesbian & Gay Org. v. Giuliani*, 143 F.3d 638, 644 (2d Cir. 1998) ("The purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held." (quoting *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395, 101 S.Ct. 1830, 68 L.Ed.2d 175 (1981))).

CRN's First Amendment claim remains live in the District Court, and there is no indication that the Attorney General has declined to enforce Section 391-oo. *Cf. Catanzano v. Wing*, 277 F.3d 99, 107 (2d Cir. 2001) ("Since . . . the State is no longer implementing the fiscal assessment laws, and there is no reason to expect that fiscal assessments are now occurring or that the legislature will reenact the laws, no controversy now exists with respect to this claim and it is therefore moot."). Therefore, enjoining enforcement of the statute during the pendency of the litigation as to the outstanding claim remains effectual relief as to all the claims, and the sought preliminary injunction is not moot.

In any event, dismissal of claims without final judgment does not render those claims moot in a preliminary injunction appeal. A preliminary injunction appeal is mooted when *all* the claims underlying that injunction are dismissed via a final judgment. *See, e.g.*, *Ruby v. Pan American World Airways, Inc.*, 360 F.2d 691, 691 (2d Cir. 1966) (per curiam); *Pierce v. Woldenberg*, 498 F. App'x 96, 97–98 (2d Cir. 2012) (summary order). That is because "[w]hen a district court enters a final

judgment in a case, interlocutory orders rendered in the case typically merge with the judgment for purposes of appellate review." *Shannon v. Gen. Elec. Co.*, 186 F.3d 186, 192 (2d Cir. 1999). That merger extinguishes the availability of the *interim* relief sought in a preliminary injunction, which is why the appeal of that preliminary injunction is moot. So where there is no final judgment, *interim* relief remains available, and the preliminary injunction appeal is not moot.

To illustrate, the District Court here did not dismiss all of CRN's claims. *See Council for Responsible Nutrition*, 2024 WL 2137834, at *2–4. The District Court could thus revise its dismissal order to resurrect CRN's preemption and vagueness claims "at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities." Fed. R. Civ. P. 54(b). Furthermore, Rule 54(b) also states that "the court may direct entry of a final judgment as to one or more, but fewer than all, claims." Accordingly, until there is a final judgment, whether the District Court properly denied a preliminary injunction on CRN's vagueness and preemption claims remains a live controversy that we have jurisdiction to review.

II. Likelihood of Success on the Merits

A. Burdens on Commercial Speech

CRN's principal First Amendment claim is that Section 391-oo unconstitutionally burdens the commercial speech of its members by limiting their sales of dietary

supplements based on that speech. For this claim to succeed, Section 391-oo must constitute a (1) content-based regulation (2) of commercial speech that (3) fails intermediate scrutiny. *See Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566, 100 S.Ct. 2343, 65 L.Ed.2d 341 (1980). It does not. Even assuming that Section 391-oo is a content-based regulation—which the parties contest—it would nonetheless satisfy intermediate scrutiny under the *Central Hudson* test. *See id.*[2]

Section 391-oo satisfies intermediate scrutiny under *Central Hudson* if "(1) the speech restriction concerns lawful activity; (2) the [state]'s asserted interest is substantial; (3) the prohibition 'directly advances' that interest; and (4) the prohibition is no more extensive than necessary to serve that interest." *Vugo, Inc. v. City of New York*, 931 F.3d 42, 51 (2d Cir. 2019) (citing *Cent. Hudson*, 447 U.S. at 566, 100 S.Ct. 2343). As to the first prong, the parties agree that the speech implicated by the statute concerns lawful activity. We thus address the remaining three prongs.

1. Substantial Governmental Interest

The Attorney General, on behalf of New York, asserts that "[t]he goal of [Section] 391-oo is to protect the health of minors by limiting their access to weight-loss and

2. The parties agree—as do we—that the speech at issue is "commercial," since it is "related solely to the economic interests of the speaker and its audience." *Cent. Hudson*, 447 U.S. at 561, 100 S.Ct. 2343.

muscle-building supplements." Appellee's Br. 31. It is well established that the state has a substantial interest in protecting the public's health. *See Rubin v. Coors Brewing Co.*, 514 U.S. 476, 485, 115 S.Ct. 1585, 131 L.Ed.2d 532 (1995) ("[T]he Government here has a significant interest in protecting the health, safety, and welfare of its citizens by preventing brewers from competing on the basis of alcohol strength, which could lead to greater alcoholism and its attendant social costs."). And when it comes to "safeguarding the physical and psychological well-being of a minor," that interest is not only substantial, it is "compelling." *Globe Newspaper Co. v. Superior Ct.*, 457 U.S. 596, 607, 102 S.Ct. 2613, 73 L.Ed.2d 248 (1982).

CRN argues that the state lacks a substantial interest in restricting the disclosure of accurate information—namely, the weight-loss and muscle-building benefits of certain supplements. By burdening the marketing of these benefits, CRN argues, retailers and producers are less likely to make consumers aware of them. But this *Central Hudson* prong is concerned with whether the state's "*asserted* interest is substantial." *Vugo*, 931 F.3d at 51 (emphasis added); *see also, e.g.*, *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 368–69, 122 S.Ct. 1497, 152 L.Ed.2d 563 (2002) (analyzing the asserted interests as articulated by the government). The state's asserted interest here is not in restricting the flow of information to consumers, but in protecting the health of minors. The question is not whether Section 391-oo is effective at achieving that objective, nor whether its costs outweigh its benefits. CRN does not dispute—nor could it reasonably—that the interest in protecting the health of minors is, at a minimum, substantial.

2. Directly Advances the Asserted Interest

Under the third *Central Hudson* prong, the Attorney General must show (1) that the asserted harms "are real" and (2) that Section 391-oo's speech restrictions "will in fact alleviate them to a material degree." *Vugo*, 931 F.3d at 52 (quoting *Edenfield v. Fane*, 507 U.S. 761, 771, 113 S.Ct. 1792, 123 L.Ed.2d 543 (1993)). She can meet this burden "by reference to studies and anecdotes" as well as "history, consensus, and 'simple common sense.'" *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 555, 121 S.Ct. 2404, 150 L.Ed.2d 532 (2001) (quoting *Fla. Bar v. Went for It, Inc.*, 515 U.S. 618, 628, 115 S.Ct. 2371, 132 L.Ed.2d 541 (1995)).

The record here contains sufficient evidence that (1) a significant number of minors consume dietary supplements aimed at losing weight or building muscle and that (2) these supplements can cause serious medical problems. In a letter to the State Legislature, Dr. Jason Nagata, a pediatrician, summarized some of the scientific literature on the issue:

> Rigorous scientific study after study has shown that these types of supplements pose serious health risks to consumers. A recent study found that youth using weight-loss supplements were three times more likely than those using ordinary vitamins to experience severe medical harm, including hospitalization, disability, and even death. Studies have linked weight loss and muscle-building supplements to organ

> failure, heart attacks, stroke, and death. The CDC estimates that supplement use leads to 23,000 emergency room visits every year, with a quarter due to the weight-loss category alone.

J. App'x at 108 (footnotes and citations omitted). The scientific evidence in the legislative record provided by Dr. Nagata and other experts certainly satisfies the Attorney General's burden to show that the asserted harms "are real." *Vugo*, 931 F.3d at 52; *cf. We the Patriots USA, Inc. v. Conn. Off. of Early Childhood Dev.*, 76 F.4th 130, 153–54 (2d Cir. 2023) (finding that the state legislature "reasonably judged" the risk of harm based on data and expert testimony in drafting the law at issue). While CRN takes issue with some studies linking supplement use to eating disorders, it does not justify why that would discredit the broader body of evidence demonstrating other health risks.

There is also sufficient indication that these adverse health effects will be reduced materially by Section 391-oo's use of marketing to identify the products subject to its age restriction. To start, it is "simple common sense," *Lorillard Tobacco*, 533 U.S. at 555, 121 S.Ct. 2404 (quoting *Went for It*, 515 U.S. at 628, 115 S.Ct. 2371), that prohibiting supplement sales to minors will reduce supplement consumption by minors. And the category of products targeted by Section 391-oo—supplements that are "labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building," N.Y. Gen. Bus. Law § 391-oo(1)(a)—is generally the same category used in the cited literature to identify

supplements that are especially harmful. *See, e.g.*, Andrew I. Geller et al., *Emergency Department Visits for Adverse Events Related to Dietary Supplements*, 373 NEJM 1531, 1533–35 (2015) (cited in J. App'x at 100, 108) (categorizing supplements by purpose, including "supplements for weight loss"); Flora Or et al., *Taking Stock of Dietary Supplements' Harmful Effects on Children, Adolescents, and Young Adults*, 65 J. Adolescent Health 455, 456–58 (2019) (cited in J. App'x at 100, 108) (categorizing supplements by principal advertised health claim). When a product's marketed purpose is an indicator of its risks, restricting sales of a product on that same basis—its marketed purpose—will directly advance the goal of reducing those risks.

3. No More Extensive than Necessary

Lastly, the Attorney General must show that Section 391-oo does "not burden substantially more speech than is necessary to further the government's legitimate interests." *Clear Channel Outdoor, Inc. v. City of New York*, 594 F.3d 94, 104 (2d Cir. 2010) (quoting *Bd. of Trs. v. Fox*, 492 U.S. 469, 478, 109 S.Ct. 3028, 106 L.Ed.2d 388 (1989)). She does not, however, need to show that it is the least restrictive means of achieving its objectives. *Id.* Rather, there must be a "reasonable" fit between the law and its objectives, though that fit need not be "perfect." *Fox*, 492 U.S. at 480, 109 S.Ct. 3028. We will defer to the Legislature's reasonable judgment about how best to achieve those objectives. *See Clear Channel*, 594 F.3d at 104.

CRN makes two arguments under this prong. First, it argues that the statute is overinclusive because it could sweep in safe products, such as children's multivitamins, that tout certain weight or muscle benefits but do not pose the same health risks. While it is certainly possible that Section 391-oo's reach may extend to less risky products, it does not appear from the record that it will "burden *substantially* more speech than is necessary" to achieve its ends. *Clear Channel*, 594 F.3d at 104 (emphasis added) (quoting *Fox*, 492 U.S. at 478, 109 S.Ct. 3028). Again, the fit need only be "reasonable," not "perfect." *Fox*, 492 U.S. at 480, 109 S.Ct. 3028.

Second, CRN argues that the Legislature could have restricted the sale of products based on their ingredients rather than their marketing. It points to Assembly Bill 431-C, which would have required the Department of Health to determine which products were covered. But the Governor vetoed that bill, and for a legitimate reason—the DOH lacked the expertise to effectively carry out the bill's objectives. The Legislature decided instead to use a product's marketing as a proxy, and we must defer to that reasonable judgment. *See Clear Channel*, 594 F.3d at 104; *Vugo*, 931 F.3d at 58–59.[3]

3. CRN's claim that Section 391-oo exceeds the state's police powers—to which it devotes two sentences of argument in a footnote—fails a fortiori. Because Section 391-oo satisfies intermediate scrutiny, it necessarily satisfies the rational-basis standard that applies to CRN's police-powers claim. *See United States v. Carolene Prods. Co.*, 304 U.S. 144, 152, 58 S.Ct. 778, 82 L.Ed. 1234 (1938).

B. Compelled Expression

In addition to prohibiting the sale of covered supplements to minors, Section 391-oo requires that retailers verify the age of any purchaser who appears younger than twenty-five. N.Y. Gen. Bus. Law § 391-oo(2). CRN argues that this requirement unconstitutionally compels its members to communicate the message that the age-restricted products are unsafe for minors. We disagree.

1. Not CRN's or Its Members' Own Expression

To succeed on this claim, CRN must show that Section 391-oo compels either "speech," *New Hope Fam. Servs., Inc. v. Poole*, 966 F.3d 145, 171 (2d Cir. 2020), or "expressive conduct," *Emilee Carpenter, LLC v. James*, 107 F.4th 92, 104 (2d Cir. 2024). In addition, CRN must show that Section 391-oo compels CRN's or its members' "*own* speech" or "*own* expressive" conduct. *Id.* at 104–05 (emphasis added).

As a threshold matter, we assume without deciding that age verification procedures can constitute expressive activity. We also need not decide whether age verification pursuant to Section 391-oo constitutes speech or conduct. Either way, we conclude as a matter of law that on this record, CRN has failed to demonstrate that the law affects its own expression. *See id.*; *see also Rumsfeld v. F. for Acad. & Inst. Rts., Inc.*, 547 U.S. 47, 63, 126 S.Ct. 1297, 164 L.Ed.2d 156 (2006) ("The compelled-speech violation in each of our prior cases . . . resulted from the fact that

the complaining speaker's *own* message was affected . . . ." (emphasis added)). In assessing whether CRN's (or its members') own message is affected by Section 391-oo, we may consider whether the statute "interfere[s] with [their] choice not to propound a point of view contrary to [their] beliefs," "forc[es] . . . [them] to include other ideas within [their] own speech that [they] would prefer not to include," or whether an observer would likely identify the compelled message with CRN or its members. *Emilee Carpenter*, 107 F.4th at 105 (citation modified); *Rumsfeld*, 547 U.S. at 65, 126 S.Ct. 1297.

Thus, in *Hurley v. Irish-American Gay, Lesbian & Bisexual Group of Boston*, the Supreme Court deemed a state court order that required a private parade organizer to allow a specific group to march in its parade to be an unlawful compulsion of the parade organizers' speech. 515 U.S. 557, 566, 115 S.Ct. 2338, 132 L.Ed.2d 487 (1995). The Supreme Court explained that "[p]arades are . . . a form of expression," and "every participating unit affects the message conveyed by the private organizers." *Id.* at 568, 572, 115 S.Ct. 2338. Hence, the order "essentially requir[ed] petitioners to alter the expressive content of their parade." *Id.* at 572–73, 115 S.Ct. 2338.

By contrast, in *Rumsfeld v. Forum for Academic and Institutional Rights*, the Supreme Court upheld a law that required law schools to permit equal access to military recruiters on their campuses despite the schools' disagreement with military policy. 547 U.S. at 63–68, 126 S.Ct. 1297. Likewise, in *PruneYard Shopping Center v. Robins*, the Supreme Court sustained a statute

which compelled a shopping center owner to permit the gathering of signatures on its premises. 447 U.S. 74, 85–88, 100 S.Ct. 2035, 64 L.Ed.2d 741 (1980). The Supreme Court found that neither case involved a situation where "the complaining speaker's *own message* was affected by the speech it was forced to accommodate." *Rumsfeld*, 547 U.S. at 63–65, 126 S.Ct. 1297 (emphasis added) (distinguishing *Hurley* from itself and *PruneYard*). Rather, the purportedly expressive activities in both cases were "not inherently expressive," because "there was little likelihood that the views of those engaging in the expressive activities would be identified with the owner, who remained free to disassociate himself from those views and who was 'not . . . being compelled to affirm [a] belief in any governmentally prescribed position or view.'" *Rumsfeld*, 547 U.S. at 65, 126 S.Ct. 1297 (alterations in original) (quoting *PruneYard*, 447 U.S. at 88, 100 S.Ct. 2035); *accord id.* ("Nothing about recruiting suggests that law schools agree with any speech by recruiters, and nothing in the [law] restricts what the law schools may say about the military's policies.").

Applying these principles, we conclude that Section 391-oo does not compel CRN's or its members' own expressive activity. At most, Section 391-oo requires sellers to inform potential buyers that the product is age-restricted and request a valid form of identification. To the extent this conveys a message to customers that any products are unsafe for minors, there is little risk that this message would be confused with CRN's or its members' own speech. Rather, "[r]equiring age verification is common when a law draws lines based on

age." *Free Speech Coal., Inc. v. Paxton*, 606 U.S. 461, 479, 145 S.Ct. 2291, 222 L.Ed.2d 643 (2025). Reasonable observers would not likely infer that conducting age verification procedures is a retailer expressing a message at all. As the Supreme Court observed in *Paxton*, state and federal laws require proof of age to obtain alcohol, tobacco, lottery tickets, tattoos, body piercings, fireworks, driver's licenses, medications, and to vote, and to marry. *Id.* (collecting examples and observing that "[i]n none of these contexts is the constitutionality of a reasonable, bona fide age-verification requirement disputed"). An observer can appreciate that the age verification requirement is a law or regulation, rather than the views or speech of CRN or its members. *Id.* at 483, 145 S.Ct. 2291 ("[A]dults have no First Amendment right to avoid age verification, and the statute can readily be understood as an effort to restrict minors' access."); *Rumsfeld*, 547 U.S. at 65, 126 S.Ct. 1297 ("We have held that high school students can appreciate the difference between speech a school sponsors and speech the school permits because legally required to do so . . . ."). Finally, Section 391-oo does not restrict how CRN or its members market their products, including the content of that marketing or to whom it is directed. Therefore, CRN and its members remain free to disassociate from any message that the products are unsafe for minors while still complying with the law.

2. Any Burden on Expression Is Incidental

A separate reason that these age verification procedures are not unconstitutional compulsions of expression is because here, any burden on expression

is incidental to an otherwise legitimate regulation. We have already explained above that Section 391-oo is a constitutionally permissible regulation of commercial speech under the *Central Hudson* test. *See supra* Section II.A. The age verification procedures in question here are the mechanism by which that regulation is implemented, and therefore its analysis folds into the same test of intermediate scrutiny.

The Supreme Court's decision in *Lorillard Tobacco Company v. Reilly* is instructive. 533 U.S. 525, 121 S.Ct. 2404, 150 L.Ed.2d 532 (2001). *Lorillard Tobacco* involved Massachusetts regulations governing how tobacco products may be displayed to minors by retailers. The Supreme Court found that the "communicative component" of the regulations—there, the "placement of tobacco products"—was regulated "for reasons unrelated to the communication of ideas." *Id.* at 569, 121 S.Ct. 2404. Applied here, while Section 391-oo implicates commercial speech as to the manufacturers, the *age verification procedures* themselves are unrelated to any communication of ideas—once Section 391-oo determines the supplements subject to regulation, the age verification procedures operate to restrict minors' access to those supplements. And here, as in *Lorillard Tobacco*, "retailers have other means of exercising any cognizable speech interest in the presentation of their products." *Id.* at 569–70, 121 S.Ct. 2404. So to the extent age verification procedures have a burden on expression, here that burden is incidental at best.

And because the age verification procedures are an incidental burden on expression, they are analyzed under

intermediate scrutiny. *Id.*; *see also Paxton*, 606 U.S. at 483, 145 S.Ct. 2291 ("Any burden experienced by adults is therefore only incidental to the statute's regulation of activity that is not protected by the First Amendment. That fact makes intermediate scrutiny the appropriate standard under our precedents." (citing *Boy Scouts of America v. Dale*, 530 U.S. 640, 659, 120 S.Ct. 2446, 147 L.Ed.2d 554 (2000))). For the same reasons that Section 391-oo satisfies intermediate scrutiny discussed above, its chosen mechanism of enforcement passes constitutional muster: the state has a substantial interest in protecting minors from certain dietary supplements, restricting sales to minors directly advances that interest, and such age restrictions are "well within the State's discretion under intermediate scrutiny." *Paxton*, 606 U.S. at 497, 145 S.Ct. 2291; *see Lorillard Tobacco*, 533 U.S. at 570, 121 S.Ct. 2404 ("The means chosen by the State are narrowly tailored to prevent access to tobacco products by minors, are unrelated to expression, and leave open alternative avenues for vendors to convey information about products and for would-be customers to inspect products before purchase.").

C. Vagueness and Overbreadth

CRN claims that Section 391-oo's scope—specifically, which products count as being "labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building," N.Y. Gen. Bus. Law § 391-oo(1)(a)—is unconstitutionally vague. We disagree.

A law is "vague" in the relevant sense when its scope—the factual situations to which it applies—is uncertain.

Because "we can never expect mathematical certainty from our language," *Grayned v. City of Rockford*, 408 U.S. 104, 110, 92 S.Ct. 2294, 33 L.Ed.2d 222 (1972), "[m]any statutes will have some inherent vagueness," *Rose v. Locke*, 423 U.S. 48, 49–50, 96 S.Ct. 243, 46 L.Ed.2d 185 (1975).

Vagueness violates due process when the gray area between covered and uncovered conduct is such that the law "fails to provide a person of ordinary intelligence fair notice of what is prohibited, or is so standardless that it authorizes or encourages seriously discriminatory enforcement." *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253, 132 S.Ct. 2307, 183 L.Ed.2d 234 (2012) (quoting *United States v. Williams,* 553 U.S. 285, 304, 128 S.Ct. 1830, 170 L.Ed.2d 650 (2008)). This test is applied more or less strictly depending on what is at stake. For example, "economic regulation is subject to a less strict vagueness test," as are "enactments with civil rather than criminal penalties." *Vill. of Hoffman Ests. v. Flipside, Hoffman Ests., Inc.*, 455 U.S. 489, 498–99, 102 S.Ct. 1186, 71 L.Ed.2d 362 (1982); *see also Arriaga v. Mukasey*, 521 F.3d 219, 223 (2d Cir. 2008) ("Laws with civil consequences receive less exacting vagueness scrutiny."). On the other hand, where a law "threatens to inhibit the exercise of constitutionally protected rights"—for instance, if it "interferes with the right of free speech"—then "a more stringent vagueness test should apply." *Hoffman Ests.*, 455 U.S. at 499, 102 S.Ct. 1186.

A *facial* vagueness challenge under the Due Process Clause, which CRN brings here, "is 'the most difficult

challenge to mount successfully' because, as a general matter, 'the challenger must establish that no set of circumstances exists under which the [law] would be valid.'" *Copeland v. Vance*, 893 F.3d 101, 110 (2d Cir. 2018) (quoting *United States v. Salerno*, 481 U.S. 739, 745, 107 S.Ct. 2095, 95 L.Ed.2d 697 (1987)); *see also United States v. Requena*, 980 F.3d 30, 39 (2d Cir. 2020). In other words, a facial challenger must show that there is no situation in which a person could be sufficiently certain that the law would apply to their conduct.

This heavy burden is lower, however, for First Amendment overbreadth claims premised on a law's vagueness.[4] In making such a claim, a challenger must show that, due to the law's vagueness, "it is unclear whether it regulates a substantial amount of protected speech." *Williams*, 553 U.S. at 304, 128 S.Ct. 1830. This is a distinct claim from a due process vagueness challenge, though, and it requires the challenger to show that the potential regulation of speech violates the First Amendment. *See Vill. of Hoffman Ests.*, 455 U.S. at 495, 102 S.Ct. 1186; *Holder v. Humanitarian L. Project*, 561 U.S. 1, 20, 130 S.Ct. 2705, 177 L.Ed.2d 355 (2010) ("[O]ur precedents make clear that a Fifth Amendment vagueness challenge does not turn on whether a law applies to a substantial amount of protected expression. Otherwise the doctrines would be substantially redundant." (citations omitted)).

4. This burden may also be lessened in certain other circumstances not relevant here. *See Requena*, 980 F.3d at 39–40.

CRN arguably makes both a due process vagueness challenge and a First Amendment overbreadth challenge. Though it conflates the two claims, we analyze them separately.

As for its vagueness claim under the Due Process Clause, CRN raises ambiguities in Section 391-oo's coverage and its failure to define terms such as "represented." Appellant's Br. 50. But it falls far short of its burden to show, on a facial challenge, "that no set of circumstances exists" for which the law's application would be unambiguous. *Copeland*, 893 F.3d at 110 (quoting *Salerno*, 481 U.S. at 745, 107 S.Ct. 2095).[5] Those circumstances are readily apparent: a dietary supplement is marketed as a weight-loss or muscle-building aid. CRN's due process challenge necessarily fails on that basis.[6]

5. Nor does CRN really attempt to meet that burden. Instead, it disputes that this burden applies to cases that implicate speech. But the Supreme Court has made clear that there is "no exception for conduct in the form of speech." *Humanitarian L. Project*, 561 U.S. at 20, 130 S.Ct. 2705. First Amendment challenges asserting overbreadth are subject to a less stringent standard in this respect, but CRN must still show that the law infringes on free speech, which CRN has failed to do here. Due process arguments unrelated to the infringement of free-speech rights cannot free-ride on this more lenient First Amendment standard.

6. If Section 391-oo opened CRN up to liability for speech by unrelated third parties without fair notice, it could be impermissibly vague in a substantial number of applications. But given the statute's text and "stated purpose," we construe the statute to apply only to the actions and statements of manufacturers and retailers. *Cf. VIP of Berlin, LLC v. Town of Berlin*, 593 F.3d 179, 187–89 (2d Cir. 2010). So any challenge premised on that hypothetical likewise fails.

CRN's First Amendment overbreadth claim fails because, as already discussed, Section 391-oo's effects on commercial speech satisfy intermediate scrutiny. CRN points to no other speech that is implicated by the asserted vagueness in the law.[7] It has thus failed to show that "a substantial amount of protected speech" is infringed. *Williams*, 553 U.S. at 304, 128 S.Ct. 1830.

D. Preemption

Finally, CRN argues that Section 391-oo violates the preemption provision of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 343-1(a), and thus the Supremacy Clause. Section 343-1(a) provides that, with certain exceptions not relevant here,

> no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce . . . (5) any requirement respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title . . . .

Section 343(r)(1), in turn, prohibits health-related claims regarding a product's nutrients, while Section 343(r)(6) makes certain exceptions for dietary supplements.

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7. To the extent CRN relies on hypothetical statements made by unaffiliated third parties, such as third parties on the internet, Section 391-oo does not reach speech by unregulated parties, and so there is no basis to think that third-party speech would be chilled or otherwise infringed.

The question before us is whether Section 391-oo's age restriction, by being triggered by (among other things) a health claim made on a product label, is therefore a "requirement respecting" such a health claim. We conclude that it is not.

A "requirement" is "[s]omething that must be done because of a law or rule; something legally imposed, called for, or demanded; an imperative command." *Requirement*, Black's Law Dictionary (12th ed. 2024). While the reduction in sales caused by Section 391-oo may lead some supplement makers to change the claims made on their labels, that potential shift in economic balancing is far from a "requirement," as that word is ordinarily understood. Rather than regulating the content of supplement labels, Section 391-oo uses the labels to identify products subject to its sales restriction.

The Supreme Court reached a similar conclusion in *Bates v. Dow Agrosciences LLC*, which involved a provision requiring that states "not impose or continue in effect any requirements for labeling or packaging [pesticides] in addition to or different from those required under" federal law. 544 U.S. 431, 436, 125 S.Ct. 1788, 161 L.Ed.2d 687 (2005) (quoting 7 U.S.C. § 136v(b)). The Court rejected the argument that a state law that merely induced a change in a product label—for example, by making actionable a breach of a warranty appearing on the label—qualified as "a requirement 'for labeling or packaging.'" *Id.* at 445, 125 S.Ct. 1788. This was because such a law "does not require the manufacturer to make an express warranty, or in the event that the manufacturer elects to do so, to

say anything in particular in that warranty." *Id.*; *see also Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 522, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992) (focusing on whether the "legal duty" created by state law constituted a preempted "requirement").

While the preemption provision here is different, the same logic applies. Section 391-oo does not require a supplement maker to put anything in particular on a product label. Rather, like a law enforcing warranties appearing on labels, Section 391-oo imposes an independent legal obligation that is triggered by a manufacturer's choice to place something particular on a label. That obligation—the duty not to sell the product to minors—is not a "requirement respecting any claim" contained on the label. 21 U.S.C. § 343-1(a).

In any event, "where the text of a preemption clause is ambiguous or open to more than one plausible reading, courts 'have a duty to accept the reading that disfavors pre-emption.'" *N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health*, 556 F.3d 114, 123 (2d Cir. 2009) (quoting *Bates,* 544 U.S. at 449, 125 S.Ct. 1788).[8] Because Section 343-1(a)

8. Citing our decision in *Buono v. Tyco Fire Products., LP*, 78 F.4th 490, 495 (2d Cir. 2023), which in turn relies on the Supreme Court's decision in *Puerto Rico v. Franklin California Tax-Free Trust*, 579 U.S. 115, 125, 136 S.Ct. 1938, 195 L.Ed.2d 298 (2016), CRN asserts that no such presumption is applicable because the FDCA contains an express preemption provision. But that is only true insofar as the text of that provision is "plain." *Franklin*, 579 U.S. at 125, 136 S.Ct. 1938; *Buono*, 78 F.4th at 495. Where the preemptive force of the text is ambiguous—as it is here—we

could plausibly be read not to preempt Section 391-oo, we are bound to apply that reading.

III. Irreparable Harm

Beyond a likelihood of success on the merits, CRN must also establish that it will likely face irreparable harm. CRN asserts in its brief two types of irreparable harm suffered by its members: the per se irreparable injury to its members' free-speech rights, and the unrecoverable "costs expended to attempt to comply with the Act's vague mandates." Appellant's Br. 58.

The First Amendment basis for irreparable injury is insufficient given our earlier analysis of CRN's First Amendment claims. Because CRN is unlikely to succeed on the merits of those claims, any irreparable injury premised on those claims alone cannot justify a preliminary injunction. *See We the Patriots USA, Inc. v. Hochul*, 17 F.4th 266, 294 (2d Cir. 2021) ("[B]ecause [Plaintiffs] have failed to demonstrate a likelihood of success on their First Amendment or other constitutional claims . . . Plaintiffs fail to meet the irreparable harm element simply by alleging an impairment of their Free Exercise right.").

With respect to the asserted economic injuries suffered by CRN's members, "ordinary compliance

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resolve that ambiguity against preemption. *See Bates*, 544 U.S. at 449, 125 S.Ct. 1788 (applying that presumption to an ambiguous express-preemption provision).

costs are typically insufficient to constitute irreparable harm." *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 115 (2d Cir. 2005). The compliance costs that CRN asserts—"time analyzing the Act's potential application to specific products," "relabeling products," "implementing age-verification procedures through common carriers," and "employing additional age-verification procedures at point of sale," Appellant's Br. 17—fall into that category.

Unrecoverable lost sales, however, can constitute irreparable harm. *See Warner Bros. v. Gay Toys, Inc.*, 658 F.2d 76, 79 (2d Cir. 1981). While the record before us contains little more than conclusory and speculative predictions of lost sales, one might reasonably assume that prohibiting sales to minors would reduce total sales at least to some degree. Nevertheless, given that CRN's claims are unlikely to succeed on the merits, the minimal allegations of lost sales alone do not demonstrate irreparable harm sufficient to warrant preliminary injunctive relief.[9]

IV. Public Interest

Lastly, CRN must establish a favorable balance of the equities. The District Court found that a preliminary injunction would not be in the public interest because the "pecuniary interests, fear of the enforcement of civil penalties, and speculative loss of revenue and sales" to CRN's members "pale in comparison to the State's goal

9. For this reason, we need not address whether CRN's five-month delay in seeking preliminary relief was an appropriate part of the District Court's calculus.

of protecting youth from products that unfettered access to dietary supplements present." *Council for Responsible Nutrition*, 2024 WL 1700036, at *10. CRN's arguments on this element—that the public interest requires adhering to the First Amendment, and that Section 391-oo fails to address its target harms—necessarily fall with its First Amendment claims. But even if its First Amendment claims had likely merit, we cannot say that the District Court's assessment of the public interest in this case was an abuse of discretion.

CONCLUSION

We have considered CRN's remaining arguments and conclude that they are without merit. For the foregoing reasons, the order of the District Court denying CRN's motion for a preliminary injunction is AFFIRMED.

APPENDIX B — OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK, FILED APRIL 19, 2024

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

24-cv-1881 (ALC)

COUNCIL FOR RESPONSIBLE NUTRITION,

Plaintiff,

-against-

LETITIA JAMES,

Defendant.

OPINION & ORDER

ANDREW L. CARTER, JR., United States District Judge:

Six months after the New York Legislature passed N.Y. Gen. Bus. Law § 391-oo, Council for Responsible Nutrition ("CRN") brings this emergency request for preliminary injunction on the eve of the Statute's effectuation, asking this Court to prevent the State from enforcing this law. For the reasons set forth below, this Court denies this extraordinary relief. Plaintiff has not demonstrated a likelihood of success on a constitutional injury that would excuse this delay. Moreover, granting a preliminary injunction is not in the public interest.

Appendix B

BACKGROUND

The following facts are drawn from the Amended Complaint ("AC"), Plaintiff's declaration in support of its motion for preliminary injunction, Defendant's declaration in opposition to the motion for preliminary injunction, Defendant's memorandum in support of its motion to dismiss, and Plaintiff's opposition to Defendant's motion to dismiss, and the documents relied upon therein.

I. STATUTORY FRAMEWORK

Beginning in 2020, members of the New York State Legislature sought to address the growing prevalence of the "serious public health problem" of eating disorders "affecting youth and adults of all races, ages, and genders." Sponsor's Mem. in Support for A10138 (2020), at 1; *accord* Sponsor's Mem. in Support, in Bill Jacket for ch. 558 (2023), at 1-2. One central concern for the Legislature was that studies showed that eating disorders are mental health condition that may be identified and diagnosed based on "the presence of what clinicians call unhealthy weight control behaviors." *See id.* One of these signals is misusing dietary aids to try to lose weight or build muscle. *See id.* Legislators were also concerned that dietary supplements used for weight loss or muscle building were readily available "alongside multivitamins and other supplements largely regarded as safe," even though there had been a number of reported instances of deaths and serious harms resulting from the largely unregulated use of dietary supplements. *Id.* Modeled after longstanding

age restrictions for alcohol and tobacco, which "have been demonstrated to reduce . . . consumption" of those products by adolescents, the Legislature sought to implement an age restriction for the purchase of dietary supplements used for losing weight or building muscle, to reduce the unsupervised use of these products by minors and, more broadly, to "draw attention to the life-threatening risks that come along with these widely used products." Sponsor's Mem. in Supp. for A10138 (2020), at 2.

On December 23, 2022, Governor Kathy Hochul vetoed Assembly Bill 431-C (Ex. B, ECF No. 25-2 at 2). She noted that "she shared the concerns of the sponsors of this bill" because of the lack of oversight from the United States Food and Drug Administration over the safety and efficacy of diet pills and dietary supplements, "the concerns about the dangerous ingredients and the links to eating disorders, particularly in young people." (*Id.*). She expressed that "[t]his legislation would require the Department of Health (DOH) to determine what products should be limited under this new law." *Id.* And, because DOH did not have the expertise necessary to make such assessments, it was "not equipped to create a list of restricted products." *Id.* For these reasons she was "constrained to veto this bill." (*Id.*).

On October 25, 2023, the Legislature enacted A5610, the subject of this action. Ch. 558, 2023 N.Y. Laws. Consistent with the original versions of the law, the Statute provides that no person, company "or other entity shall sell or offer to sell or give away, as either a

retail or wholesale promotion, . . . [a] dietary supplement[1] for weight loss or muscle building within this state to any person under eighteen years of age." Ch. 558, § 1, 2023 N.Y. Laws (to be codified at N.Y. Gen. Bus. Law § 391-oo(2). As enacted, the Statute defines "dietary supplement for weight loss or muscle building" as "a class of dietary supplement as defined in section three hundred ninety-one-o of this article1 that is labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building." Gen. Bus. Law § 391-oo (1)(a). Exempted from the age-based sales restriction are "protein powders, protein drinks and foods marketed as containing protein unless the protein powder, protein drink or food . . . contains an ingredient other than protein which would, considered alone, constitute a dietary supplement for weight loss or muscle building." *Id.* The Statute also contains a number of provisions clarifying its scope and guiding enforcement. In particular, the Statute states that a supplement is "labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building" where its "labeling or marketing bears statements or images that express or imply that the product will help . . . modify, maintain, or reduce body weight, fat, appetite, overall metabolism, or the process by which nutrients are metabolized" or "maintain or increase muscle or strength." *Id.* § 391-oo(6)(b)(i)-(ii).

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1. "Dietary supplement" is defined, in relevant part, as an ingestible product that "contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid . . ." and which is labeled as a "dietary supplement" under federal law. *See* Gen. Bus. Law § 831 (renumbered from Gen. Bus. Law § 391-o).

The Statute also directs courts, in enforcement proceedings, to consider whether a dietary supplement contains certain ingredients such as a steroid, or "creatine, green tea extract, raspberry ketone, garcinia cambogia, green coffee bean extract," or "an ingredient approved by the federal Food and Drug Administration for weight loss or muscle building," as the inclusion of such ingredients commonly associated with weight loss or muscle building may bring a product within the Statute's restrictions. *Id.* § 391-oo(6)(a)(i)-(iii). Further, the Statute provides that a dietary supplement may be subject to the age-based sales restriction through the actions of the retailer by "placing signs, categorizing, or tagging the supplement with statements" suggesting that the supplement will impact weight, fat, appetite, metabolism, muscle or strength, or by "grouping the supplements with other weight loss or muscle building products in a display, advertisement, webpage, or area of the store." *Id.* § 391-oo(6)(d)(i)-(iii).

The Statute authorizes the Attorney General, in her discretion, to enforce violations of the Statute through special proceedings in state court. Upon notice to the alleged offender, and if a court finds a violation after considering the enumerated factors set forth in the Statute, the court may issue an injunction and impose a civil penalty of no more than $500 per violation. *Id.* § 390-oo(5). The Statute takes effect on April 22, 2024. Ch. 558, § 2, 2023 N.Y. Laws.

Plaintiff, Council for Responsible Nutrition, is a nonprofit trade organization that represents various dietary supplement manufacturers and distributors. (AC,

ECF No. 44 ¶ 12.) CRN brings this action against Attorney General Leticia James in her official capacity, seeking declaratory and injunctive relief to prevent enforcement of the Statute.

PROCEDURAL HISTORY

On March 13, 2024, five months after the Statute was enacted, Plaintiff commenced this action, seeking a declaration that the Statute is facially invalid and an injunction barring the Attorney General from enforcing it. (ECF No. 1.) Three weeks later, on April 3, 2024, Plaintiff made an emergency motion for an order to show cause for a temporary restraining order and a preliminary injunction, seeking immediate relief ahead of the Statute's effective date. (ECF Nos. 14-25.) On April 4, 2024, the Court denied Plaintiff's application for a temporary restraining order and directed the Attorney General to respond to Plaintiff's motion by April 9, 2024. (ECF No. 31.) The Court conducted a hearing on the motion on April 10, 2024, and Plaintiff thereafter amended its complaint to incorporate the additional allegations set forth in the ten declarations that were filed in support Plaintiff's preliminary injunction motion. (ECF No. 44). Plaintiff and Defendant filed supplemental letter briefing regarding age verification and compelled speech. (ECF Nos. 45, 48).

STANDARD OF REVIEW

Where, as here, "a preliminary injunction will affect government action taken in the public interest pursuant to a statute or regulatory scheme, the moving party must

demonstrate (1) irreparable harm absent injunctive relief, (2) a likelihood of success on the merits, and (3) public interest weighing in favor of granting the injunction." *L.T. v. Zucker*, 2021 U.S. Dist. LEXIS 196906, *7 (N.D.N.Y., Oct. 13, 2021) (quoting *Friends of the E. Hampton Airport, Inc. v. Town of E. Hampton*, 841 F.3d 133, 143 (2d Cir. 2016)).

"[A] preliminary injunction is an extraordinary and drastic remedy, one that should not be granted unless the movant, by a clear showing, carries the burden of persuasion." *Sussman v. Crawford*, 488 F.3d 136, 139 (2d Cir. 2007); *see also Anwar v. Fairfield Greenwich Ltd.*, 728 F. Supp. 2d 462, 472 (S.D.N.Y. 2010) ("Temporary restraining orders and preliminary injunctions are among the most drastic tools in the arsenal of judicial remedies, and must be used with great care.") (internal citations omitted).

DISCUSSION

I. CRN Has Alleged Sufficient Facts to Establish Article III Standing.

A plaintiff must prove: (1) an injury in fact; (2) that is "fairly traceable" to the actions of the defendant; and (3) redressability in order to establish Article III standing. *Tweed-New Haven Airport Auth. v. Tong*, 930 F.3d 65, 70 (2d Cir. 2019).

To establish Article III standing in the context of a motion for a preliminary injunction, *Cacchillo v. Insmed,*

Inc., 638 F.3d 401, 404 (2d Cir. 2011), an association that relies on injuries to individual members to establish its standing must name at least one injured member. As elaborated below, CRN has demonstrated associational standing. Several of CRN's members are manufacturers or suppliers that sell finished dietary supplements in the State of New York, including through retail operations and other online platforms, and these members are governed by the Statute. (FAC ¶¶ 20-21). CRN has alleged sufficient facts to demonstrate that at least one of its members has standing. *See* ECF Nos. 19, 22-24.

An injury sufficient to satisfy Article III must be "concrete and particularized" and "actual or imminent, not 'conjectural' or 'hypothetical.'" *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560, 112 S. Ct. 2130, 119 L. Ed. 2d 351 (1992) (citations omitted). An allegation of future injury may suffice if the threatened injury is "certainly impending," or there is a "'substantial risk' that the harm will occur." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409, 414 n.5, 133 S. Ct. 1138, 185 L. Ed. 2d 264 (2013) (emphasis and internal quotation marks omitted). "Pre-enforcement challenges to criminal statutes are cognizable under Article III," as it is well established that a "plaintiff need not first expose [her]self to liability before bringing suit to challenge . . . the constitutionality of a law threatened to be enforced." *Picard*, 42 F.4th at 97 (internal quotation marks and citations omitted). Courts apply a three-prong test to assess the existence of a cognizable injury in fact in the context of pre-enforcement challenges, which requires a plaintiff to demonstrate: (1) "an intention to engage in a course of conduct arguably affected with

a constitutional interest"; (2) that the intended conduct is "proscribed by" the challenged law; and (3) that "there exists a credible threat of prosecution thereunder." *Susan B. Anthony List*, 573 U.S. at 159 (internal quotation marks and citation omitted). *See Nastri v. Dykes*, 2024 U.S. App. LEXIS 7445, *2-3 (2d Cir., Mar. 29, 2024) (noting that "[w]hile many pre-enforcement cases involve a threat of *criminal* prosecution, the fear of civil penalties can likewise be sufficient.") (internal citation and quotation marks omitted). CRN has satisfied all three elements to establish that it has suffered an injury in fact related to the prospect of the State's enforcement of the Statute.

Defendant argues, inter alia, that CRN fails to allege that its members have any concrete "intention to engage in a course of conduct" prohibited by law, *Vitagliano v. County of Westchester*, 71 F.4th 130, 137-38 (2d Cir. 2023), that would subject them to a "credible threat" of enforcement, *Cayuga Nation*, 824 F.3d at 331-32. (Def. Memo. at 6-7). Defendant also suggests that Plaintiff's seller members have not identified factually specific details to nudge their injuries from the constitutionally impermissible speculative realm to concrete and particularized injuries in fact. (*Id.*). These claims are without merit. At least one of CRN's seller members, XYMOGEN, has alleged a certainly impending injury that could very well expose the company to the threat of enforcement. (ECF No. 23 ¶¶ 19-21). XYMOGEN manufactures dietary supplements, and notes that at least six of its products will be impacted by the Statute. (*Id.* at 17). If XYMOGEN voluntarily redesigns labels for impacted products, it must temporarily age-restrict

the products in New York until the new labels are available or halt the sale of the affected products until all existing inventory is out. (*Id.*) The question of how to handle inventory in stock with current label claims if age verification protocols are not implemented before the Statute takes effect is sufficient to demonstrate injury in fact. CRN also claims that compliance costs that its members have already incurred to assess which products are affected and to implement age verification are also sufficient to demonstrate standing. (ECF No. 22, ¶ 15; ECF No. 24, ¶ 14; ECF No. 3, ¶¶ 12-13, 16-17, 21, 24-29; Compl. ¶¶ 165-180). This Court agrees. *See, e.g., Grand River Enters. Six Nations v. Boughton*, 988 F.3d 114, 121 (2d Cir. 2021) ("[a] regulated entity may plead an 'injury in fact' by plausibly alleging compliance costs associated with an increased regulatory burden."); *see also Clementine Co., LLC v. Adams*, 74 F.4th 77, 86 (2d. Cir. 2023) (finding that Plaintiffs plausibly alleged injury in fact because of compliance costs associated with hiring additional staff to check proof of vaccination requirement). "Any monetary loss suffered by the plaintiff satisfies this element; even a small financial loss suffices." *Carter v. HealthPort Techs., LLC*, 822 F.3d 47, 55 (2d Cir. 2016) (internal citation and quotation marks omitted).

Finally, CRN's fear of enforcement is not contrived. Presuming that the State will immediately begin enforcement after the Statute takes effect, officials could plausibly use the "Dietary Supplement Label Explorer" as created by Strategic Training Initiative for the Prevention of Eating Disorders ("STRIPED") to begin identifying and categorizing products and issuing penalties accordingly. (ECF No. 15 ¶¶ 75, 78, 80).

Because CRN has alleged sufficient facts to demonstrate that at least one of its members has standing, it has properly pleaded associational standing. *Do No Harm v. Pfizer Inc.*, 96 F.4th 106, 2024 U.S. App. LEXIS 5428, *1-2.

II. CRN Has Failed to Prove Likelihood of Success on the Merits.

A. CRN Has Failed to Show Likelihood of Success on First Amendment Claim.

This Circuit has held that "[c]onsideration of the merits is virtually indispensable in the First Amendment context, where the likelihood of success on the merits is the dominant, if not the dispositive, factor." *N.Y. Progress and Prot. PAC v. Walsh*, 733 F.3d 483, 488 (2d Cir. 2013). And, when a party seeks a preliminary injunction on the basis of a potential First Amendment violation, the likelihood of success on the merits will often be the determinative factor. *Id.* (internal citation and quotation marks omitted).

i. The First Amendment's Doctrinal Regime

CRN locates its purported First Amendment injury as an unconstitutional restriction on protected commercial speech. Speech is commercial when it "'does no more than propose a commercial transaction.'" *Conn. Bar Ass'n v. United States*, 620 F.3d 81, 93 (2d Cir. 2010) (quoting *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66, 103 S. Ct. 2875, 77 L. Ed. 2d 469 (1983)). Moreover, "commercial speech [constitutes] 'expression related solely to the economic interests of the speaker and its audience.'" *Id.* at

94 (quoting *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 561, 100 S. Ct. 2343, 65 L. Ed. 2d 341 (1980)). The Supreme Court elucidated that "the Constitution presumes that attempts to regulate speech are more dangerous than attempts to regulate conduct." *44 Liquormart v. R.I.*, 517 U.S. 484, 512, 116 S. Ct. 1495, 134 L. Ed. 2d 711 (1996). Consequently, the First Amendment "directs that government may not suppress speech as easily as it may suppress conduct and that speech restrictions cannot be treated as simply another means that the government may use to achieve its ends." *Id.* Finally, the Court elaborated that "these basic First Amendment principles clearly apply to commercial speech." *Id.*

ii. Whether the Statute Implicates the First Amendment

Defendant argues that the Statute does not regulate speech, rather it is directed solely toward conduct: namely, restricting the sale of certain dietary supplements to a particular class of consumers. Returning to the plain text of the Statute, the Legislature explicitly states that "[n]o person, firm, corporation, partnership, association, limited liability company, or other entity shall sell or offer to sell or give away, as either a retail or wholesale promotion, an over-the-counter diet pill or dietary supplement for weight loss or muscle building within this state to any person under eighteen years of age." N.Y. Gen. Bus. Law § 391-oo(2). Standing alone, this provision is a cabined, conduct-based age restriction that "simply regulates business behavior." *Village of Hoffman Estates*

v. Flipside, Hoffman Estates, Inc., 455 U.S. 489, 492-93, 496, 102 S. Ct. 1186, 71 L. Ed. 2d 362 (1982) (finding that an ordinance that prohibited the sale of certain items "designed or marketed for use" with drugs did not infringe on First Amendment rights, and even if a commercial speech interest was implicated it was only the "attenuated interest in displaying and marketing merchandise in the manner that the retailer desires."); *see also Art & Antique Dealers League of Am., Inc. v. Seggos*, 523 F. Supp. 3d 641, 646 (S.D.N.Y. 2021) (holding that statutory prohibition of in-store display of product was an "ordinary economic regulation of commercial activity" that "impose[d] and incidental burden on 'speech.'").

Here, the age restriction might be viewed as merely an incidental burden on commercial speech. In *Lorillard Tobacco*, the Supreme Court found that among regulations promulgated by Massachusetts' Attorney General that governed the sale and advertising of cigarettes, smokeless tobacco, and cigars, a prohibition on self-service displays that required buyers to have "direct contact with a sales person" and undergo age verification withstood First Amendment scrutiny. *Lorillard Tobacco v. Reilly*, 533 U.S. 525, 121 S. Ct. 2404, 150 L. Ed. 2d 532 (2001). Notably, the Court found that even though Massachussetts' display-related sales provisions regulated conduct that may have had a "communicative component," the State sought to regulate the placement of tobacco products "for reasons unrelated to the communication of ideas." *Id.* at 569. Justice Stevens' concurrence in *Lorillard* is similarly instructive. Noting the Court's long recognition of the need to differentiate between legislation that targets

conduct and legislation that targets conduct for legitimate non-speech related reasons that incidentally burden expression, he states:

> However difficult that line may be to draw, it seems clear to me that laws requiring that stores maintain items behind counters and prohibiting self-service displays fall squarely on the conduct side of the line. Restrictions as to the accessibility of dangerous or legally-restricted products are a common feature of the regulatory regime governing American retail stores. I see nothing the least bit constitutionally problematic in requiring individuals to ask for the assistance of a salesclerk in order to examine or purchase a handgun, a bottle of penicillin, or a package of cigarettes. *Id.* at 604 (Stevens, J., concurring in part and dissenting in part).

In practice, the Statute targets the same conduct-based regulation by placing dietary supplements behind the proverbial counter and requiring age verification. The Statute's core purpose is to inhibit minors' access to dietary supplements given the connection of unsupervised use to eating disorders. CRN claims that the Act does not impose restrictions based on anything inherent to a product itself, but restricts access based purely on what has been *said* about the product or its ingredients in the labeling, marketing, or advertising of the products. But this is a misreading of the legislation. The Statute does in fact impose age-based restrictions for products that

contain "an ingredient approved by the federal Food and Drug Administration for weight loss or muscle building; a steroid; or creatine, green tea extract, raspberry ketone, garcinia cambogia, and green tea coffee bean extract." N.Y. Gen. Bus. Law § 391-oo(6)(a)(i)-(iii). Courts *may consider* whether the labeling, marketing, grouping, or representation of products outside of the scope of the listed ingredients bears statements of images that express or imply that the product will help: "modify, maintain, or reduce body weight, fat, appetite, overall metabolism, or the process by which nutrients are metabolized, maintain or increase muscle or strength." N.Y. Gen. Bus. Law § 391-oo(6)(b)-(d) (emphasis added). But this explanatory provision aiming to assist courts with enforcement of the Statute "neither limits what" CRN sellers "may say nor requires them to say anything." *Clementine Co., LLC v. Adams*, 74 F.4th 77, 86 (2d. Cir. 2023) (citing *Rumsfeld v. F. for Acad. & Institutional Rts., Inc.* ("*FAIR*"), 547 U.S. 47, 60, 126 S. Ct. 1297, 164 L. Ed. 2d 156 (2006)).

In *Clementine Co., LLC v. Adams*, the Second Circuit held that the City's Key to NYC program which required certain indoor venues to check the COVID-19 vaccination status of patrons and staff before permitting entry did not even implicate Plaintiffs' First Amendment rights, in part because the requirement regulated non-expressive conduct. *Id.* at 86-87. The Court noted that while necessitating refunds for customers who could not provide proof of vaccination and requiring the hiring of additional staff were plausible allegations of injury in the Article III sense, turning away some patrons did not constitute a violation of free speech rights. *Id.* Similarly,

requiring age verification for adults who wish to purchase dietary supplements does not necessarily implicate the First Amendment simply because CRN's seller members incur compliance costs, or lose the percentage of sales that targeted youth. Again, the Statute regulates conduct not speech. It affects what sellers "must do," require proof of legal age to purchase over-the-counter dietary pills or dietary supplements for weight loss or muscle building. The Statute does not regulate what these sellers "may or may not say." *Id.* at 86 (citing *FAIR*, 547 U.S. at 60).

CRN Member sellers are free to market, describe, or label their products however they so choose in accordance with federal and state statutory requirements regarding advertising. XYMOGEN can continue to label, market, and sell its product "Appe-Curb" and represent that it "combats cravings naturally" and "supports healthy weight". (Ex. G, ECF No.37-7 at 2-3). Nature's Bounty can maintain that its "Metabolism Booster" product "promote[s] abdominal fat loss and boost[s] fat metabolism." (*Id.* at 3). Nutrilite can target its "Slimmetry Dietary Supplement" to "anyone looking to support their weight-loss efforts with a convenient supplement" by "help[ing] you maintain a healthy waistline." (*Id.* at 6). The Statute does not prohibit these statements, alter them in any way, nor *say* anything about them. It only requires that customers over the age of eighteen verify their age before purchasing these products. And "[b]ecause 'every civil and criminal remedy imposes some conceivable burden on First Amendment protected activities,' a conduct-regulating statute of general application that imposes an incidental burden on the exercise of free speech rights does not implicate the

First Amendment.'" *Clementine Co., LLC*, 74 F.4th at 87 (quoting *Arcara*, 478 U.S. at 706).

Because the Statute regulates conduct, and at most incidentally burdens commercial speech, it does not implicate the First Amendment. Thus, Plaintiff has failed to demonstrate likelihood of success of a cognizable free speech injury.

iii. Whether the Statute Survives Intermediate Scrutiny

The Court need not undertake a levels of scrutiny analysis because the Statute does not implicate the First Amendment. But Plaintiff still fails to demonstrate a likelihood of success on this claim because—in all probability—the statute survives intermediate scrutiny. To determine whether a regulation of commercial speech is constitutionally permissible, courts must determine whether (1) the expression is protected by the First Amendment, concerns lawful conduct, and is not misleading; (2) the asserted governmental interest is substantial; (3) the regulation directly advances the asserted government interest; (4) and the regulation is no more extensive than necessary to serve that interest. *Central Hudson Gas & Elec. Corp. v. Public Svcs. Comm.*, 447 U.S. 557, 566, 100 S. Ct. 2343, 65 L. Ed. 2d 341 (1980). It is well established that "the party seeking to uphold a restriction on commercial speech carries the burden of justifying it." *Edenfield v. Fane*, 507 U.S. 761, 770, 113 S. Ct. 1792, 123 L. Ed. 2d 543 (1993) (internal citations omitted). Plaintiff has conceded that the State

has a substantial government interest in protecting public health and regulating misleading information. (Pl. Memo. at 19). CRN has also admitted that eating disorders in minors are unquestionably real harms. (*Id.* at 21). The Court therefore focuses its analysis on the third and fourth prongs of the *Central Hudson* inquiry.

1. The Third *Central Hudson* Prong

The third *Central Hudson* prong requires that the speech restriction directly and materially advance the asserted governmental interest. "This burden is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Lorillard Tobacco Co.*, 533 U.S. at 556 (internal citation omitted). "New York is not required to produce 'empirical data come . . . accompanied by a surfeit of background information" in order to satisfy intermediate scrutiny." *Art & Antique Dealers*, 523 F. Supp. 3d at 647 (quoting *Lorillard Tobacco Co.*, 533 U.S. at 555) (citations and internal quotation marks omitted).

CRN claims that the State has not proffered any evidence to suggest that the harms it seeks to address—the prevalence of eating disorders and the health harms from the unregulated use of dietary supplements used for weight loss and muscle building—are directly mitigated by the Statute. Further, Plaintiff argues that the Act cites to "irrelevant materials masquerading as genuine evidence" and that the Legislature "should have demanded

to see the body of research on the causal link between these types of supplements and" eating disorders." (Pl. Memo. at 21-22). These arguments are without merit. The Supreme Court has recognized that state laws may be justified "by reference to studies and anecdotes . . . or even based solely on history, consensus, and 'simple common sense.'" *Lorillard Tobacco Co.*, 533 U.S. at 555 (quoting *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 628, 115 S. Ct. 2371, 132 L. Ed. 2d 541 (1995)).

Given the ample evidence in the legislative record and public health discourse, the State has sufficiently met its burden—at this stage in the litigation—to demonstrate that the Statute directly and materially advances the harms it seeks to address. For example, in his testimony submitted to the Legislature in support of the Statute, Dr. Joseph Nagata cited several different studies to demonstrate this causal connection: (1) The U.S. weight-loss and muscle-building supplement industry generates over $2.5 billion in annual revenue and youth are prominent consumers of these products; (2) a recent study found that youth using weight-loss supplements were three times more likely than those using ordinary vitamins to experience severe medical harm, including hospitalization, disability, and even death; (3) The American Academy of Pediatrics recently issued two reports strongly cautioning against teens using these products for any reason; (4) Youth who use over-the-counter diet pills are six times more likely to be diagnosed with an eating disorder compared to nonusers; (5) Use of muscle-building supplements has also been linked to eating disorders. This evidence suggests that this Statute provides substantial rather

than ineffective or remote support for the government's intended purpose. (Ex. E, ECF No. 37-5 at 2-3. *See L.T. v. Zucker*, 2021 U.S. Dist. LEXIS 196906 *17-20 (N.D.N.Y., Oct. 13, 2021) (upholding mask mandate for children in school as surviving intermediate scrutiny and relying in part on Defendant New York government official's cite to third-party reports and studies to demonstrate the rising threat of COVID-19 which the government had an important interest in stopping).

2. The Fourth *Central Hudson* Prong

The fourth *Central Hudson* prong asks "whether the speech restriction is not more extensive than necessary to serve the interests that support it." *Lorillard Tobacco Co.*, 533 U.S. at 556 (citing *Greater New Orleans, supra*, at 188). The Supreme Court has made it clear that "the least restrictive means" is not the standard; instead, the case law requires a reasonable "'fit between the legislature's ends and the means chosen to accomplish those ends, . . . a means narrowly tailored to achieve the desired objective.'" *Went For It, Inc., supra*, at 632 (internal citation omitted). That fit "is not necessarily perfect, but reasonable" and "represents not necessarily the single best disposition but one whose scope is in proportion to the interest served; that employs not necessarily the least restrictive means but . . . a means narrowly tailored to achieve the desired objective." *Art & Antique Dealers League of Am., Inc.*, 523 F. Supp. 3d at 646-47 (citing *Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480, 109 S. Ct. 3028, 106 L. Ed. 2d 388 (1989)) (internal quotations and citation omitted). Essentially, "the regulation [may] not burden substantially

more speech than is necessary to further the government's legitimate interests." *Safelite Grp., Inc. v. Jepsen*, 764 F.3d 258, 265 (2d Cir. 2014).

Here, the Statute's regulations are not more extensive than necessary to serve the State's interest in curbing youth incidences of eating disorders. The Legislative history of the Statute demonstrates that the specifications and factors added not only clarified its scope in order to guide enforcement, but also responded to the concerns expressed in Governor Hochul's 2022 veto of the bill. (Ex. B, No. 25-2 at 2). She noted that "[t]his legislation would require the Department of Health (DOH) to determine what products should be limited under this new law." *Id.* And, because DOH did not have the expertise necessary to make such assessments, it was "not equipped to create a list of restricted products." *Id.* Section six of the Act demonstrates the extent to which this legislation is tailored to its goal of limiting minors' unfettered access to dietary supplements for weight loss and muscle-building. N.Y. Gen. Bus. Law § 391-oo(6). *See, e.g., Art & Antique Dealers League of Am., Inc.*, 523 F. Supp. 3d at 646-47 (analyzing the fourth *Central Hudson* prong and finding that the display prohibition was narrowly tailored to New York's interest in halting the sale of illegal ivory within its borders); *see also Lorillard Tobacco Co.*, 533 U.S. at 556 (conducting analysis of fourth *Central Hudson* prong and finding that placing tobacco products behind counters served the state's interest "in preventing access to tobacco products by minors" and were "an appropriately narrow means of advancing that interest"). Notably, this Statute does not institute a complete ban on "the sale of dietary

supplements that are labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building." N.Y. Gen. Bus. Law § 391-oo(1). In fact, the Statute carves out protein powders, protein drinks and foods marketed as containing protein (unless the product contains an ingredient that in isolation would constitute a dietary supplement for weight loss or muscle building). *Id.* at § 391-oo(1)(a). Because the Statute also leaves "open alternative avenues for vendors to convey information about products" the restriction is not more extensive than necessary to serve the government's interest. *Lorillard Tobacco Co.*, 533 U.S. at 570.[2]

Even if the Statute implicated First Amendment rights, it would still withstand intermediate scrutiny. Accordingly, Plaintiff has failed to establish likelihood of success on its First Amendment claim.

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2. This Court also looks to similar statutes that mandate age or identity verification related to the sale of certain regulated products, none of which have been invalidated on First Amendment grounds. (Gov't Suppl. Ltr., ECF No. 48) ("21 U.S.C. § 830(e)(1)(A) (requiring sellers of pseudoephedrine place products behind the counter, to check identification of purchaser, and record and maintain purchaser information); N.Y. Alcohol Beverage Control Law § 65(6)(a) (restricting provision of alcohol); N.Y. Pub. Health Law § 1399-cc(3) (restricting sale of tobacco products); see also N.Y. Alcohol Beverage Control Law § 65-d(1) (requiring notices setting forth age-based restrictions on provision of alcohol and warning that providing false identification in order to purchase alcohol is unlawful); N.Y. Pub. Health Law § 1399-cc(2) (requiring notices that tobacco products cannot be sold to persons under 21 years of age").

Appendix B

The Statute is Not an Excessive Imposition of the State's Police Powers

This Statute falls well within the ambit of the Legislature's broad police powers to enact laws aimed at protecting health and safety. *Lyn v. Inc. Vill. Of Hempstead*, 308 F. App'x 461, 464 (2d Cir. 2009) (quoting *City of Erie v. Pap's A.M.*, 529 U.S. 277, 296, 120 S. Ct. 1382, 146 L. Ed. 2d 265 (2000)), including that of its children. *See Ginsberg v. New York*, 390 U.S. 629, 639, 88 S. Ct. 1274, 20 L. Ed. 2d 195 (1968) (noting that "[t]he well-being of its children is of course a subject within the State's constitutional power to regulate."). Challenges to a State's exercise of its police powers are reviewed for reasonableness. *Jacobson v. Massachusetts*, 197 U.S. 11, 35, 25 S. Ct. 358, 49 L. Ed. 643 (1905). Under rational basis review, laws have a "strong presumption of validity" such that attacks to rationality "must discredit any conceivable basis which could be advanced to support the challenged provision, regardless of whether that basis has a foundation in the record, or actually motivated the legislature." *United States v. Amalfi*, 47 F.4th 114, 124-25 (2d Cir. 2022). Given that this Statute survives the more demanding level of intermediate scrutiny, *supra*, it easily satisfies rational basis review. A restriction preventing minors from directly purchasing certain dietary supplements is a rational means of reducing the unsupervised use of those products, often by youth who struggle with eating disorders. CRN fails to prove that it will likely succeed on a claim of excessive imposition of police powers.

B. The Act is Not Preempted by Federal Law

Plaintiff asserts that the Statute is preempted by 21 U.S.C. § 343-1(a), which expressly preempts any state "requirement respecting any claim [about nutritional levels and health benefits] . . . made in the label or labeling of food that is not identical to the requirement of [21 U.S.C.] § 343(r)." 21 U.S.C. § 343-1(a). Section 343(r) governs voluntary claims about health-related benefits that dietary supplement manufacturers are permitted to make about their products. *Id.* § 343(r)(1)(B) (statements describing "the relationship of any nutrient . . . to a disease or health-related condition"), (r)(6) (providing that dietary supplement labels may make certain claims about the health-related benefits provided manufacturer has "substantiation that such statement is truthful and not misleading," among other things. *See generally POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 114, 134 S. Ct. 2228, 189 L. Ed. 2d 141 (2014) (explaining preemption requirements under the law).

As the Court has already determined, the Statute does not mandate any alterations to the labeling of dietary products, it merely institutes an age restriction. Because there is no basis for preemption, Plaintiff fails to establish that it will succeed on the merits of this claim. There exists no such violation of the Supremacy Clause.

C. The Statute is Not Unconstitutionally Vague on its Face

A statute is void for vagueness where it fails to provide: (1) "people of ordinary intelligence a reasonable

opportunity to understand what conduct it prohibits;" or (2) "explicit standards for those who apply," thereby risking "resolution on an ad hoc and subjective basis[.]" *See Cunney v. Bd. of Trustees of Vill. of Grand View, N.Y.*, 660 F.3d 612, 621 (2d Cir. 2011) (internal citations omitted). "Animating this first vagueness ground is the constitutional principle that individuals should receive fair notice or warning when the state has prohibited specific behavior or acts." *Thibodeau v. Portuondo*, 486 F.3d 61, 65 (2d Cir. 2007). "In reviewing the ordinance's language for vagueness, "we are relegated . . . to the words of the ordinance itself, to the interpretations the court below has given to analogous statutes, and, perhaps to some degree, to the interpretation of the statute given by those charged with enforcing it." *Cunney*, 660 F.3d at 621 (citing *Grayned v. City of Rockford*, 408 U.S. 104, 110, 92 S. Ct. 2294, 33 L. Ed. 2d 222 (1972)). To succeed on a facial challenge, as CRN asserts here, the plaintiff "must demonstrate that the law is impermissibly vague in all of its applications." *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 497-98, 102 S. Ct. 1186, 71 L. Ed. 2d 362 (1982).

Here, the plain language of the Statute is uncompromisingly clear such that people of ordinary intelligence would have a reasonable opportunity to understand what conduct it prohibits, particularly selling items defined and categorized as dietary supplements to minors under the age of eighteen. Moreover, the law is not vague in all of its applications. At least one member of CRN, XYMOGEN, has identified a number of "impacted products and intends to either revise product labeling and marketing to remove applicable claims and/or to age-

restrict impacted products," and has "removed certain claims made in relation to six of [its] products." (ECF No. 23 ¶¶ 13, 17). This evidence is enough to defeat Plaintiff's required showing that the law is unconstitutionally vague. *See Village of Hoffman Estates*, 455 U.S. at 495 (reversing facial vagueness challenge because a statute is not vague on its face merely "because it is unclear in *some* of its applications to the conduct of [plaintiff] and of other hypothetical parties.") (emphasis in original).

Accordingly, CRN has failed to establish that it will succeed on the merits of each of its claims.

III. CRN Has Failed to Prove Irreparable Harm

CRN asserts that it will suffer irreparable harm absent injunctive relief, namely the infringement on First Amendment freedoms and economic injury because of compliance costs and lost revenue due to the age restriction. "Where a plaintiff alleges injury from a rule or regulation that directly limits speech, the irreparable nature of the harm may be presumed." *Bronx Household of Faith v. Bd. of Educ.*, 331 F.3d 342, 349 (2d Cir. 2003). Although "[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury," *Elrod v. Burns*, 427 U.S. 347, 373, 49 L. Ed. 2d 547, 96 S. Ct. 2673 (1976), in "instances where a plaintiff alleges injury from a rule or regulation that may only potentially affect speech, the plaintiff must establish a causal link between the injunction sought and the alleged injury, that is, the plaintiff must demonstrate that the injunction will prevent the feared deprivation of

free speech rights." *Bronx Household of Faith v. Bd. of Educ.*, 331 F.3d 342, 350 (2d. Cir. 2003).

The Court has found that the Statute does not implicate the First Amendment. Because CRN has failed to demonstrate it will likely prevail in showing that the age restriction on dietary supplements has violated its First Amendment rights, it has likewise failed to establish an irreparable harm. *L.T. v. Zucker*, 2021 U.S. Dist. LEXIS 196906, *7-8 (N.D.N.Y., Oct. 13, 2021) (denying irreparable harm where Plaintiffs failed to demonstrate likelihood of success on First Amendment claim).

Furthermore, Plaintiff's substantial and inexcusable delay in moving for preliminary relief five months after the State was enacted in October 2023, erodes its claims of immediate, irreparable, and impending injury. When determining whether a moving party faces irreparable harm without a preliminary injunction, district courts "should generally consider [any] delay" on the movant's part in seeking the injunctive relief. *Tom Doherty Assocs., Inc. v. Saban Ent., Inc.*, 60 F.3d 27, 39 (2d Cir. 1995)); see also *Tough Traveler, Ltd. v. Outbound Prods.*, 60 F.3d 964, 968 (2d Cir. 1995) (months-long delay in bringing suit and moving for preliminary injunction negates presumption of irreparable harm. These delays undermine the theory justifying preliminary injunctions, namely "that there is an urgent need for speedy action to protect the plaintiff's rights." *Central Point Software, Inc. v. Glob. Software & Accessories, Inc.*, 859 F. Supp. 640, 644-45 (E.D.N.Y. 1994). Although a delay in seeking a preliminary injunction "does not always undermine an

alleged need for preliminary relief, months-long delays in seeking preliminary injunctions have repeatedly been held by courts in the Second Circuit to undercut the sense of urgency accompanying a motion for preliminary relief." *Silber v. Barbara's Bakery*, 950 F. Supp. 2d 432, 439 (E.D.N.Y. 2013).

At the Order to Show Cause Hearing, Plaintiff's counsel described that the five-month delay was not "tremendous," and that Plaintiff's delay in bringing this cause of action and request for emergency injunctive relief was due to its voluminous briefing. (Hearing Tr., ECF No. 50 at 13). This Court is not persuaded. Plaintiff's unwarranted delay in moving for emergency preliminary relief further demonstrates that the purported compliance-related economic injuries are neither immediate or irreparable.

IV. The Public Interest and Balancing of the Equities Do Not Support Preliminary Relief

Even if CRN could establish a likelihood of prevailing on the merits, the public interests that would be harmed outweigh the alleged harm to Plaintiff. *L.T.*, 2021 U.S. Dist. LEXIS 196906, *29-31. When balancing the equities, it is clear that preliminary relief would serve CRN's own interest, and not the public interest.

CRN has admitted that eating disorders in minors are unquestionably real harms. (Pl. Memo. at 21). Enjoining the Statute, which seeks to protect minors from the physical and mental health harms associated with the use of dietary supplements for weight loss and muscle building,

would deprive New York residents of the protections of the law. *See, e.g., L.T.*, 2021 U.S. Dist. LEXIS 196906, *29-31 (evidence that demonstrated the rise of COVID-19 may imperil thousands of lives, endanger children, and cause schools to shutdown weighed heavily against enjoining enforcement of the mask mandate); *see also N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health*, 545 F. Supp. 2d 363, 368 (S.D.N.Y. 2008) ("The public interest . . . in enforcement of legislation enacted in the public interest, weigh[s] heavily against granting a stay of enforcement.").

A Center for Disease Control study found that five percent of teens have used diet pills, powders, or liquid in the past month without a doctor's approval in order to lose weight or prevent weight gain.[3] (Def. Opp. at n.6). Another study from the Journal of Adolescent Health found that supplements sold for weight loss, muscle building, and energy were associated with almost three times the risk for severe medical outcomes compared to vitamins.[4] (*Id.*) Curbing these incidences of eating disorders in youth is a serious public health problem. CRN's pecuniary interests, fear of the enforcement of civil penalties, and speculative loss of revenue and sales pale in comparison to the State's goal of protecting youth from products that

3. Paula Cody, M.D., M.P.H., *UW Health, Dietary Supplements: Not Safe for Teens (or Anyone, Really)* (Aug. 23, 2017), available at https://tinyurl.com/38t5bsfa; citing Centers for Disease Control and Prevention (CDC), *1991-2021 High School Youth Risk Behavior Survey Data*, available at http://nccd.cdc.gov/youthonline/.

4. Harvard T.H. Chan School of Public Health, Dietary Supplements Linked with Severe Health Events in Children, Young Adults (June 5, 2019), available at https://tinyurl.com/3v32x2n.

unfettered access to dietary supplements present. It would be unquestionably against the public interest to impede enforcement of N.Y. Gen. Bus. Law § 391-oo. The Court denies the emergency injunctive relief that Plaintiff seeks.

CONCLUSION

For the reasons set forth above, Plaintiff's emergency request for a preliminary injunction is hereby **DENIED**. The Clerk of the Court is directed to close the open motion at ECF No. 14.

SO ORDERED.

Dated: April 19, 2024
New York, New York

/s/ Andrew L. Carter, Jr.
ANDREW L. CARTER, JR.
United States District Judge

APPENDIX C — DENIAL OF REHEARING OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT, FILED DECEMBER 30, 2025

UNITED STATES COURT OF APPEALS
FOR THE
SECOND CIRCUIT

Docket No: 24-1343

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York, on the 30th day of December, two thousand twenty-five.

COUNCIL FOR RESPONSIBLE NUTRITION,

Plaintiff-Appellant,

v.

LETITIA JAMES, IN HER OFFICIAL CAPACITY AS NEW YORK ATTORNEY GENERAL,

Defendant-Appellee.

ORDER

Appellant Council for Responsible Nutrition has filed a petition for rehearing *en banc*. The active members of the Court have considered the request for rehearing *en banc*.

IT IS HEREBY ORDERED that the petition is denied.

Appendix C

FOR THE COURT:

/s/ Catherine O'Hagan Wolfe
Catherine O'Hagan Wolfe, Clerk