In the
United States Court of Appeals
for the Second Circuit

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

No. 24-1343

COUNCIL FOR RESPONSIBLE NUTRITION,
Plaintiff-Appellant,
v.
LETITIA JAMES, in her official capacity as New York Attorney General,
Defendant-Appellee.

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 nor 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.

TAMAR S. WISE, (Michael B. Leeuw, Arianna K. McLaughlin, *on the briefs*), Cozen O'Connor, New York, NY, *for Plaintiff-Appellant*.

GRACE X. ZHOU, Assistant Solicitor General, (Barbara D. Underwood, Solicitor General, Ester Murdukhayeva, Deputy Solicitor General, *on the brief*), *for* Letitia James, Attorney General of the State of New York, New York, NY, *for Defendant-Appellee*.

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.

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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 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

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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).

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 (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 (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 (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

[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.

566). 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 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 (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 (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 (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 (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 (2001) (quoting *Fla. Bar v. Went for It, Inc.*, 515 U.S. 618, 628 (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 (quoting *Went for It*, 515 U.S. at 628), 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 (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. 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). Again, the fit need only be "reasonable," not "perfect." *Fox*, 492 U.S. at 480.

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]

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.

[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 (1938).

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 (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.

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 (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. Hence, the order "essentially requir[ed] petitioners to alter the expressive content of their parade." *Id.* at 572–73.

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. 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 (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 (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 (alterations in original) (quoting *PruneYard*, 447 U.S. at 88); *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 (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 ("[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 ("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 (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. 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. 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 ("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 (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; *see Lorillard Tobacco*, 533 U.S. at 570 ("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 (1972), "[m]any statutes will have some inherent vagueness," *Rose v. Locke*, 423 U.S. 48, 49–50 (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 (2012) (quoting *United States v. Williams*, 553 U.S.

285, 304 (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 (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.

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 (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. 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; *Holder v. Humanitarian L. Project*, 561 U.S. 1, 20 (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)).

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

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

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).[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]

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.

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[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. 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.

[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.

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.

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 (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. 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 (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).[8] Because Section 343-1(a) could plausibly be read not to preempt Section 391-oo, we are bound to apply that reading.

[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 (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; *Buono*, 78 F.4th at 495. Where the preemptive force of the text is ambiguous—as it is here—we resolve that ambiguity against preemption. *See Bates*, 544 U.S. at 449 (applying that presumption to an ambiguous express-preemption provision).

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 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 of protecting youth from products that unfettered access to dietary

[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.

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.