24-1343-cv

United States Court of Appeals

for the

Second Circuit

COUNCIL FOR RESPONSIBLE NUTRITION,

Plaintiff-Appellant,

– v. –

LETITIA JAMES, in her official capacity as New York Attorney General,

Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIEF AND SPECIAL APPENDIX FOR PLAINTIFF-APPELLANT

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, the undersigned counsel for Plaintiff-Appellant Council for Responsible Nutrition ("CRN") certifies that CRN is a non-governmental entity with no parent corporation and no publicly held company owns 10% or more of CRN's stock.

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PRELIMINARY STATEMENT

Plaintiff-Appellant, Council for Responsible Nutrition ("CRN"), is a trade association that has represented the dietary supplement industry, including manufacturers and suppliers, for over fifty years. CRN is challenging an unconstitutional New York law that prohibits the sale to minors 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)(a) (the "Act"). That means, in practical terms, if Company A manufactures a zinc dietary supplement and (based on appropriate substantiation about zinc) states that the product "helps promote muscle growth," while Company B manufactures an identical zinc dietary supplement but includes nothing on its label about muscle growth, retailers can receive substantial fines for selling Product A to minors, but Product B may not be subject to the same age-restriction and risk of fines.

The State says it enacted the Act to protect minors from consuming dangerous ingredients and to curb eating disorders among minors. CRN and its members share the government's concerns regarding the sale of dangerous ingredients to children and the prevalence of eating disorders. But it is not enough to have a noble goal—legislation must be drafted to accomplish that goal without depriving parties of their constitutional rights. The Act fails to do so. It runs afoul of the First Amendment, and the void-for-vagueness doctrine, and the State has not demonstrated that the Act

survives constitutional scrutiny to justify these constitutional infringements. CRN therefore brought this action and sought a preliminary injunction to enjoin enforcement of the Act.

On April 19, 2024, the District Court denied CRN's motion for a preliminary injunction, holding that CRN was not likely to prevail on the merits. But the District Court erred in multiple ways.

First, the District Court held that CRN was unlikely to prevail on its First Amendment claim because the Act only regulates *conduct*, not *speech*. But that ignores how the Act actually works. The Act only regulates products *based on the speech associated with them*. That is, it does not regulate specific "dangerous" ingredients; instead, the New York Attorney General ("NYAG" or "State") will first have to look at the *speech* made about a product (potentially by any number of parties, *e.g.*, a manufacturer, a retailer, or even an influencer) to see if the product makes structure/function claims about weight loss or muscle building. And only after analyzing that content (and determining that the speech touts either of those properties), can the NYAG (or a court) determine whether the product is covered by the Act, and whether the Act proscribes the *conduct* in question (the sale of the product).

The Act's *content*-based trigger distinguishes it from the *conduct*-based regulations that the District Court relied on in its ruling. Here, it is speech—not

conduct—that determines whether a product is covered by the Act. Under decades of First Amendment jurisprudence, this is an infringement on speech that is only permissible if the State meets its burden to demonstrate that the Act survives the requisite level of constitutional scrutiny.

Because the Act imposes a content-based burden on commercial speech, the government has to satisfy at least intermediate scrutiny—*i.e.*, a showing that the Act directly and materially furthers a substantial government interest and is narrowly tailored to do so. But the District Court's cursory analysis of intermediate scrutiny was unfaithful to this Court's precedent. Most egregiously, the District Court's analysis considered the relevant nexus to be between dietary supplements *generally* and eating disorders in minors. But that is not how the Act works. It does not regulate dietary supplements *generally* or based on their ingredients; it regulates them based on the *speech* associated with the particular supplement. That is why Product A would be subject to the Act while the identical Product B arguably would not. But the District Court ignored the complete lack of any legislative history showing any connection between the Act's stated goal and the restrictions the Act imposes. (If minors cannot buy Product A but *can* buy the identical Product B, with the same ingredients, then the Act does not *in fact* directly and materially address the sale of "dangerous" ingredients or the prevalence of eating disorders in children, as is required for intermediate scrutiny.) The District Court also erred in finding that

the Act was narrowly tailored. The New York legislature initially passed a predecessor bill ("Predecessor Bill") aimed at the same government concern but targeting ingredients, not marketing. Even though the Predecessor Bill was ultimately vetoed, it demonstrates that the Act could have been drawn in a way that does not burden speech—a point fatal to the "narrowly tailored" prong of intermediate scrutiny.

The District Court also erred in analyzing the void-for-vagueness doctrine. First, the District Court applied the wrong standard—it ignored that where, as here, speech rights are implicated, courts apply a different, more forgiving standard to determine whether a regulation is unconstitutionally vague. Next, the District Court, in conclusory fashion, found the statute is "uncompromisingly clear." But that *ipse dixit* neither explains the statute nor answers the questions that CRN's members have about how to comply. The Act's key terms—those that need to be understood to determine whether a product is subject to the Act—are undefined. The Act does not say *who* needs to make the statement about weight loss or muscle building in order to trigger the age restriction (would a social media influencer or independent news reporter count?), *where* they need to say it (does a scientist's statement in a scientific journal about possible uses of an ingredient count?), with what degree of certainty the statement needs to be made (would a retail employee's statement to her friend that she noticed weight loss after her new vitamin

C regimen count?) or even *what* needs to be said (is one statement that a product "supports healthy muscles" in a long list of label claims sufficient?). In the Company A/Company B example above, it is unclear if Company A's labeling counts as an "otherwise represented" statement that would bring Product B under the Act. The lack of clear criteria make it impossible to know whether one is complying with the Act. The result is that manufacturers have already curtailed their speech to steer clear of the Act's zone of regulation. And enforcement agencies will have to enforce the Act based on ad hoc, discretionary determinations. These are independent grounds for finding the Act void for vagueness.

The District Court also erred in finding that the Act—an attempt by a state legislature to expand upon the labeling and advertising requirements that are codified in federal law—was not likely preempted by federal law.

And finally, the District Court erred in failing to find that these constitutional violations are irreparable harms and that granting the injunction is in the public interest.

CRN therefore respectfully requests that the Court reverse the District Court's holding in its entirety and direct the entry of a preliminary injunction.

JURISDICTIONAL STATEMENT

The District Court had subject-matter jurisdiction under 28 U.S.C. § 1331. The District Court denied a preliminary injunction on April 19, 2024. ECF 52. CRN

timely filed a notice of appeal. ECF 59. This Court has jurisdiction under 28 U.S.C. § 1292(a)(1).

STATEMENT OF THE ISSUES PRESENTED FOR REVIEW

1. Whether the District Court erred in holding that CRN failed to show likelihood of success on the merits of its claims that:
    a. the Act is void for vagueness under the First and Fourteenth Amendments of the United States Constitution and Article 1 Section 6 of the New York Constitution.
    b. under 42 U.S.C. § 1983, the Act violates the First Amendment.
    c. under 42 U.S.C. § 1983, the Act is an excessive imposition of the State's police powers.
    d. under 42 U.S.C. § 1983, the Act is a violation of the Supremacy Clause because it is preempted by federal law.
2. Whether the District Court erred in holding that CRN failed to demonstrate irreparable harm sufficient to warrant a preliminary injunction.
3. Whether the District Court erred in holding that the public interest and balancing of the equities did not support a preliminary injunction.

STATEMENT OF THE CASE

This case involves a challenge to the Act under the federal and state Constitutions. On April 3, 2024, CRN moved for a preliminary injunction to stay enforcement of the Act. On April 19, 2024, the Honorable Andrew L. Carter, Jr. denied CRN's motion. *See Council for Responsible Nutrition v. James*, No. 24-cv-1881, 2024 WL 1700036 (S.D.N.Y. Apr. 19, 2024). CRN appeals from this order.

I. Dietary Supplements and the Federal Regulatory Scheme

Many Americans do not get enough vital nutrients and vitamins from their diets alone. JA128[1] ¶¶32-33. The government has warned, *e.g.*, that Americans of all ages are not consuming enough calcium, vitamin D, and fiber, which presents serious health concerns. *Id.* Calcium and vitamin D assist in building strong bones, fiber helps maintain regularity, and all three may support the maintenance of a healthy weight and/or strong muscular build. *Id.* ¶¶33-34.

Dietary supplements address these types of deficiencies and are products that add to or supplement a person's diet. JA127 ¶29. As the United States Food and Drug Administration ("FDA") has explained, dietary supplements "can help improve or maintain overall health and help provide adequate amounts of essential nutrients that the body needs to function." *Id.* ¶31. They are part of a "comprehensive care plan for many Americans[.]" *Id.* Dietary supplements can

[1] References herein to "JA" refer to the Joint Appendix.

contain various vitamins, minerals, botanicals, and other dietary ingredients. JA15 ¶7. Common dietary supplements include (among many others) vitamin C, vitamin D, calcium, and probiotics. *Id.*

Dietary supplements are subject to federal regulation. *See Ferrari v. Vitamin Shoppe Indus. LLC*, 70 F.4th 64, 67 (1st Cir. 2023). This includes the Federal Food, Drug, and Cosmetics Act ("FDCA"), whose purpose is "to protect consumers from harmful products." *Id.* at 67. The FDA enforces the law and ensures "dietary supplements are safe, well-manufactured, and accurately labeled." JA130 ¶39. The FDA oversees federal labeling requirements (*e.g.*, packaging, inserts, and other promotional materials), and the Federal Trade Commission ("FTC") is responsible for advertising. *Id.* ¶40. "Congress amended the FDCA through the Dietary Supplement Health and Education Act of 1994 ("DSHEA") to establish a uniform framework to regulate dietary supplements." *Ferrari*, 70 F.4th at 67. In doing so, Congress emphasized, "the right of access of consumers to safe dietary supplements is necessary in order to promote wellness." *Id.* at 73. It also clarified that "dietary supplements are not drugs and should not be regulated as drugs." *Id.* at 73.

Under this regulatory scheme, dietary supplement manufacturers can make "structure/function" claims about dietary supplements. *Id.* at 68. To make a structure/function claim, a manufacturer must substantiate that the claim is truthful and not misleading. *See* 21 U.S.C. § 343(r)(6). Manufacturers must submit a copy

of their structure/function claims to FDA within 30 days of first making such claims for their products. *Id.*

Structure/function claims are critical to the dietary supplement industry. JA70-71 ¶18. Product packaging, labeling, and other advertising are how companies communicate regarding their product's benefits and/or uses. *Id.* This information assists consumers in making educated healthcare decisions regarding dietary supplements. JA26 ¶48. These product claims also enable healthcare practitioners to make therapeutic recommendations to patients. JA70-71 ¶18.

II. The Legislature Passes the Act as a Work-Around to a Vetoed Bill

In 2022, the legislature sought to address the concern that weight loss and muscle-building dietary supplements may "contain unlisted, illegal pharmaceutical ingredients that pose serious risks" to consumer health. JA94. To address this concern, it passed the Predecessor Bill, which restricted the sale of certain dietary supplements to minors based on a list of ingredients that the New York Department of Health ("DOH") would identify. *Id.* But on December 23, 2022, New York Governor Kathy Hochul vetoed the Predecessor Bill. JA131 ¶46. The Governor explained that the DOH "does not have the expertise necessary to analyze ingredients used in countless products, a role that is traditionally played by the FDA" and it would "be unfair to expect retailers to determine which products they can and

cannot sell over the counter to minors, particularly while facing the threat of civil penalties." JA131-32 ¶¶46-47.

After the Governor's veto, the Predecessor Bill's sponsors pivoted. The Predecessor Bill aimed to address potentially dangerous ingredients by regulating specific ingredients. Bill A5610D, which became the Act, purported to address the same concern, *i.e.*, that certain dietary supplements "often contain unlisted, illegal pharmaceutical ingredients that pose serious risks." JA94. But instead of identifying potentially dangerous ingredients, the new legislation was changed to regulate dietary supplements based on the *speech* associated with the product. As the legislature further 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 Act notes that "[b]y implementing an age-based restriction on sales, [it] can draw attention to the health risks of using these products and reduce the incidents of use among youth." *Id.*

The Act bans the sale of "dietary supplements for weight loss or muscle building" to minors. *See* §391-oo. It defines "dietary supplement for weight loss or muscle building" as a dietary supplement that "is labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building." §391-

oo(a)(1).[2] The Act provides four primary, but non-exclusive, factors for those enforcing the Act to consider in "determining whether [a] … dietary supplement is labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building:"

> (a) Whether the product contains:
>
> (i) an ingredient approved by the federal Food and Drug Administration for weight loss or muscle building;
>
> (ii) a steroid; or
>
> (iii) creatine, green tea extract, raspberry ketone, garcinia cambogia, green coffee bean extract;
>
> (b) whether the product's labeling or marketing bears statements or images that express or imply that the product will help:
>
> (i) modify, maintain, or reduce body weight, fat, appetite, overall metabolism, or the process by which nutrients are metabolized; or
>
> (ii) maintain or increase muscle or strength;
>
> (c) whether the product or its ingredients are otherwise represented for the purpose of achieving weight loss or building muscle; or

[2] The Act provides a carve-out for "protein powders, protein drinks and foods marketed as containing protein" unless the product "contains an ingredient other than protein which would, considered alone, constitute a dietary supplement for weight loss or muscle building." *Id.*

> (d) whether the retailer has categorized the dietary supplement for weight loss or muscle building by:
>
> > (i) placing signs, categorizing, or tagging the supplement with statements described in paragraph (b) of this subdivision;
> >
> > (ii) grouping the supplements with other weight loss or muscle building products in a display, advertisements, webpage, or area of the store; or
> >
> > (iii) otherwise representing that the product is for weight loss or muscle building.

§391-oo(6) (emphasis added).

The Act also imposes age verification requirements for covered products on retail establishments and "delivery seller[s]" including "online retailers" that sell Covered Products. §391-oo(2)-(4). Each violation of the Act may result in a civil penalty of up to $500. §391-oo(5).

III. The Disconnect Between the Act, the Harms it Aims to Address, and the Evidence Considered in Its Legislative History

The Act does not explain how restricting dietary supplements based on their *marketing* has any connection to minors' consumption of dangerous ingredients. JA93-95. Nor does it substantiate any nexus to the goal of reducing eating disorders in minors—another vaguely referenced justification by the legislature. *See id.*

The Act is accompanied by a "Justification" section, which includes just four citations in support of the regulation. *Id*. But these cited authorities relate to the consumption of products laced with *illegal* or *improper pharmaceutical ingredients*,

not dietary supplements. JA136-38 ¶¶70-75. Not a single citation concerned minors or lawful dietary supplements, let alone the *marketing* of those products to minors. *Id.* To date, the State has failed to explain, let alone provide any evidence for, how restricting the sale of some dietary supplements based on marketing addresses the State's concern in protecting minors, particularly where the law appears to allow the sale of identical products (without that marketing) to minors.

IV. CRN and its Members Grapple with the Act

CRN is the leading trade association representing the dietary supplement and functional food industry. JA15-16 ¶9. Since 1973, CRN has advanced its mission of bettering consumers' health and nutrition through the availability of safe, legal, and responsibly developed, sourced, manufactured, and marketed science-based dietary supplements, functional food, and ingredients for consumers' better health and nutrition. *Id.* It has over 180 member companies. JA18 ¶17.

CRN's members share in CRN's commitment to transparency, accountability, high-ethics, safety, and responsibility in the dietary supplement industry. *Id.* ¶18. They comply with all laws and regulations governing dietary supplements in the areas of manufacturing, marketing, quality control, and safety. *Id.* ¶17. CRN members also go above the requirements of law, such as by complying with CRN's self-regulatory initiatives—including its Code of Ethics—and by utilizing third-party certification programs that independently review and test dietary supplement

manufacturing processes and products for safety and quality. JA18-19 ¶20-22; JA63 ¶¶9-10; JA78 ¶6.

CRN and its members do not understand what the Act actually requires or even what it means to "represent" a product or an ingredient as aiding in weight loss or muscle building. JA20 ¶25. Any number of products or ingredients could play a role in a body's weight, muscle mass, or metabolism, directly or indirectly. *Id.*

The Act sets forth factors that purport to assist in determining whether a product falls under its scope, but these factors just introduce more ambiguity. One factor allows for the consideration of a few specific ingredients (such as green tea extract), even though the Act is focused "on the way products are marketed, *regardless of their ingredients.*" §391-oo(6)(a)(iii) (emphasis added). And green tea extract may be used in products for its antioxidant properties and marketed as supporting the heart, liver, or brain. JA39 ¶10. CRN's members do not know if the Act applies to products containing a specified ingredient, such as green tea extract, where they do not intentionally market that product as aiding in weight loss or muscle building. *Id.*; JA64 ¶14; JA72-3 ¶24; JA80 ¶13.

The Act also allows for the consideration of whether a "product's labeling or marketing bears statements or images that express or imply that the product will help" with, *inter alia,* "overall metabolism, or the process by which nutrients are metabolized." §391-oo(6). The Act does not explain what it means for an *image* to

imply an effect on the process by which nutrients are metabolized by the body. *See id.* Nor are CRN or its members able to divine the legislature's intent. JA20 ¶¶ 25-26.

In any event, the factor has nothing to do with "weight loss" or "muscle building." "Metabolism" is generally understood as the whole sum of reactions that occur within each cell, providing the body with energy used for vital processes. JA39 ¶11. The body needs critical nutrients to metabolize carbohydrates, proteins and fats for reasons wholly unrelated to weight loss or muscle building. *Id.* It is unclear whether the Act would apply to those products that aid in "metabolism" in the biological sense.

The Act's legislative history fails to provide any further clarity. The New York Assembly convened on June 1, 2023, to discuss the Act. *See* JA138 ¶78. Its sponsor, Assemblywoman Nily Rozic, was unable to answer basic questions about the Act's application and scope, including a straightforward question asking, "when looking at marketing, … what … specifically" does the Act consider. *Id.* ¶79. Nor could Assemblywoman Rozic state with a yes-or-no answer whether the Act age-restricted a product advertised with fat-burning propensities. JA139-40 ¶¶85-87. That led to the following exchange with Assemblywoman Mary Beth Walsh:

> ASSEMBLYWOMAN WALSH: … retailers are going to have to try to figure out whether what they're selling in their store is something that they're going to have to age check now. So I just want -- for the

> legislative record I'm just trying to make it really clear for them in trying to interpret this ...
>
> ASSEMBLYWOMAN ROZIC: [W]hat I would say is any … retailer who is concerned should keep in mind that we are -- we are trying to protect minors at the end of the day and this is specifically tailored for someone under the age of 18 trying to buy these pills or supplements.

JA139 ¶¶81-82. Assemblywoman Rozic did not provide further clarification.[3]

CRN's members are unsure where the NYAG will draw the line for enforcement. JA39-40 ¶12. To steer as far clear as possible from any potential interpretation that could result in liability, some CRN members have already decided to eliminate or restrict sales of certain products in New York. JA24-25 ¶¶41-43; JA75 ¶31. This reduces marketplace competition and deprives adults of purchasing options. *Id.*

Other CRN members have refrained from engaging in protected speech. JA27 ¶50. For example, one CRN member removed lawful structure/function claims from six of its products on a nationwide basis, some of which referred to metabolism in a biological sense. JA70-71 ¶¶17, 19. In those examples, metabolism refers to a bodily process related to the human body work efficiently, not weight loss or muscle growth. *Id.*

[3] The transcript is a public record available at https://nyassembly.gov/av/session/ June 1, 2023, session.

CRN members have been restricted in effectively marketing their products and providing consumers with helpful health information. JA-26 ¶48; JA-30 ¶63; JA70-71 ¶¶18. CRN members have had to institute age-verification restrictions on products they do not intentionally market for weight loss or muscle growth. JA72-73 ¶24. These companies have taken these steps not because it is clear that the Act applies, but in "a substantial abundance of caution in light of the Act's amorphous requirements." JA70 ¶17.

In any event, dietary supplement manufacturers and retailers have incurred substantial costs to comply with the Act, including: (1) time analyzing the Act's potential application to specific products; (2) restricting sales of certain products into New York; (3) limiting commercial speech and relabeling products; (4) implementing age-verification procedures through common carriers, which increases shipping costs; and (5) employing additional age-verification procedures at point of sale, which requires age-verification software and integration coding into existing webpages. JA21-30 ¶¶ 28–39, 43–65; JA69-76 ¶¶11–37; JA38-40 ¶¶8–12; JA42-45 ¶¶8–15; JA47-48 ¶¶10–13; JA50-52 ¶¶8–15; JA54-56 ¶¶8–15; JA58-59 ¶¶8–16; JA62-65 ¶¶8–18; JA78-81 ¶¶8–17.

Compliance will also mean lost profits, including lost sales to minors. JA30 ¶66. Moreover, because current shipping services do not enable verification for ages 18 and over (only 21 and over), CRN's members will lose sales to adults ages 18 to

21 who, under the Act, can lawfully purchase any product. JA27-28 ¶¶54-55; JA73-74 ¶27. CRN members will also lose sales to adults that either lack government-issued identification, would prefer to purchase dietary supplements anonymously, or who cannot stay home to sign for packages.[4] JA-29 ¶59; JA30 ¶¶65-66; JA32-33 ¶74; JA149-50 ¶¶132-37. As a result, dietary supplements will become more expensive and less accessible to New York consumers. JA30 ¶¶64-65.

V. The District Court Proceedings

On March 13, 2024, CRN filed its Verified Complaint. *See* ECF 1.[5] CRN then sought a preliminary injunction. JA9. The District Court held a hearing on April 10, 2024. JA84. During that hearing, the District Court asked the parties to file supplemental briefs addressing the issues of burdened and compelled speech. ECF 45.

On April 19, 2024, the District Court denied CRN's motion for a preliminary injunction. JA174-98. The District Court held that CRN was unlikely to prevail on the merits of its claims. *Id.* It reasoned that the Act regulated conduct such that any burden on the First Amendment was purely incidental, and that, in any event, the

[4] Where a recipient cannot sign for a package, the carrier will reroute the package back to the sender, and many CRN members have safety policies that require the destruction of returned consumable products. JA28-29 ¶58.

[5] CRN filed an Amended Verified Complaint on April 11, 2024, which incorporated by reference the declarations supporting CRN's motion for preliminary injunction. JA122-71.

Act would survive intermediate scrutiny under *Central Hudson Gas and Electric Corporation v. Public Service Commission*, 447 U.S. 557, 566 (1980). JA182-91. The District Court further held that because the Act would survive *Central Hudson*, it was also a proper exercise of the State's police powers. JA91-92. Finally, the District Court found CRN unlikely to prevail on the merits of its argument that the Act raised preemption concerns. JA92-93.

The District Court addressed CRN's vagueness argument in just four cursory sentences. JA93-94. It held, without explanation, that "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." *Id.* It also held that "the law is not vague in all of its applications" because a CRN member could identify certain instances in which it would suppress its speech or age-restrict its products in an abundance of caution. *Id.*

Finally, the District Court held that CRN could not establish irreparable harm because of its failure on the merits and because CRN did not move for injunctive relief sooner, and that the balancing of the equities and the public interest do not support an injunction because "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[.]" JA194-97.

CRN subsequently sought clarification of the District Court's ruling that the "plain language of the Statute is uncompromisingly clear." JA-199; ECF 54. The District Court refused to clarify its Order, noting only that the Act restricts products both based on its ingredients and what is said about the products, and that therefore the Act is "clear." JA199-200.

The District Court subsequently ruled on the State's motion to dismiss, granting it in part but declining to dismiss CRN's First Amendment claim, noting that the Act's legislative history "plausibly support[s] the inference that [it] might very well regulate protected speech." ECF 58 at 4-5.

CRN timely filed this appeal pursuant to 28 U.S.C. § 1292(a)(1) on May 14, 2024. JA201.

SUMMARY OF THE ARGUMENT

The District Court erred by denying CRN's motion for a preliminary injunction. Given the gravity of the Act's unwarranted constitutional intrusions, CRN more than adequately demonstrated a likelihood of success on the merits, and the District Court abused its discretion in denying the requested injunctive relief.

First, the Act regulates, chills, and compels protected speech. It is a textbook example of a content-based speech regulation: it is triggered by certain speech—namely, representations that (in the eyes of a regulator or a court) a product will aid in "weight loss" or "muscle growth." The Act effectively chills companies from

making otherwise truthful and lawful "structure/function" claims about dietary supplements. The Act also burdens speech based on content by forcing manufacturers making specific claims to implement costly age-verification procedures and incur lost profits, among other burdens. These manufacturers are also compelled, through implementing age verification, to convey the State's view that safe dietary supplements are somehow dangerous, a view with which they vigorously disagree.

The State cannot justify these impositions on speech under any applicable standard. It has no substantial interest in depriving the public of truthful information where there is no evidence that restricting safe dietary supplements based on their marketing—while allowing the sale of similar products (sold without such representations)—will do anything to reduce eating disorders in minors or protect minors from dangerous ingredients. Even if the State had a scintilla of evidence otherwise (which it does not), those objectives could be accomplished by regulations that burden substantially less speech.

Second, the Act is unconstitutionally vague. While the District Court held that the Act was not unconstitutional in all of its applications, that is the wrong legal standard to apply where, as here, a statute implicates the First Amendment. *See Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 494-95 (1982). Rather, a statute is unconstitutionally vague where "a substantial number of

its applications are unconstitutional." *See United States v. Stevens*, 559 U.S. 460, 473 (2010). The Act does not satisfy this standard. The Act leaves its core terms undefined and purports to impose liability without regard to who has spoken, where they spoke, and what they said. The only guidance the Act offers for those who wish to comply or those who need to enforce it amounts to overbroad, pliable, and know-it-when-I-see-it factors, which fail to draw lines between protected speech and marketing that could result in crippling civil penalties.

Third, the Act violates the Supremacy Clause. The federal government has comprehensively regulated the dietary supplement industry through its own laws and regulations. The Act, nevertheless, imposes requirements on structure/function claims that differ fundamentally from federal law. The Act accordingly violates the FDCA's express preemption provision.

Finally, CRN demonstrated irreparable harm through the constitutional infirmities of the Act, as well as the public interest in enjoining the Act. CRN respectfully requests that the Court reverse the District Court and remand for further proceedings.

STANDARD OF REVIEW

A preliminary injunction that "will affect government action taken in the public interests pursuant to a statute" requires the moving party to establish: "(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." *See Agudath Israel of Am. v. Cuomo*, 983 F.3d 620, 631 (2d Cir. 2020) (internal quotations omitted).

The Court "review[s] a district court's denial of a motion for a preliminary injunction for abuse of discretion" but its "legal conclusions *de novo*." *Safelite Grp., Inc. v. Jepsen*, 764 F.3d 258, 261 (2d Cir. 2014). A district court abuses its discretion if it "relied on incorrect law." *TCPIP Holding Co. v. Haar Commc'ns, Inc*., 244 F.3d 88, 92 (2d Cir. 2001). Where the First Amendment is at issue, "an appellate court has an obligation to make an independent examination of the whole record in order to make sure that the judgment does not constitute a forbidden intrusion on the field of free expression." *Jepsen*, 764 F.3d at 261.

ARGUMENT

I. The District Court Erred in Finding CRN Unlikely to Prevail on the Merits of its Claims

A. The Act Violates the First Amendment by Targeting, Burdening, and Compelling Protected Speech Based on Content

1. The District Court Erred in Holding that the Act Regulates Conduct Rather than Speech

The District Court incorrectly held that the Act is a "conduct-based" restriction that only regulates business behavior. The court concluded that the Act "regulates conduct, and at most incidentally burdens commercial speech." JA186. This characterization of the Act is wrong and ignores the Act's fundamental structure

and mechanism of enforcement. The Act *only* applies to products based on whether they are "labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building." *Id.* §391-oo(a)(1). In other words, the age verification process contemplated by the Act only gets triggered by certain *speech*; and absent that speech, the Act does not apply. That is not conduct-based regulation, it is speech regulation, plain and simple.

This is not the first time that a statute appears to implicate both speech and conduct. And appellate courts have provided important guidance for this situation, distinguishing between conduct-based regulations that apply *regardless* of speech, and those that are *predicated on* speech. "When the conduct regulated depends on—*and cannot be separated from*—the ideas communicated, a law is functionally a regulation of speech." *Honeyfund.com Inc. v. Governor*, 94 F.4th 1272, 1278 (11th Cir. 2024) (emphasis added); *see also Centro de la Comunidad Hispana de Locust Valley v. Town of Oyster Bay*, 868 F.3d 104, 112 (2d Cir. 2017) (finding statute regulating roadside employment solicitation regulated speech rather than conduct because town officials "must monitor and evaluate *the speech* of those stopping … vehicles and they may sanction the speaker only if a suspect says the wrong thing") (emphasis added). On the other hand, a statute regulates conduct where the law is not triggered by "the content of [the regulated party's] speech or the fact that they were engaged in speech at all." *Clementine Company, LLC v. Adams*, 74 F.4th 77,

86 (2d Cir. 2023). This is the legal framework the District Court should have applied.

The Eleventh Circuit's *Honeyfund* case is particularly instructive. There, a plaintiff brought a First Amendment challenge to a Florida law that banned workplace training on certain topics. *See* 94 F.4th at 1275. The state defended the law on the grounds that it was merely "a 'restriction on the *conduct*' of holding the mandatory meeting, '*not a restriction on the speech*' that takes place at that meeting." *Id.* at 1278 (emphasis in original). The Eleventh Circuit rejected this argument as an "attempt to control speech by recharacterizing it as conduct." *Id.* at 1275. As the court explained, "hiding speech restrictions in conduct rules is not only a dubious constitutional enterprise—it is a losing constitutional strategy." *Id.* at 1278. Relying on precedent, the Eleventh Circuit held that "[w]hen the conduct-not-speech defense is raised," courts should simply "ask whether enforcement authorities must examine the content of the message that is conveyed to know whether the law has been violated." *Id.* If they must, the law is a regulation of speech. *See id.*

The Eleventh Circuit then concluded: "[t]he only way to discern which mandatory trainings are prohibited is to find out whether the speaker disagrees with Florida. That is a classic—and disallowed—regulation of speech." *Id.* at 1277. The court further explained:

> That characterization reflects a clever framing rather than a lawful restriction. True enough—the [a]ct facially regulates the mandatory nature of banned meetings rather than the speech itself. But the fact that only mandatory meetings *that convey a particular message and viewpoint* are prohibited makes quick work of Florida's conduct-not-speech defense. To know whether the law bans a meeting, enforcement authorities must examine the content of the message that is conveyed. If Florida disapproves of the message, the meeting cannot be required … because the conduct and the speech are so intertwined, regulating the former means restricting the latter. In short, the disfavored 'conduct' cannot be identified apart from the disfavored speech. That duality makes the Act a textbook regulation of core speech protected by the First Amendment.

Id. at 1278–79; *see also Holder v. Humanitarian L. Project*, 561 U.S. 1, 28 (2010) (statute implicates speech where it is only triggered based on the content of a message); *Oyster Bay*, 868 F.3d at 112 (statute implicated speech where conduct was regulated only to the extent certain speech was involved).

This Court's opinion in *Adams* stands in helpful contrast. *See* 74 F.4th 77. There, this Court considered two local theaters' First Amendment challenge to a law that required certain indoor businesses "to check the vaccination status of patrons and staff and to refuse entry to individuals who could not produce proof of [COVID-19] vaccination." *Id.* at 81. The theaters argued that their First Amendment rights were violated by the mandate. *Id.* at 84. But the application of the law was triggered by whether the indoor venue at issue was a public gathering space where strangers were more likely to gather for extended periods—not what type of speech the venue was making (or enabling), or if it was making (or enabling) any speech at all. *Id.* at

86. Indeed, as this Court noted, the regulation "applied to a wide variety of indoor venues, most of which would be hard-pressed to argue that there is any speech involved in their services, such as casinos, bowling alleys, billiard halls, restaurants, and gyms." *Id.* As such, this Court held that the law was a "broadly applicable health measure[]" that did not regulate "expressive conduct." *Id.* And it therefore concluded that the law did not implicate the First Amendment because it required venues to check vaccines status irrespective of "the content of [the plaintiff's] speech or the fact that they were engaged in speech at all." *Id*.

Applying this framework, it is clear that the Act regulates speech, not conduct. The only way to determine whether particular products are covered by the age-verification requirement is to examine whether the product is "labeled," "marketed," or "otherwise represented" for the purpose of weight loss or muscle building. In other words, the content of the speech associated with a product determines whether it is covered by the law and, thus, whether the age restrictions apply. That makes the Act a speech-regulating statute.

The Act's stated purpose and plain text make clear that it implicates speech. *See Sorrell v. IMS Health Inc.*, 564 U.S. 552, 565 (2011) (in evaluating whether the Act implicates the First Amendment, a court may consider the "statute's stated purpose."). The legislature's purported purpose is clear: the Act deliberately

"targets" dietary supplements "based on their marketing." JA94.[6] To effectuate that purpose, the Act applies only to "dietary supplements for weight loss or muscle building," which are defined by reference to speech—specifically, whether the product is "labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building." *Id.* §391-oo(a)(1). The Act is "aimed at influencing the supply of information, a core First Amendment concern," and "when a statute aims to restrict the availability of such information for some purposes, that restriction must be judged under the First Amendment." *IMS Health Inc. v. Sorrell*, 630 F.3d 263, 272 (2d Cir. 2010), *aff'd*, 564 U.S. 552. And unlike the law in *Adams*, the Act applies *only* based on "the content of [the plaintiff's] speech or the fact that they were engaged in speech at all." *See* 74 F.4th at 86.

While the District Court relied on *Adams* in denying the preliminary injunction, it misapplied its central holding. The District Court focused on the language in *Adams* that noted that the challenged law "affect[ed] what indoor theater venues 'must *do*'—check the vaccination status of patrons and staff—not what they may or may not say.'" JA185-86 (citing *Adams*, 74 F.4th at 86).[7] But in *Adams*,

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[6] The District Court relied on these very facts to find that CRN's stated a plausible claim for First Amendment injury and denied the NYAG's motion to dismiss this claim. ECF 58, at 4-5.

[7] For this proposition, *Adams* relied on *Rumsfeld v. FAIR, Inc.*, 547 U.S. 47 (2006), in which the Supreme Court held that a law withholding federal funds to schools that "den[y] military recruiters access equal to that provided other recruiters" did not violate the First Amendment. *Id.* at 51. The court held that the statute only required

this Court first made a predicate finding that the District Court quoted, but did not apply: the challenged statute in *Adams* was not "regulating expressive conduct," and instead "was a public health regulation of general application against the physical premises in which plaintiffs *happen to* perform theater." 74 F.4th at 85-86 (emphasis added) (citing *Arcara v. Cloud Books. Inc.*, 478 U.S. 697 (1986)). That is distinguishable from, for example, the problematic law in *Honeyfund*, which regulated only the meetings that conveyed a particular message. It is also distinguishable from the Act, which regulates only products that convey a particular message.

The District Court's attempt to align this case with *Adams* was premised on a fundamental misreading of the statute. The District Court repeatedly referred to the Act as regulating "dietary supplements" generally. JA184 (noting "Statute targets the same conduct-based regulation by placing ***dietary supplements*** behind the proverbial counter and requiring age verification" and its "core purpose is to inhibit minors' access to ***dietary supplements***"). The District Court sought to analogize the general application of the vaccine mandate in *Adams* to the age verification

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schools to afford equal access to military recruiters, but did not get in the way of the schools expressing any views on the military; as such, the statute regulated conduct, not speech. *Id.* at 60. In other words, that statute "can be understood without reference to speech." *Honeyfund.com, Inc. v. DeSantis*, 622 F. Supp. 3d 1159, 1176 (N.D. Fla. 2022), *aff'd*, 94 F.4th 1272. That is distinguishable from the Act, which *cannot* be "understood without reference to speech." *Id.*

requirement in the Act. But the analogy is inapt; the Act does not regulate "dietary supplements" *generally*, it regulates *certain* dietary supplements based on the *speech associated with them.*

The District Court also justified its holding by noting that the Act not only regulates products based on associated speech, but also age-restricts a few specific ingredients. JA185 (citing §391-oo(6)(a)). But that characterization of the Act is misleading and incomplete. Most importantly, the District Court's focus ignores that the sponsor memo accompanying the Act itself makes clear that it is "focused on the way products are marketed, *regardless of their ingredients*." JA94 (emphasis added). The Act applies first and foremost to products that are "labeled, marketed, or otherwise represented" with certain speech. §391-oo(a)(1). It is only to assist in that speech-based inquiry that the Act then sets forth four factors for courts to "consider," one of which is the list of the few ingredients the District Court referenced. *Compare id. with* §391-oo(6). The other three factors require examining speech and expression. *See* §391-oo(6)(b)-(d). And while the District Court noted that "courts *may consider* whether the labeling, marketing, grouping, or representation of products outside the scope of the listed ingredients [promotes weight loss or muscle building]," JA185 (emphasis in original), that characterization ignores that the first threshold inquiry—the definition of the product that is subject to the Act—requires consideration of the speech associated with the product. *See*

§391-oo(2) (prohibiting the sale of a "dietary supplement for weight loss or muscle building within this state to any person under eighteen years of age"); and §391-oo(1)(a) (defining "dietary supplements for weight loss or muscle building" as a product "labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building").

The District Court's ruling relied on distinguishable law. The District Court cited *Hoffman*, 455 U.S. 489, *Art & Antique Dealers League of America, Inc. v. Seggos*, 523 F. Supp. 3d 641 (S.D.N.Y. 2021), and *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001), for the proposition that a statute that "simply regulates business behavior" is not a regulation of speech. But that statement is wrong as a general proposition and fails to appreciate the materially distinguishable facts of those cases.[8] The regulation in *Hoffman*, for example, did not implicate the First Amendment because it did not concern protected speech at all—only communications that proposed illegal transactions. *See* 455 U.S. at 489. And the regulations in *Lorillard* and *Seggos* addressed how businesses physically present products for sale. Indeed, in *Lorillard*, the Supreme Court recognized that a retailer's decision on where to place product only "*may* have a communicative component," and that the law regulated the placement of heavily-regulated tobacco

[8] Commercial speech is protected by the First Amendment. *See, e.g.*, *Sorrell*, 544 U.S. at 571-72.

products "for reasons unrelated to the communication of ideas." 533 U.S. at 569 (emphasis added); *see also id.* at 604 (Stevens., J., concurring) (calling the display only a "marginal communicative function").

Here, by contrast, the Act regulates every conceivable means of communication—marketing, labeling, and so-called "other representations"—that a company (or any third party) may have with consumers. That "free flow of commercial information is indispensable." *Virginia Bd. of Pharm. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 765 (1976). And courts have routinely acknowledged the particular importance of speech that assists consumers in making informed decisions concerning their health. *See Sorrell*, 564 U.S. at 566; *United States v. Caronia*, 703 F.3d 149, 167 (2d Cir. 2012). The District Court's attempt to analogize truthful marketing claims associated with dietary supplements with a retailer's display decisions for inherently problematic products was erroneous, and the District Court's determination that the First Amendment is not implicated by the Act is likewise erroneous.

2. The Act is a Content-Based Restriction on Commercial Speech and Fails Intermediate Scrutiny

The District Court did not meaningfully address CRN's argument that the Act impermissibly burdens speech based on content. "A statute is presumptively inconsistent with the First Amendment if it imposes a financial burden on speakers because of the content of their speech." *Simon & Schuster, Inc. v. Members of N.Y.*

State Crime Victims Bd., 502 U.S. 105, 115 (1991) (internal quotation omitted). But that is exactly what the Act does. If a company wants to disseminate truthful information about its product's relationship to weight loss or muscle growth, it must implement costly age verification procedures, forfeit sales to consumers—including lawful consumers between the ages of 18 and 21 (because of the limitations of currently-available shipping practices)—and risk the imposition of civil penalties. JA72-76 ¶¶23-36. "[A] law is content-based if 'a regulation of speech 'on its face' draws distinctions based on the message a speaker conveys," *i.e.*, if the law "singles out specific subject matter for differential treatment." *Barr v. Am. Ass'n of Political Consultants, Inc.*, 591 U.S. 610, 618-19 (2020) (quoting *Reed v. Town of Gilbert, Ariz.*, 576 U.S. 155, 163 (2015)). Here, the Act clearly imposes a content-based burden on speech that is "presumptively inconsistent with the First Amendment." *Simon & Schuster*, 502 U.S. at 115 (finding law constitutionally suspect where it "impose[d] a financial disincentive only on speech of a particular content," and noting "[w]e have long recognized that even regulations aimed at proper governmental concerns can restrict unduly the exercise of [First Amendment] rights"); *see also Sorrell*, 564 U.S. at 566 ("Lawmakers may no more silence unwanted speech by burdening its utterance than by censoring its content."); *Reed*, 576 U.S. at 163 (regulation is content-based if law facially "draws distinctions based on the message a speaker conveys.").

Other than labeling this burden "incidental," the District Court did not address this key First Amendment implication at all.

a) *The District Court Erred in Finding that the Act Survived Intermediate Scrutiny*

The District Court also erred in its application of intermediate scrutiny under *Central Hudson*, an analysis the court held was not even necessary given its determination that the First Amendment was not implicated (or was only incidentally implicated).[9] The *Central Hudson* test determines whether a government's regulation of commercial speech passes constitutional muster. *See Oyster Bay*, 868 F.3d at 112.[10] The threshold question under *Central Hudson* is whether the speech

[9] Nonetheless, the District Court's cited authority demonstrates that laws that burden speech (even incidentally) must still survive constitutional scrutiny. *See Lorillard*, 533 U.S. 525; *Seggos*, 523 F. Supp. 3d 641.

[10] Both the Supreme Court and this Court have left open the possibility that content-based burdens of speech must satisfy a heightened level of scrutiny (i.e., above intermediate scrutiny). In *Sorrell*, the Supreme Court made clear that "[t]he First Amendment requires heightened scrutiny whenever the government creates 'a regulation of speech because of disagreement with the message it conveys.'" *Sorrell*, 564 U.S. at 566; *see also Barr*, 591 U.S. at 618. In *Vugo Inc. v. City of New York* , this Court declined to extend the *Sorrell* heightened scrutiny for content-based restrictions to commercial speech, but left open the possibility that "strict scrutiny applied to some commercial speech restrictions after *Sorrell*," where the challenged statute "impose[d] an aimed, content-based burden" on particular speakers. 931 F.3d 42, 49 n.7 (2d Cir. 2019). This Court contrasted the *Vugo* circumstances, where, unlike *Sorrell*, "[t]here is no suggestion that the City is trying to "quiet truthful speech with a particular viewpoint that it fears might persuade." *Id.* (cleaned up). The Court concluded that "strict scrutiny might apply to some commercial speech restrictions out of concern that the government is seeking to keep would-be recipients of the speech in the dark or otherwise prevent the public from receiving certain truthful information." *Id.* (cleaned up).

concerns lawful activity and is non-misleading. *See Central Hudson*, 447 U.S. at 567. Assuming that prong is satisfied (as it is here), a court will consider three additional questions: whether the government's interest is substantial, whether the regulation *directly* and *materially* advances the government's substantial interest; and whether the regulation is narrowly tailored. *Id*. The government bears the burden of justifying a restriction of commercial speech under intermediate scrutiny and may not satisfy its burden "by mere speculation or conjecture." *Lorillard Tobacco Co.*, 533 U.S. at 556.

Where the government fails to carry its burden as to even one of the *Central Hudson* factors, this Court has routinely found a statute's regulation of commercial speech is unconstitutional. *See Oyster Bay*, 868 F.3d at 116–18 (ordinance prohibiting solicitation from streets failed intermediate scrutiny); *Caronia*, 703 F.3d at 169 (regulation of speech promoting the lawful, off-label use of FDA-approved drugs failed intermediate scrutiny); *Jepsen*, 764 F.3d at 260, 264–66 (law prohibiting automobile glass repairers from naming affiliates failed intermediate scrutiny); *IMS Health Inc. v. Sorrell*, 630 F.3d 263, 282 (2d Cir. 2010), *aff'd*, 564 U.S. 552 (2011) (law banning sale of prescriber-identifiable data for marketing failed intermediate scrutiny); *Alexander v. Cahill*, 598 F.3d 79, 89 (2d Cir. 2010) (with one exception, regulations regarding attorney advertising failed intermediate scrutiny); *Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth.*, 134 F.3d 87, 101–02 (2d Cir. 1998) (denial

of brewery's proposed label failed intermediate scrutiny); *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 72–73 (2d Cir. 1996) (statute requiring disclosure of growth hormones in dairy products failed strict scrutiny).

Here, the District Court's analysis of each of the *Central Hudson* factors was erroneous, and each provides an independent ground for reversal.

b) *The District Court Erred in Failing to Analyze Central Hudson's "Substantial Interest" Requirement*

The District Court started its analysis by proclaiming that CRN has "conceded that the State has a substantial government interest in protecting public health and regulating misleading information." JA187. But the District Court mischaracterized what the NYAG itself set forth as the State's interest in passing the Act. *See Amestoy*, 92 F.3d at 73 (noting in assessing the substantial interest prong of *Central Hudson*, court must "rely only upon those interests set forth by [the state] before the district court"). In its Opposition to CRN's Motion for Preliminary Injunction, the State made clear that the government interest underlying the Act was "reducing the incidence of the use of dietary supplements for weight loss and muscle building by minors and promoting awareness of the potential dangers of the unregulated consumption of such dietary supplements more generally." ECF 36, at 19-20. The NYAG never claimed to have an interest in "regulating misleading information," and there has been no suggestion by the NYAG in this case (or in the Act's legislative history) that the Act is intended to regulate "misleading information."

Indeed, the threshold question in the *Central Hudson* analysis, which the NYAG did not contest, is that the speech at issue "concerns lawful activity and is not misleading." *Amestoy*, 92 F.3d at 72.

The District Court's conclusion on the *Central Hudson* "substantial interest" prong was also erroneous because CRN has never *conceded* that the State government has a substantial interest in regulating the marketing of dietary supplements. Indeed, CRN had made its position clear that "the State has no interest at all, let alone one that is substantial, in burdening accurate health information or depriving citizens of a basis to exercise a meaningful choice concerning their individualized health needs and discern what is in their own best interests." ECF 25 at 19. A half-century of Supreme Court jurisprudence demonstrates that it is *not* a substantial government interest to protect minors from information for their own protection. In *Thompson v. Western States Medical Center*, the Supreme Court held that "the fear that people would make bad decisions if given truthful information cannot justify content-based burdens on speech." 535 U.S. 357, 374 (2002) (no government interest "in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information") (cleaned up).

The District Court thus erred in its scant analysis of *Central Hudson's* "substantial interest" prong and by presuming, without support, that CRN had

conceded that the State had a substantial government interest in targeting the marketing of dietary supplements.

c) *The District Court Erred in its Analysis of Central Hudson's "Material and Direct Advancement" Prong*

The District Court also erred in finding that the Act satisfied *Central Hudson's* requirement that the State demonstrate that the Act "*directly advances*" the substantial government interest in a *material* way.

In reaching its conclusion, the District Court considered only the relationship between providing minors with access to allegedly problematic dietary supplements and the public health goal of protecting minors from eating disorders. But that is separate and apart from what the Act actually regulates; the District Court did not consider the relationship between (on one hand) the regulation of the *marketing* of a dietary supplement and (on the other hand) eating disorders in minors. And the State has failed to provide any evidence that the content-based restrictions on truthful marketing of dietary supplements has any connection at all to eating disorders in minors—much less that the restrictions will "in fact" address eating disorders in minors to a "material degree." *Caronia*, 703 F.3d at 164; *see also Ibanez v. Fla. Dep't of Bus. & Pro. Regul., Bd. of Acct.*, 512 U.S. 136, 146-49 (1994) (aggregating cases where evidence was insufficient to establish requirement); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 506-07 n.16 (state failed to prove speech regulation would have "significant" impact on aimed objective "without any findings of fact,

or indeed, any evidentiary support whatsoever"); *Seggos*, 523 F. Supp. 3d at 647-48 (considering studies reflecting decrease in commerce and display of ivory in New York). That evidentiary void in the record is stark and renders the Act an unconstitutional infringement on speech.

The purported "evidence" on which the District Court relied to bridge the gap between the Act's regulation of speech and the harm it purports to address is woefully inadequate. The primary evidence is an advocacy letter by a doctor named Joseph Nagata ("Nagata Letter"), which self-servingly characterizes different studies, none of which were attached to the letter itself. JA188-89 (citing JA108-11.) As described by the District Court, the Nagata Letter only purported to connect dietary supplements and eating disorders in minors—it did *not* purport to link, in any way, the marketing associated with dietary supplements with eating disorders in minors. *Id*. The letter does not mention marketing at all—and that is because it was written *in support of the Predecessor Bill* that did not target marketing, only dangerous ingredients. JA109. And, in any event, the Nagata Letter suggests, at most, that muscle-building supplements have been "linked to eating disorders." JA108. A suggestion of a "link" is not the same as a showing that restricting the sale of muscle growth supplements will do *anything*—let alone "in fact" help to a "material degree"—to address eating disorders in minors.

Furthermore, the Nagata Letter blatantly mischaracterizes the study on which it purports to rely for even its limited proposition. *Id.*[11] The underlying study focused on *competitive adult athletes* who consumed ten specified products, many of which the Act does not even cover.[12] Moreover, that study revealed only a marginal difference among these adult athletes with respect to eating disorders and concluded that "*the magnitude of differences were small, and interpretations regarding supplement use and risk for disordered eating should be made with caution*." *Id.* (emphasis added). The underlying study therefore undermines the credibility of any conclusions drawn about the effects of dietary supplements on eating disorders in minors. *Cf.* JA138 ¶77 (meta-analysis of empirical studies found "the evidence to date does not support a causative role for dietary supplements in eating disorders").

The District Court's citation to *L.T. v. Zucker*, No. 1:21-CV-1034, 2021 WL 4775215 (N.D.N.Y. Oct. 21, 2021), underscores this point. There, in a constitutional challenge to a Covid-era mask mandate, the government pointed to third-party studies to support the proposition that masks help reduce the spread of airborne diseases. *See id.* at *10-11 The studies directly linked the statutory obligation

[11] Nagata JM, Peebles R, Hill KB, Gorrell S, Carlson JL. Associations between ergogenic supplement use and eating behaviors among university students. Eat Disord. 2020. doi:10.1080/10640266.2020.171263.

[12] The article is available at www.ncbi.nlm.nih.gov/pmc/articles/PMC7483647/.

(wearing masks) with the statutory goal (reducing transmission of the disease). Here, there is no connection anywhere in the record between dietary supplement *marketing* and eating disorders among minors.

Indeed, the fact that minors may legally consume dietary supplements, even if they are marketed or labeled as promoting weight loss or muscle building, further undermines the State's arguments that it satisfies *Central Hudson*'s direct advancement prong. In *Caronia*, this Court held that a regulation that interfered with a pharmaceutical manufacturer's ability to promote off-label uses of drugs failed *Central Hudson*'s third prong for this same reason:

> [T]he government's construction of the FDCA's misbranding provisions does not directly advance its interest in reducing patient exposure to off-label drugs or in preserving the efficacy of the FDA drug approval process because the off-label use of such drugs continues to be generally lawful.

703 F.3d at 167 (internal quotation omitted). Here, too, the fact that a minor can still legally consume products covered by the Act similarly demonstrates that the restrictions on access to these products based on their marketing "provides only ineffective or remote support for the government's purpose." *Id.*

Finally, the District Court failed to address CRN's argument that the over-inclusivity and under-inclusivity of the Act undermine the suggestion that the Act will "in fact" "directly" address "to a material degree" the harms of underage eating disorders. As this Court held in *Vugo, Inc.*, "[u]nderinclusiveness is problematic

insofar as it "raise[s] doubts about whether the government is in fact pursuing the interest it invokes, rather than disfavoring a particular speaker or viewpoint," or "reveal[s] that a law does not actually advance a compelling interest." 931 F.3d at 53; *see also Jepsen*, 764 F.3d at 265 (regulation failed intermediate scrutiny where it advanced interest "in an indiscernible or *de minimis* fashion.").

Here, the Act casts a net too wide in the wrong part of the river—it age-restricts products with safe and legal ingredients that do not actually assist with weight loss or muscle building, while allowing the sale of *any* product—no matter how dangerous or beneficial to weight loss or muscle building—so long as there are no representations on the label or marketing of that product to that effect. That does not prevent any of the harms the Act purports to address. For this reason alone, the District Court misapplied *Central Hudson* third prong.

d) *The District Court Erred in its Evaluation of Central Hudson's "Narrow Tailoring" Factor*

The District Court also erred in its analysis of *Central Hudson's* narrow tailoring requirement. Specifically, the government is required to show that "the regulation [does] not burden substantially more speech than necessary to further its legitimate interests." *Oyster Bay*, 868 F.3d at 115.

In *Oyster Bay*, this Court affirmed the lower court's finding that an ordinance regulating roadside solicitation of day laborers failed the fourth *Central Hudson* prong because, *inter alia*, that ordinance was "extremely far-reaching in that it

prohibit[ed] speech that pose[d] no threat to safety." *Id*. at 104. Here, the District Court failed to consider the limitless reach of the Act, which goes far beyond any conceivable connection to protecting against eating disorders in minors. For example, a manufacturer of a children's multivitamin that claims, in its truthful marketing, that it helps sustain strong muscles may well be burdened by the age-verification requirement even though its marketing poses no threat to the development of eating disorders in minors. A law that extends so far beyond its original purpose is not "narrowly drawn."

Moreover, this Court has consistently held that the "narrowly tailored" prong of *Central Hudson* is not met where there is—even conceivably—an alternative legislative means to achieve the same government interest without an imposition on speech. *See, e.g.*, *Oyster Bay*, 868 F.3d at 115; *Jepsen*, 764 F.3d at 265. And while the District Court acknowledged that the Predecessor Bill sought to address the same government interest without targeting speech (JA190), it failed to conclude on this basis that the Act failed *Central Hudson*'s "narrowly tailored" requirement. Instead, the District Court reasoned that the reformulated Act is somehow an upgrade with a "clarified [] scope." JA190. But whether it is an "upgrade" (it is not) or has a "clarified scope" (it does not) is irrelevant under the "narrowly tailored" *Central Hudson* requirement, which is concerned with the extent to which the legislation

could have avoided implicating or burdening speech.[13] The very existence of the Predecessor Bill, which was ingredient-based and did not implicate or burden speech, demonstrates that the State had options to achieve its policy aims that do not infringe on speech. Ultimately, "[i]f the First Amendment means anything, it means that regulating speech must be a last … resort." *See Thompson*, 535 U.S. at 373.[14]

3. The Act Also Compels Speech and Fails Strict Scrutiny

The Act also improperly compels speech by forcing manufacturers, retailers, and other sellers of products subject to the Act to convey a state-sponsored message through the age-verification procedure *that the product is unsafe for minors*. "The government may not compel a person to speak its own preferred messages," and it does not "matter whether the government seeks to compel a person to speak its message when he would prefer to remain silent or to force an individual to include

[13] For substantially the same reasons that the Act does not satisfy the *Central Hudson* analysis, the State has also exceeded its police powers and the District Court erred in holding otherwise. *See, e.g.*, *DoorDash, Inc. v. City of New York*, 1:21-cv-7564, 2023 WL 6118229, at *20 (S.D.N.Y. Sept. 19, 2023) ("In order for a local law to come within the police power of a municipality [], it must bear a reasonable relationship to the objective sought to be promoted, i.e., public safety, health or welfare.").

[14] The District Court analogized the Act to alcohol and tobacco laws, or requiring the placement of inherently dangerous products like cigarettes behind the counter, "none of which have been invalidated on First Amendment grounds." JA190-91. This analogy is inapt. Dietary supplements are not age restricted like cigarettes, alcohol, or guns because they do not have the same inherent danger.

other ideas with his own speech that he would prefer not to include. All that offends the First Amendment just the same." *303 Creative LLC v. Elenis*, 600 U.S. 570, 586-87, 589 (2023) (invalidating Colorado statute that would force wedding website designer to convey messages with which she disagreed: "If she wishes to speak, she must either speak as the State demands or face sanctions for expressing her own beliefs," including fines; "Under our precedents, that 'is enough,' more than enough, to represent an impermissible abridgment of the First Amendment's right to speak freely"); *Wooley v. Maynard*, 430 U.S. 705, 706 (1977) (state cannot compel private speaker "to be an instrument for advocating public adherence to an ideological point of view he finds unacceptable"); *New Hope Family Services, Inc. v. Poole*, 966 F.3d 145, 171 (2d Cir. 2020) (statute that forced adoption agency to convey message with which it disagreed on religious grounds).

The Act's age-verification requirement requires manufacturers and retailers to use an age-verification procedure to convey the message that dietary supplements are dangerous for minors—a message with which CRN and its members strongly disagree. Compelled speech warrants strict scrutiny. *See Nat'l Inst. Fam. & Life Advocs. v. Becerra*, 585 U.S. 755, 766 (2018) (compelled speech triggers strict scrutiny and "may be justified only if the government proves that they are narrowly

tailored to serve compelling state interests"). The District Court erroneously failed to consider the compelled speech implications of the Act.[15]

B. The Act is Unconstitutionally Vague

The District Court also erred in its vagueness analysis. A law is unconstitutionally vague where it "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." *F.C.C. v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012) (cleaned up). It is particularly important for a statute involving speech to provide clear guidance to those subject to it and to enforcement agencies "to ensure that ambiguity does not chill protected speech." *Id.* at 253-54.

The District Court upheld the Act because it was "not vague in all of its applications[.]" JA193 (citing *Hoffman*, 455 U.S. at 497-98). But that was not the proper inquiry. As the Supreme Court made clear in *Hoffman*, considering whether a statute is "vague in all of its applications" is the most exacting standard and applies only where "the enactment implicates no constitutionally protected conduct." *Id.* at 494-95. Instead, "[i]n First Amendment cases . . . this Court has lowered that very high bar … [t]o "'provide[] breathing room for free expression [and has] substituted a less demanding though still rigorous standard.'" *Moody v. NetChoice, LLC*, 603 U.S. _____, 2024 WL 3237685, at *8 (2024); *see also Johnson v. United States*, 576

[15] Because the Act fails intermediate scrutiny, it necessarily fails strict scrutiny.

U.S. 591, 602 (2015) (noting, in the context of a First Amendment implication, the Supreme Court's "holdings squarely contradict the theory that a vague provision is constitutional merely because there is some conduct that clearly falls within the provision's grasp").

Here, the Act plainly implicates the First Amendment. Indeed, the District Court's ruling on the State's motion to dismiss confirms the implication of the First Amendment, holding that CRN plausibly alleged a First Amendment violation. *See* ECF 58 at 5 (finding, in denying motion to dismiss First Amendment claim, that CRN alleged facts that "plausibly support the inference that the Statute might very well regulate protected speech."). CRN therefore did not need to show that the Act is vague in all of its applications—only that the Act is unconstitutionally vague because "a substantial number of its applications are unconstitutional, judged in relation to the statute's plainly legitimate sweep." *Stevens*, 559 U.S. at 473. Moreover, this less rigorous standard applies even where the First Amendment is "*implicate[d]*"—even if it is not necessarily violated. *See United States v. Requena*, 980 F.3d 30, 39 (2d Cir. 2020) (no need to show vagueness "in all applications" where statute "*implicates* rights protected by the First Amendment") (emphasis added); *see also Smith v. Goguen*, 415 U.S. 566, 573 (1974) (heightened vagueness standard applies where "statute's literal scope [] is capable of reaching expression sheltered by the First Amendment").

The District Court also erred by looking at the wrong evidence and drawing the wrong conclusion. A statute is unconstitutionally vague "if it fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits." *Cunney v. Bd. of Trustees of Vill. of Grand View, N.Y.*, 660 F.3d 612, 621 (2d Cir. 2011). Alternatively, a law is unconstitutionally vague "if it authorizes or even encourages arbitrary and discriminatory enforcement." *Id.* Specifically, "[s]tatutes must provide explicit standards for those who apply" them to avoid "resolution on an ad hoc and subjective basis, with the attendant dangers of arbitrary and discriminatory application."" *Id.* Either of those grounds is sufficient to warrant a finding that a statute is unconstitutionally vague.

The District Court did not engage either prong—it did not look at the type of notice the Act provides those subject to its obligations, and it did not consider the extent to which there are clear guidelines for enforcement. Instead, it concluded the Act was not unconstitutionally vague by pointing to a CRN member's declaration that it had suppressed certain speech to ensure compliance with the Act—a purported admission that someone knows how to understand the Act's reach. JA193-94 (citing JA67-76). But a regulated party's compliance efforts are not a proper inquiry in a vagueness analysis. *See Cunney*, 660 F.3d at 621 ("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."). Indeed, that declaration only reflects that a CRN member opted to self-censor informative, truthful speech on a nationwide basis because it could not determine whether it would trigger the Act. JA70 ¶17. That does not demonstrate the certainty of the statute, quite the opposite: it reflects only that "[v]ague restrictions on speech force potential speakers to steer far wider of the unlawful zone than if the boundaries of the forbidden areas were clearly marked." *Baggett v. Bullitt*, 377 U.S. 360, 372 (1964); *Reno v. Am. Civil Liberties Union*, 521 U.S. 844, 870-71, 874 (1997) ("The vagueness of a [content-based regulation of speech] raises special First Amendment concerns because of its obvious chilling effect" and "unquestionably silences some speakers whose messages would be entitled to constitutional protection").

The District Court also concluded—without analysis—that 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." JA193. But the court did not explain the "uncompromisingly clear" meaning of the Act, nor does the Act's plain language provide meaningful notice to those wishing to comply.

The Act's central prohibition relates to dietary supplements that are "labeled, marketed, or otherwise represented for the purpose of achieving weight loss or

muscle building." §391-oo(a)(1). But none of these key phrases, central to understanding what products are subject to the statute, are defined. For example, it is not clear whether statements made by third parties on the Internet qualifies as "otherwise represented"—and if so, does the statute require a dietary supplement manufacturer to scour the Internet for all possible references to each ingredient to determine whether it has been touted for weight loss or muscle building. Nor is it clear whether a product is subject to the Act as a product marketed "for ***the*** purpose of muscle building" if its label says it can be used for muscle building ***and*** brain health. And if one retailer displays a product on a shelf labeled "Weight Management Products" or on an endcap display with exercise equipment and weights, it is unclear if that implicates that retailer or other retailers carrying that product who may not be aware of that placement.

The District Court's ruling did not address, let alone resolve, questions relating to the Act's scope. These questions are not on the fringe of the statute—they go to the essence of what the Act regulates and the notice that those subject to the Act need to ensure their compliance. That so many unanswered questions come to mind illustrates the vagueness of the statute. *See Ass'n of Nat'l Advertisers, Inc. v. Lungren*, 809 F. Supp. 747, 761-62 (N.D. Cal. 1992) (noting some hypothetical applications of term "may be [] fanciful example[s], but in light of the legislature's

failure to define" key terms, "where does fanciful possibility end and intended coverage begin?") (quoting *Baggett*, 377 U.S. at 373).

The phrase "otherwise represented," which has no plain meaning and is not limited in any way in the Act, is particularly problematic. The only meaning of "otherwise represented" that makes any sense is that it means something *different* than "labeled" or "marketed"—but that's the only clue the Act gives as to understanding that phrase. Ultimately, "otherwise represented" is susceptible to any number of meanings, such that "a speaker [could not] confidently assume [range of speech-related actions] do not violate the [statute]." *Reno*, 521 U.S. at 871, 873 (finding statute unconstitutionally vague in the absence of definitions for key terms, which it called "open-ended"). The District Court therefore erred in failing to consider whether the failure to define vague key terms created a gap in guidance for compliance, supporting a finding of unconstitutional vagueness. *See, e.g.*, *Stephenson v. Davenport Cmty. Sch. Dist.*, 110 F.3d 1303, 1310 (8th Cir. 1997) ("[F]ailure to define the pivotal term of a regulation can render it fatally vague;" term "gang" was undefined and vague); *Grocery Manufacturers Ass'n v. Sorrell*, 102 F. Supp. 3d 583, 643-44 (D. Vt. 2015) (statute was unconstitutionally vague for failure to define a key term, "natural").

The NYAG argued below that the undefined terms are perfectly clear because the Act includes a list of other factors for courts to consider to help understand the

undefined phrase "labeled, marketed, or otherwise represented as for the purpose of achieving weight loss or muscle building." But (as noted) this list does nothing to resolve the uncertainty of the Act's reach. The non-exhaustive factors themselves refer to the same undefined key language (a product can be subject to the Act if its ingredients are "otherwise represented" for purposes of weight loss or muscle building), third-party conduct (*i.e.*, how a retailer groups its supplements, which could draw into its reach Amazon and social media placement), or invoke new undefined and potentially limitless terms (*i.e.*, "whether the product's labeling or marketing ***bears statements*** or ***images*** that ***express or imply*** that the product will help … ***overall metabolism*** or ***the process by which nutrients are metabolized***"). §391-oo(6)(b) (emphasis added). Indeed, rather than putting a finer point on the vague and undefined terms that comprise the definition of a product that is subject to the Act, these factors *expand* (and sometimes contradict) them, as illustrated in this chart:

Term in Primary Definition	**Purported "Clarification"**
"for the purpose of achieving weight loss" §391-oo(1)(a).	"will help modify, maintain, or reduce body weight, fat, appetite, overall metabolism, or the process by which nutrients are metabolized" §391-oo(6)(b)(i).
"for the purpose of achieving … muscle building" §391-oo(1)(a).	"will help … maintain [muscle] or increase muscle or strength" §391-oo(6)(b)(ii).
"labeled, marketed, or otherwise represented" §391-oo(1)(a).	"labeling or marketing bears statements or images that express or imply"; "whether the product *or its ingredients* are otherwise represented for the purpose of achieving weight loss or muscle building" §391-oo(6)(b), (c).

The Act is also unconstitutionally vague on the separate ground that it fails to establish "minimal guidelines to govern law enforcement." *See City of Chicago v. Morales*, 527 U.S. 41, 60 (1999). Given the lack of definition for the key terms in the statute that trigger liability, the NYAG would be determining, in its own judgment and pursuant to its own discretion, what types of labeling, marketing or other" representations subject a product to the Act—*i.e.*, whether to consider third party statements, whether to consider statements on the Internet, and even whether to consider statements made in one product's marketing binding on another product with the same ingredients but not the same marketing. The Act does not state *who* needs to make statements about weight loss or muscle building, *where* the statements need to be made, *to whom* they need to be made, *how* directly the marketing needs to address weight loss or muscle building, or with *what* state of mind. It is the

enforcement agency (and ultimately the courts) that will be tasked with drawing the line as to what qualifies to subject a product to the Act, absent clear criteria in the statute. This invites arbitrary, ad hoc enforcement that renders the Act unconstitutionally vague. *See Morales*, 527 U.S. at 62 (finding statute unconstitutionally vague where, *inter alia*, an undefined key term left police with too much discretion in enforcement); *Kolender v. Lawson*, 461 U.S. 352, 360-61 (1983) (finding statute impermissibly vague where it failed to establish the standards by which the state would enforce); *Goguen*, 415 U.S. at 576 (same); *United Food & Com. Workers Union, Loc. 1099 v. Sw. Ohio Reg'l Transit Auth.*, 163 F.3d 341, 360 (6th Cir. 1998) (finding likelihood of success on merits of vagueness claim where guidelines for enforcement lacked "objective definition"). If, as Governor Hochul said in vetoing the Predecessor Bill, the DOH "does not have the expertise necessary to analyze ingredients used in countless products," it defies credulity to think that the NYAG and the judiciary will fare any better.

C. The Act is Preempted by Federal Law

The labeling and marketing of dietary supplements are comprehensively regulated by the federal government (the FDA and FTC). Dietary supplements are regulated under the FDCA and are the sole focus of DSHEA. State laws that regulate such labeling/marketing must be consistent with the FDCA, DSHEA, and the FTC Act. *See Ackerman v. Coca-Cola Co.*, No. CV–09–03952010 WL 2925955, at *7

(E.D.N.Y. July 21, 2010) (state laws that are not "identical" to the FDCA's labeling requirements are preempted).

In recent years, both the First and the Ninth Circuits have held that state law claims that seek to impose further restrictions on labeling with regard to structure/function claims are preempted by federal law. *See Ferrari* 70 F.4th at 67; *DiCroce v. McNeil Nutritionals*, 82 F.4th 35, 41 n.5 (1st Cir. 2023); *Dachauer v. NBTY*, 913 F.3d 844, 848 (9th Cir. 2019). The First Circuit made clear that Congress enacted DSHEA to ensure there are no federal "barriers that impede the ability of consumers to improve their nutrition through the free choice of safe dietary supplements." *Ferrari*, 70 F.4th at 73 (citing Senate Report No. 103-410 (1994)). Indeed, DSHEA was based on the finding that "safety problems with dietary supplements are relatively rare and that legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness." *Id.* at 73 (cleaned up).

The Act plainly adds an additional restriction on structure/function claims that are not present in the federal laws that govern dietary supplements. The District Court ignored this and simply held "the Statute does not mandate any alterations to the labeling of dietary products, it merely institutes an age restriction." JA192. But that is the wrong inquiry. The court needed to consider whether the imposition of additional restrictions on structure/function claims is preempted by federal law. As

the *Ferrari* Court noted, "[s]tructure/function claims under § 343(r)(6) fall within § 343(r)(1)'s ambit …. [t]hus, the FDCA expressly preempts any state law that establishes labeling requirements for structure/function claims that are not identical to the requirements" for permissible structure/function claims. *See* 70 F.4th at 68.

II. CRN Demonstrated Irreparable Harm

The District Court also erred in holding that CRN failed to establish irreparable harm. The threat of constitutional harm *constitutes* irreparable injury. *See, e.g., A.H. by & through Hester v. French*, 985 F.3d 165, 184 (2d Cir. 2021) ("The denial of a constitutional right ordinarily warrants a finding of irreparable harm."); *Agudath Israel of Am.*, 983 F.3d at 637 ("[T]he deprivation of First Amendment rights is an irreparable harm). The District Court appeared to acknowledge that "[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." JA194 (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976)).

The District Court linked its irreparable harm finding to its holding that CRN failed to demonstrate likelihood of success on its First Amendment claim. JA195. But as described above, the District Court erred in its First Amendment analysis. Its reliance, therefore, on case law regarding "instances where a plaintiff alleges injury from a rule or regulation that *may only potentially affect speech*," JA194, is inapt.

Indeed, this Court has found irreparable harm even without likelihood of success on a constitutional claim, so long as there is a showing "that the First Amendment is sufficiently implicated." *Amestoy*, 92 F.3d at 72. Here, it is unquestionable that the Act implicates the First Amendment by triggering liability based on a party's speech. The District Court conceded, in denying the NYAG's motion to dismiss the First Amendment claim, that the Act's legislative history "plausibly support[s] the inference that [it] might very well regulate protected speech." ECF 58 at 4-5. On this basis alone the District Court should have found there to be irreparable harm.

To the extent the District Court relied on any delay by CRN in seeking a preliminary injunction as part of its irreparable harm analysis, that consideration was erroneous. CRN did not delay in seeking injunctive relief—it filed its motion before the law even went into effect, while evaluating how the law affected its members (a complicated task given the uncertainties of the law). In any event, delay does not rebut irreparable harm where a plaintiff asserts a constitutional violation. *See Jolly v. Coughlin*, 76 F.3d 468, 482 (2d Cir. 1996); *see also Tripathy v. Lockwood*, No. 22-949-PR, 2022 WL 17751273, at *2 (2d Cir. Dec. 19, 2022) (reversing district court's holding of no irreparable harm due to 29-month delay given allegation of constitutional violation); The District Court relied on *Tom Doherty Associates, Incorporated v. Saban Entertainment*, 60 F.3d 27, 39 (2d Cir. 1995), but there, this

Court found that a four-month delay did *not* negate irreparable harm and made clear that "[t]he cases in which we have found that a delay rebutted the presumption of irreparable harm are ***trademark and copyright cases*** in which the fair inference was drawn that the owner of the mark or right had concluded that there was no infringement but later brought an action because of the strength of the commercial competition." *Id.* (emphasis added); *see also Tough Traveler, Ltd. v. Outbound Prods.*, 60 F.3d 964 (2d Cir. 1995) (same).

In any event, even if CRN prevails in this lawsuit, the Eleventh Amendment bars it from obtaining any monetary damages. That is irreparable injury sufficient to support preliminary injunctive relief, and the District Court erred in failing to so hold. *See Entergy Nuclear Vermont Yankee, LLC v. Shumlin*, 733 F.3d 393, 423 (2d Cir. 2013); *Chamber of Com. of the United States. v. Edmondson*, 594 F.3d 742, 770-71 (10th Cir. 2010) ("Imposition of monetary damages that cannot later be recovered for reasons such as sovereign immunity constitutes irreparable injury."). CRN's members will be unable to recover costs expended to attempt to comply with the Act's vague mandates. *See Book People, Inc. v. Wong*, 91 F.4th 318, 341 (5th Cir. 2024) ("complying with a regulation later held invalid almost *always* produces the irreparable harm of nonrecoverable compliance costs"); *New York v. U.S. Dep't of Homeland Sec.*, 969 F.3d 42, 86 (2d Cir. 2020) (irreparable harm where compliance costs would not be recoverable).

III. The Public Interest and Balancing of Equities Support Injunctive Relief

The public interest and balancing of the equities also favor enjoining the Act. Upholding the Constitution is certainly in the public interest. *See N.Y. Progress & Prot. PAC v. Walsh*, 733 F.3d 483, 488 (2d Cir. 2013). As a result, "the Government does not have an interest in the enforcement of an unconstitutional law." *Id.* (cleaned up). That should end the inquiry.

Even if it did not, the District Court erred in concluding that any harm suffered by CRN's members "pale in comparison to the State's goal of protecting youth from products that unfettered access to dietary supplements present." JA197. The State never established that the Act *actually* addresses that harm. Instead, the District Court simply assumes that which the State must prove. Moreover, the Act chills speech that relates to New Yorkers' healthcare decisions and restricts minors' access to potentially beneficial supplements—a fact that the District Court failed to consider.

CONCLUSION

For the reasons set forth herein, the District Court erred in denying CRN's motion for preliminary injunction. CRN respectfully requests that this Court reverse and remand directing the District Court to enter a preliminary injunction.

Dated: July 3, 2024

Respectfully submitted,

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SPECIAL APPENDIX

SPECIAL APPENDIX
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McKinney's General Business Law § 391-oo

§ 391-oo. Sale of over-the-counter diet pills and dietary supplements for weight loss or muscle building

Effective: April 22, 2024
Currentness

1. For purposes of this section the following terms shall have the following meanings:

(a) "Dietary supplements for weight loss or muscle building" means a class of dietary supplement as defined in section three hundred ninety-one-o of this article that is labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building, but shall not include protein powders, protein drinks and foods marketed as containing protein unless the protein powder, protein drink or food marketed as containing protein contains an ingredient other than protein which would, considered alone, constitute a dietary supplement for weight loss or muscle building.

(b) "Over-the-counter diet pills" means a class of drugs labeled, marketed, or otherwise represented for the purpose of achieving weight loss that are lawfully sold, transferred, or furnished over-the-counter with or without a prescription pursuant to the federal food, drug, and cosmetic act, 21 U.S.C. section 301 et seq., or regulations adopted thereunder.

(c) "Retail establishment" means any vendor that, in the regular course of business, sells dietary supplements for weight loss or muscle building or over-the-counter diet pills at retail directly to the public, including, but not limited to, pharmacies, grocery stores, other retail stores, and vendors that accept orders placed by mail, telephone, electronic mail, internet website, online catalog, or software application.

(d) "Delivery sale" means any sale of over-the-counter diet pills or dietary supplements for weight loss or muscle building to a consumer if:

(i) the consumer submits the order for the sale by means of a telephone or other method of voice transmission, mail, or the internet or other online service, or the seller is otherwise not in the physical presence of the buyer when the request for purchase or order is made; or

(ii) the over-the-counter diet pills or dietary supplements for weight loss or muscle building are delivered to the buyer by common carrier, private delivery service, or other method of remote delivery, or the seller is not in the physical presence of the buyer when the buyer obtains possession of the over-the-counter diet pills or dietary supplements for weight loss or muscle building.

(e) “Delivery seller” means a vendor, including online retailers, who makes delivery sales of over-the-counter diet pills or dietary supplements for weight loss or muscle building. Such vendors shall include persons who accept orders placed by mail, telephone, electronic mail, internet website, online catalog, or software application.

2. 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. Retail establishments shall require proof of legal age for purchase of such products. For purposes of this section, proof of legal age shall mean (a) a valid driver's license or non-driver's identification card issued by the commissioner of motor vehicles, the federal government, any United States territory, commonwealth or possession, the District of Columbia, a state government within the United States, a provincial government of the dominion of Canada, or the city of New York, or (b) a valid passport issued by the United States government or any other country, or (c) an identification card issued by the armed forces of the United States, indicating that the individual is at least eighteen years of age, or (d) a student identification card, provided such card indicates the date of birth of the individual. Such identification need not be required of any individual who reasonably appears to be at least twenty-five years of age; provided, however, that such appearance shall not constitute a defense in any proceeding alleging the sale of any over-the-counter diet pills and dietary supplements for weight loss or muscle building to an individual under eighteen years of age.

3. (a) Any person operating a retail establishment may perform a transaction scan as a precondition for the purchase of over-the-counter diet pills or dietary supplements for weight loss or muscle building.

(b) In any instance where the information deciphered by the transaction scan fails to match the information printed on the driver's license or non-driver identification card, or if the transaction scan indicates that the information is false or fraudulent, the attempted transaction shall be denied.

(c) In any proceeding pursuant to subdivision five of this section, it shall be an affirmative defense that such person had produced a driver's license or non-driver identification card apparently issued by a governmental entity, successfully completed that transaction scan, and that over-the-counter diet pills or dietary supplements for weight loss of muscle building were sold, delivered or given to such person in reasonable reliance upon such identification and transaction scan. In evaluating the applicability of such affirmative defense, the court shall take into consideration any written policy adopted and implemented by the seller to effectuate the provisions of this section. Use of a transaction scan shall not excuse any person operating a retail establishment from the exercise of reasonable diligence otherwise required by this section.

(d) A retail establishment or employee of such establishment shall only use a device capable of deciphering any electronically readable format, and shall only use the information recorded and maintained through the use of such devices, for the purposes contained in this subdivision. No retail establishment or employee of such establishment shall resell or disseminate the information recorded during such a scan to any third person. Such prohibited resale or dissemination includes but is not limited to any advertising, marketing or promotional activities. Notwithstanding the restrictions imposed by this subdivision, such records may be released pursuant to a court ordered subpoena or pursuant to any other statute that specifically authorizes the release of such information. Each violation of this subdivision shall be punishable by a civil penalty of not more than one thousand dollars.

(e) A retail establishment or employee of such establishment may electronically or mechanically record and maintain only the information from a transaction scan necessary to effectuate this section. Such information shall be limited to the following: (i) name, (ii) date of birth, (iii) driver's license or non-driver identification number, and (iv) expiration date.

4. Notwithstanding subdivision two of this section, a delivery seller, including an online retailer, who mails or ships over-the-counter diet pills or dietary supplements for weight loss or muscle building to consumers:

(a) shall not sell, deliver, or cause to be delivered any over-the-counter diet pills or dietary supplements for weight loss or muscle building to a person under eighteen years of age; and

(b) shall use a method of mailing or shipping:

(i) that requires the purchaser placing the delivery sale order, or an adult who is at least eighteen years of age to sign to accept delivery of the shipping container at the delivery address; and

(ii) that requires the person who signs to accept delivery of the shipping container to provide proof, in the form of a valid, government-issued identification bearing a photograph of the individual, that the person is at least eighteen years of age.

5. Whenever there shall be a violation of this section, an application may be made by the attorney general in the name of the people of the state of New York, to a court or justice having jurisdiction by a special proceeding to issue an injunction, and upon notice to the defendant of not less than five days, to enjoin and restrain the continuance of such violation; and if it shall appear to the satisfaction of the court or justice that the defendant has, in fact, violated this section, an injunction may be issued by the court or justice, enjoining and restraining any further violations, without requiring proof that any person has, in fact, been injured or damaged thereby. Whenever a court shall determine that a violation of this section has occurred, the court may impose a civil penalty of not more than five hundred dollars.

6. When determining whether an over-the-counter diet pill or dietary supplement is labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building, the court shall consider, but is not limited to, the following factors:

(a) whether the product contains:

(i) an ingredient approved by the federal Food and Drug Administration for weight loss or muscle building;

(ii) a steroid; or

(iii) creatine, green tea extract, raspberry ketone, garcinia cambogia, green coffee bean extract;

(b) whether the product's labeling or marketing bears statements or images that express or imply that the product will help:

(i) modify, maintain, or reduce body weight, fat, appetite, overall metabolism, or the process by which nutrients are metabolized; or

(ii) maintain or increase muscle or strength;

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(c) whether the product or its ingredients are otherwise represented for the purpose of achieving weight loss or building muscle; or

(d) whether the retailer has categorized the dietary supplement for weight loss or muscle building by:

(i) placing signs, categorizing, or tagging the supplement with statements described in paragraph (b) of this subdivision;

(ii) grouping the supplements with other weight loss or muscle building products in a display, advertisement, webpage, or area of the store; or

(iii) otherwise representing that the product is for weight loss or muscle building.

Credits
(Added L.2023, c. 558, § 1, eff. April 22, 2024.)

McKinney's General Business Law § 391-oo, NY GEN BUS § 391-oo
Current through L.2024, chapters 1 to 59, 61 to 121. Some statute sections may be more current, see credits for details.

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