IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

COUNCIL FOR RESPONSIBLE NUTRITION Plaintiff, v. LETITIA JAMES, in her official capacity as New York Attorney General, Defendant.	Case No. : 1:24-cv-01881

PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF ITS EMERGENCY MOTION FOR ORDER TO SHOW CAUSE FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

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INTRODUCTION

Plaintiff, Council for Responsible Nutrition ("CRN"), is a trade association that has represented the dietary supplement industry, including its manufacturers and suppliers, for over half a century. CRN has championed laws, policies, and practices promoting transparency, accountability, safety, and strong ethical principles in the dietary supplements industry. It also has supported and continues to support legislation that constructively and properly addresses issues relating to minors' access to unhealthy and illegal substances. But N.Y. Gen. Bus. Law § 391-oo (the "Act") is not such a law. CRN brought this action to declare this new law unconstitutional and now asks this Court to enjoin the Attorney General of New York from enforcing the law pending the resolution of the constitutional challenge.

The Act, which is set to go into effect on April 22, 2024, bans the sale of certain dietary supplements to minors, as well as to adults that lack sufficient government identification. But the Act does nothing to regulate minors' purchase of products containing unhealthy or illegal ingredients, or otherwise address health concerns related to minors, including the purported purpose of the Act to reduce the incidents of eating disorders. Under this guise of addressing eating disorders in minors, the regulation precludes the sale of dietary supplement products where there is a "*representation*" by *anyone*, *anywhere*, suggesting that the product (or one of its ingredients) may assist in weight loss, muscle building, muscle maintenance, the process by which nutrients are metabolized by the human body, or other ambiguous statements and factors that purportedly position a dietary supplement as a product that can be used for the "purpose of achieving weight loss or muscle building."

This draws into the Act's orbit vast numbers of products that pose no risk to minors. Worse—the Act provides no meaningful guidelines for understanding which products are covered by its prohibitions. The Act's own sponsor could not demarcate any line between permissible and

impermissible sales. There is, accordingly, a reason this is the first legislation of its kind in the United States: the Act is unconstitutionally vague, abridges protected First Amendment speech, is preempted by comprehensive federal laws and regulations, and constitutes an excessive imposition of the State's police power.

CRN's members have gladly accepted and adhered to extensive laws and regulations governing dietary supplements where doing so benefits the public. But while the Act purports to address eating disorder prevention in minors, a noble purpose that CRN and all of its members support—it utterly fails to accomplish this purpose. Instead, the Act's age restrictions are an overly broad overreach that will affect perfectly lawful conduct. Indeed, the Act regulates dietary supplements that are safe, legal, and have no connection to eating disorder behavior in minors.

The Act's haphazard definitions also lead to additional absurd results. Minors may continue to purchase products with known associations with eating disorders, or which directly claim a propensity for weight loss or muscle building, so long as those products are not labeled under federal law as dietary supplements. For instance, the Act does not apply to any products bearing a nutrition facts panel. Further, the law does nothing to address the sale of adulterated, illegal products containing dangerous ingredients *so long as those products are not represented as weight loss or muscle building products*. At the same time, the Act may function to restrict the sale of supplements appropriate for minors, such as multivitamins designed for children, and impose liability on manufacturers of those products due to the subjective perceptions of some unrelated third party or influencer in some corner of the Internet who happens to believe that a product helped them lose weight or get stronger,

Despite all these vagaries, the State of New York ("State") expects CRN's members to divine the requirements that the Act's sponsor was unable to articulate. If CRN's members fail to

do so correctly, they face enforcement by the Attorney General, reputational harm, litigation costs, and potentially prohibitive civil penalties of $500 per violative sale. CRN members will and are, engaging in their best efforts to try to comply with the Act—by curtailing their First Amendment-protected speech, diverting time and money to reviewing product claims, revising marketing and advertising materials, and implementing novel and logistically complex age verification procedures that largely preclude the sale of dietary supplements to lawful consumers between the ages of 18 and 21 years old, as well as imposing additional logistical access hurdles on all adults. But they should not have to do so. It is the New York legislature that should have to amend the Act or pass a law that can withstand constitutional scrutiny.

The Act also has the unintended effect of harming the public. By regulating speech instead of ingredients, the Act chills speech that is designed to assist consumers in making educated decisions concerning their health. The Act also makes dietary supplements less accessible and more expensive for adults, as the uncertainties surrounding which products are restricted could push dietary supplement manufacturers out of the market *entirely*. In turn, transaction costs for consumers will increase as companies try to comply with the Act, and it will become more difficult—if not impossible—for some adults to obtain dietary supplements that they have every legal right to purchase and consume. And, of course, the Act deprives minors of dietary supplements that may be beneficial for their health, including supplements that might help support the health of minors dealing with eating disorder health complications.

CRN is overwhelmingly likely to succeed on the merits of these claims, and this Court should enjoin the Attorney General's enforcement of the Act to prevent CRN and its members from sustaining irreparable harm. The relief CRN seeks is warranted by a balancing of equities and the broader public interest.

FACTUAL BACKGROUND[1]

CRN brought this suit against Leticia James, Attorney General for the State of New York, in her official capacity, seeking a declaration that the Act is unconstitutional and a temporary restraining order and preliminary injunction against the enforcement of the Act. The Act regulates the dietary supplement industry. CRN is the leading trade association for dietary supplement manufacturers and ingredient suppliers. *See* SM Decl., at ¶ 9.[2] The State justifies the Act's impositions on First Amendment rights, consumer access to information, and private businesses based on the proposition that dietary supplements cause eating disorders in minors and that the Act will address that concern.

CRN and its members do not—and would not—engage in activity that harms the public whose health it is their mission to support. CRN contends that there is no nexus between dietary supplements and eating disorders, and that the Act will not address eating disorder related concerns based on consistent scientific evidence demonstrating that, "[t]he evidence to date does not support a causative role for dietary supplements in eating disorders."[3] In fact, while dietary supplement use amongst minors is relatively "low," nearly all minors consuming such products do so for reasons wholly unrelated to weight loss or muscle building.[4]

That is precisely why the Act's sponsor could not identify a single study demonstrating a relationship between dietary supplements and eating disorders. *See* NY Committee Report, 2023

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[1] CRN incorporates by reference the facts alleged in its Verified Complaint ("VC"). *See* ECF 1.
[2] CRN refers to the concurrently filed declarations by reference to the initials of the declarant.
[3] *See* Susan J. Hewlings, Eating Disorders and Dietary Supplements: A Review of the Science, NUTRIENTS 15(9):2026 (2023), https://doi.org/10.3390/nu15092076 ("Nutrients Paper"), at p. 8. The Verified Complaint describes in detail the extent to which the New York State Legislature's belief that dietary supplements cause eating disorders is not only misplaced, but wholly unsupported by any credible scientific evidence. *See* VC, at ¶¶ 63–76, 95–113.
[4] *See* Anita A. Panjwani, Ph.D, et al., Trends in Nutrient and non-Nutrient containing Dietary Supplement Use among U.S. Children from 1999-2016, J PEDIATR. 2021 Apr. 231:131–140, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8005463/ ("Nutrient Trends").

NY A.B. 5610 (NS), New York Two Hundred Forty-Sixth Legislative Session ("Bill No. 5610"), at nn. 1-4. It is also why, in passing the Act, other legislators decided simply to "trust" that such research "is probably out there," although they "haven't seen it." *See* NY Assembly Transcript ("Tr."), relevant excerpts attached hereto as **Exhibit A**, at 106, 111. The materials cited by the Legislature in connection with the Act's purpose similarly fail to support the Act's premise, as they relate solely to dangerous *pharmaceutical* or other illegal ingredients not contained in any dietary supplements manufactured or supplied by CRN's members. *See* Bill No. 5610.

The disconnect between the Act and its proffered justification is unsurprising. In 2022, the New York State Legislature sought to restrict the sale of weight loss and muscle building supplements based on a list of ingredients determined by the New York State Department of Health ("DOH"). *See* VC ¶¶ 43–44. Its initial bill principally addressed the concern that "[a]lthough they are sold alongside multivitamins and other supplements largely regarded as safe," dietary supplements "often contain unlisted, illegal pharmaceutical ingredients that pose serious risks" to consumer health. *See id.*[5] However, Governor Hochul vetoed that bill, citing the DOH's lack of expertise, and reasoning that "[i]t 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." *See* Veto No. 122, attached hereto as **Exhibit B**.

After the Governor's veto, the Legislature pivoted to "target[ing] [dietary supplements] based on their marketing" and "[r]egardless of their ingredients or efficacy" while still proclaiming to address the inclusion of dangerous illegal ingredients in dietary supplements. *See* Bill No. 5610. Thus, the Act attempts to work around the Governor's 2022 veto by regulating the sale of dietary

[5] The federal Food and Drug Administration ("FDA") already prohibits dietary supplements from including such unlisted, illegal, or dangerous ingredients, and regulates the industry on this basis.

supplements based on speech—which rests upon the Legislature's unsubstantiated belief that there is a nexus between safe, legal dietary supplements and eating disorders in minors—while doing nothing to viably advance its substantiated concern of addressing illegal dietary supplements containing dangerous ingredients.

Specifically, the Act imposes age verification requirements and bars the sale of dietary supplements to minors where the supplement—*or one of its ingredients*—is "labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building[.]" *See* generally § 391-oo. It also authorizes civil penalties of up to $500 for each violative sale. *See id.* § 391-oo(5). What it fails to do, however, is define what it means to "represent[]" a dietary supplement "for the purpose of achieving weight loss or muscle building." *See id.*

To determine whether a sale violates the Act, courts must consider several non-exclusive factors. *See* § 391-oo(6). Those factors are whether: (1) the product contains certain types of identified ingredients; (2) the product's marketing or labeling "bears statements or images that imply that the product will help: [] modify, maintain, or reduce body weight, fat, appetite, overall metabolism, or the process by which nutrients are metabolized; or [] maintain or increase muscle or strength"; (3) whether the product or its ingredients are otherwise represented for the purpose of achieving weight loss or building muscle"; and (4) "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.

Id. The statute does not provide definitions or further context for any of the terms used in these factors. *See generally id.*

The dietary supplement industry, including CRN and its members, have no idea what the Act proscribes. *See* SM Decl., at ¶¶ 25–26. As the General Counsel for Vitamin Shoppe—a nationwide retailer of supplements that operates in New York and sells a number of products manufactured by CRN's members—has explained:

> [W]hat is a "dietary supplement for weight loss or muscle building?" I honestly don't know, and I have been a dietary supplement lawyer for a decade. What's more, I have sat in multiple meetings with my peers from other leading supplement and retail companies, and they don't know either.[6]

Even the Act's own sponsor—Assemblywoman Nily Rozic—was unable to explain when the Act would bar the sale of a dietary supplement product. *See* Ex. A, Tr. at pp. 105, 109–10, 115–18.

This confusion is due to the Act's vague language. In failing to define "representations," CRN's members may face liability for the sale of virtually any dietary supplement. No shortage of safe and beneficial ingredients, such as water and calcium, have been linked to weight loss or muscle building. *See* VC, at ¶¶ 33, 159. The Act also specifically identifies green tea extract as an ingredient that may trigger age restrictions, even though it is commonly used in supplements for its antioxidant benefits. *See id.* at ¶ 123. And, worst of all, a CRN member may face liability for selling a product that has no relationship with weight loss or muscle building because of the conduct of an unaffiliated third party, regardless of whether the communication was directed to minors, known to the CRN member, or even accurate.

Limiting the scope of "representations" does not resolve the ambiguity of the Act, and only heightens the absurdity of the regulation. CRN members may still face liability because of a third party's subjective interpretation of their statements. For instance, claims as to "metabolism" may refer to a host of life-sustaining chemical or physical reactions in the body that are not

[6] *See* Carlos Lopez, *The Vitamin Shoppe general counsel criticizes NY age-restriction law*, NAT. PROD. INSIDER (Mar. 1, 2024), https://www.naturalproductsinsider.com/supplement-regulations/the-vitamin-shoppe-general-counsel-criticizes-ny-age-restriction-law.

meaningfully related to weight loss.[7] Such a construction also would not limit minors' access to the types of dietary supplements that the Act aims to restrict. If a manufacturer age-restricts their product because of an accurate statement as to an ingredient's effect on a prohibited purpose, a minor can simply purchase a different product online containing that ingredient, perhaps in an even greater quantity, but unencumbered by any representations as to weight loss or muscle building.

To that end, the Act merely redirects sales to less responsible manufacturers, which undermines one of the Legislature's main articulated purposes for enacting the statute: preventing the sale of dietary supplements containing "unlisted, illegal pharmaceutical risks that pose serious risks" to consumer health. *See* Bill No. 5610.[8] The Act does *nothing* to restrict the sale of such products directly, and, in fact, broadly permits the sale of such products where they are unrelated to weight loss or muscle building. Nor does the Act target the manufacturers of those illegal dietary supplements. CRN members do not sell illegal supplements; and they will attempt to comply with the law, even where, in the case of the Act, it is incomprehensibly vague and expansively broad. CRN members will be left to restrict the sale of their safe dietary supplements, while manufacturers already selling illegal products, which may operate internationally, will simply continue to do so.

[7] For instance, folate plays a key role in the synthesis of DNA and other genetic materials, in amino acid metabolism. *See, e.g.*, Folate, NAT'L INST. OF HEALTH, https://ods.od.nih.gov/factsheets/Folate-HealthProfessional/#h14.

[8] FDA laws and regulations, of which CRN's members adhere to and confirm adherence through a number of self-regulatory initiatives, prohibit the sale of these ingredients. *See* SM Decl., at ¶¶ 19–21. The Act's own cited authority reflects that CRN and its members are not culpable of the misconduct the Act aims to regulation. In footnote four, the Act cites to an incident involving an unsafe pharmaceutical ingredient, and, in that article, CRN is on record *criticizing* the government for failing to act sooner. *See* Bill 5610, n.4. None of CRN's members supplied or manufactured products containing the illegal ingredient, and CRN publicly called on the FDA to use "the full range of its regulatory authority," including "detentions, seizures, voluntary and mandatory recalls, injunctions, criminal prosecution, etc." to protect consumers. *See* Statement by S. Mister, CRN (Apr. 12, 2013) https://www.crnusa.org/newsroom/crn-responds-fdas-warning-dmaa.

Because the Act imposes liability based on truthful speech, CRN's members have already begun curtailing their protected commercial speech due to the fear that the Attorney General may enforce the Act's vague yet wide-ranging requirements against them.[9] The Act also materially impedes CRN's ability to carry out its mission through its historical activities, namely, the dissemination of educational information on dietary ingredients to the public.[10] In both instances, the Act chills nationwide communications and, unfortunately, deprives the public of accurate, non-misleading, and scientifically corroborated information designed to assist consumers in making informed decisions concerning their health.[11]

Such ambiguity has also caused CRN members to undertake or meaningfully consider undertaking novel and costly compliance efforts, including: (1) restricting sales of certain products into New York; (2) further limiting commercial speech; (3) implementing age verification procedures through the use of common carriers, which increases shipping costs and restricts the sale of dietary supplements to lawful consumers between the ages of 18 and 21 and adults without government identification; (4) employing additional age verification procedures at the point of sale, which requires the acquisition of age verification software and integration coding into existing webpages; and (5) overall, erring on the side of self-censorship and over-restriction in

[9] All harms are described in full and elaborated upon in each of the nine declarations filed concurrently with this memorandum of law. *See* SM Decl., at ¶¶ 28–39, 43–51; AL Decl., at ¶¶ 10–12; BR Decl., at ¶¶ 11–15; GB Decl., at ¶¶ 12–15; SP Decl., at ¶¶ 14–18; TR Decl., at ¶¶ 15–21; TB Decl., at ¶¶ 14–17;.

[10] *See* SM Decl., at ¶¶ 28–39. CRN has historically carried out its mission by educating consumers on facilitating its members' compliance with all applicable laws and regulations. Because of the Act's chilling effect on speech and its vague language, CRN can no longer do both. The Act places CRN into a lose-lose situation which prevents it from carrying out its mission through its usual activities, as it must choose to: (1) abandon its protected speech to ensure that CRN's own actions do not bring a member out of compliance with the broadest possible interpretation of the Act; or (2) continue educating the public about dietary supplements, at the cost of making it even harder for members to determine whether they are in compliance with the Act.

[11] *See id.* at *supra* nn. 8-9.

connection with the sale, marketing, and distribution of safe and legal dietary supplements.[12] Notwithstanding these efforts, CRN members still fear enforcement by the Attorney General under the broadest interpretation of the Act, which would subject CRN members to civil penalties, litigation expenses, and reputational harm. [13] CRN members also anticipate lost revenue from market conditions, lost sales from minors and lawful consumers, and impairments to their existing business relationships, including with retailers, distributors, and other third parties. [14]

ARGUMENT

CRN seeks a temporary restraining order and preliminary injunction to preserve the status quo and enjoin the State from enforcing the Act until the resolution of this litigation. CRN is entitled to such relief because it can demonstrate "(1) irreparable harm absent injunctive relief, (2) a likelihood of success on the merits, and (3) public interest weighing in favor of granting the injunction." *See Agudath Israel of Am. v. Cuomo*, 983 F.3d 620, 631 (2d Cir. 2020) (internal quotations omitted); *see also Antonyuk v. Hochul*, 635 F. Supp. 3d 111, 124 (N.D.N.Y. 2022) ("In the Second Circuit, the standard for issuance of a temporary restraining order is the same as the standard for a preliminary injunction."). Each factor weighs decidedly in CRN's favor.

I. CRN HAS A SUBSTANTIAL LIKELIHOOD OF SUCCESS ON THE MERITS

A. The Act is Unconstitutionally Vague

CRN is substantially likely to succeed on the merits of Count I of its Complaint because the Act is void for vagueness under the United States and the New York Constitutions. "In our

[12] *See* SM Decl., at ¶¶ 28–39, 43–65; AL Decl., at ¶¶ 8–12; BR Decl., at ¶¶ 8–15; EU Decl., at ¶¶ 10–13; GB Decl., at ¶¶ 8–15; MF Decl., at ¶¶ 8–15; SY Decl., at ¶¶ 8–16; SP Decl., at ¶¶ 8–18; TR Decl., at ¶¶ 11–37; TB Decl., at ¶¶ 8–17.
[13] *See* SM Decl., ¶¶ 31–39; AL Decl., at ¶ 12; BR Decl., at ¶¶ 12–15; EU Decl., at ¶¶ 10–11; GB Decl., at ¶¶ 13–15; SP Decl., at ¶¶ 16–18; TR Decl., at ¶ 37; TB Decl., at ¶¶ 14–17.
[14] *See* SM Decl., ¶¶ 40, 66–74, 84; EU Decl., ¶¶ 10–13; MF Decl., ¶¶ 9–15; SY Decl., ¶¶ 11–16; SP Decl., at ¶¶ 14–18; TR Decl., at ¶¶ 32–37.

constitutional order, a vague law is no law at all." *U.S. v. Davis*, 139 S. Ct. 2319, 2323 (2019). A statute is thus void for vagueness under both the United States and the New York Constitutions where it fails to provide: (1) "people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits;" *or* (2) "explicit standards for those who apply," thereby risking "resolution on an *ad hoc* and subjective basis[.]" *See Cunney v. Bd. of Trustees of Vill. of Grand View, N.Y.*, 660 F.3d 612, 621 (2d Cir. 2011) (cleaned up); *see also People v. New York Trap Rock Corp.*, 442 N.E.2d 1222, 1225 (N.Y. 1982).

Statutes violate both of these independent requirements where liability depends on "wholly subjective judgments without statutory definitions, narrowing context, or settled legal meanings." *See Cunney*, 660 F.3d at 622 (cleaned up); *see also, e.g.*, *NetChoice, LLC v. Yost*, No. 2:24-CV-00047, 2024 WL 555904, at *13-14 (S.D. Ohio Feb. 12, 2024) (law governing operators of websites that "target children" or "are reasonably anticipated to be accessed by children," would "leave many operators unsure as to whether it applies to their website," where terms were undefined and required subjective assessment); *Nichols v. Vill. Of Pelham Manor*, 974 F. Supp. 243, 254 (S.D.N.Y. 1997) ("By employing, without defining, a term like 'objection,' the Village ordinance forces people to guess, at their peril, whether certain public reactions to their expression would be regarded as 'objections' in the meaning of the statute.").

Courts thus invalidate statutes that have insufficient definitions of key terms. *See id; see also, e.g.*, *Conant v. Walters*, 309 F.3d 629, 639 (9th Cir. 2002) (statute was vague where "recommendation" was undefined and required subjective assessments of communications); *Grocery Mfrs. Ass'n v. Sorrell*, 102 F. Supp. 3d 583, 594 (D. Vt. 2015) (granting motion for preliminary injunction based on vagueness challenge where statute banned use of word "natural," or undefined other "words of similar import."); *Backpage.com, LLC v. Cooper*, 939 F. Supp. 2d

805, 834 (M.D. Tenn. 2013) (granting preliminary injunction where statute was likely vague due to use of terms "offer" and "commercial sex act.").

Similarly, statutes are unconstitutionally vague where application or liability hinges on subjective assessments and matters of perception. *See, e.g.*, *Women's Med. Ctr. of Nw. Houston v. Bell*, 248 F.3d 411, 422 (5th Cir. 2001) (holding law unconstitutional where it imposed liability not on "own objective behavior" of regulated party, "but on the subjective viewpoints of others."); *Nichols*, 974 F. Supp. at 254 (statutes cannot "force[] [regulated parties] to guess, at their peril, whether certain public reactions to their expression" give rise to liability); *Gay Men's Health Crisis v. Sullivan*, 792 F. Supp. 278, 295–96 (S.D.N.Y. 1992) (statute was vague where it required regulated party to "gauge the reactions of members of the public" and "engage in subjective analysis"); *Westbrook v. Teton Cnty. Sch. Dist. No. 1*, 918 F. Supp. 1475, 1490 (D. Wyo. 1996) (statute triggered based on "criticism" was vague because "speech that is criticism to some is not criticism to others.") (cleaned up).

These concerns are heightened where a statute regulates speech. When faced with a vague law, "people stop speaking" because "they cannot determine whether their speech is legal or illegal." *Westbrook*, 918 F. Supp. at 1489. Because of this concern, a statute is void for vagueness where an "indeterminacy" in a law "might cause the suppression of protected speech[.]" *Nichols*, 974 F. Supp. at 254; *see also Stahl v. City of St. Louis, Mo.*, 687 F.3d 1038, 1041 (8th Cir. 2012) (holding law that predicated liability on subjective grounds was "especially problematic because of the ordinance's resulting chilling effect on" speech).

"The degree of vagueness that the Constitution tolerates—as well as the relative importance of fair notice and fair enforcement—depends in part on the nature of the enactment." *Vill. of Hoffman Ests. v. Flipside, Hoffman Ests., Inc.*, 455 U.S. 489, 498 (1982). A violation of

the Act would yield civil penalties, which may accrue quickly and substantially. But even more troublingly, an enforcement action would cause CRN members to sustain significant reputational harm, as an alleged violation may suggest a disregard for the health and well-being of the very consumers CRN's members serve. The Act is accordingly "quasi-criminal and its prohibitory and stigmatizing effect may warrant a relatively strict test." *Id.; see also F.C.C. v. Fox Television Stations, Inc.*, 567 U.S. 239, 255 (2012) (explaining "finding of wrongdoing can result in [] harm" to reputation, further warranting relief from vague law).

The Act is unconstitutionally vague under any formulation of the void-for-vagueness test. The specifics about *which* products are subject to the Act are so indeterminate that even the Act's own legislative sponsor could not identify its core proscription. Specifically, during the New York Assembly's June 1, 2023, meeting, Assemblywoman Rozic could not answer the most basic questions about the Act: what does it require, when does it apply, and what does it prohibit? *See* Ex. A, Tr. at 105, 109-10, 116-18. The State cannot expect CRN's members to know what is required of them when the Act's own sponsor does not. *See Hayes v. New York Att'y Grievance Comm. of the Eight Jud. Dist.*, 672 F.3d 158, 169 (2d Cir. 2012) ("[I]f administrators cannot determine the meaning of a prohibition, those subject to it can hardly be expected to do so.").

Assemblywoman Rozic's inability to state what the Act bans is unsurprising, as ambiguity permeates the statute at every level. The statute bans the sale of dietary supplements to minors where a product or one of its ingredients is "represented for the purpose of achieving weight loss or muscle building." *See* § 391-oo(1). The Act does not define "representation." *See id.* Nor does it give any constrain "representation" with reference to the speaker, their intent, the recipient, the accuracy of the information, or the avenue in which it was made. *See id.*

As a result, the "representation" prong of the Act could, in theory, apply to any statement made by anyone, anywhere—including the endless abyss of the internet—and it could apply regardless of whether the statement was authorized by the company facing liability, the intent of the speaker, or whether the statement was heard or read by a minor in New York. It is impossible for CRN's members to "steer clear between lawful and unlawful conduct," in these circumstances and in the absence of meaningful guidelines for compliance. *See Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972). Indeed, the Act may impose liability based on third-party representations over which CRN's members have no control, and evaluating whether there was such a "representation" rests on just as much unconstitutional subjectivity as determinations found unconstitutionally vague in other legislation, *i.e.*, "targeting," *Yost*, 2024 WL 555904, at *13-14, "objecting," *Nichols*, 974 F. Supp. at 254, or "recommending," *Conant*, 309 F.3d at 639.

In fact, reasonable minds could differ not only as to whether there was a "representation," but whether the "representation" was that a product or ingredient would aid in "weight loss or muscle building." *See* § 391-oo(1). That is because "weight loss or muscle building" is itself amorphous and fails to provide concrete direction for compliance or enforcement, much like other terms that may be understood in a general sense, but not in a manner sufficient to satisfy Due Process. *See, e.g.*, *Cooper*, 939 F. Supp. 2d at 834 (term "commercial sex act" was vague because it "could encompass a range of" activity and had "undefined parameters").

Taken to the logical extreme, and given the lack of meaningful guideposts, following the Act's plain language could conceivably bar the sale of every dietary supplement on the market. Dietary supplements containing water may violate the Act because there are certainly representations on the Internet that water assists in weight loss. Even a manufacturer that limits

its speech and sells a product that does not assist in weight loss or muscle building could face civil penalties because an unrelated third party may intentionally *or* inadvertently insinuate otherwise.

This demonstrates a fundamental deficiency in the new law: by prohibiting seemingly all conduct, the Act provides no real guidance as to what conduct is permissible. *See Brache v. Westchester Cnty.*, 658 F.2d 47, 50–51 (2d Cir. 1981) (a statute is vague on its face when "expressed in terms of such generality that no standard of conduct is specified at all.") (cleaned up); *see also, e.g.*, *Arriaga v. Mukasey*, 521 F.3d 219, 228 (2d Cir. 2008) ("A statute that reaches a substantial amount of innocent conduct confers an impermissible degree of discretion on law enforcement authorities to determine who is subject to the law.") (internal quotations omitted).

While the Act provides some enumerated factors that purport to provide considerations for the types of products that may fall under its ambit, they do nothing to resolve the insoluble vagueness. That is because the factors are just as "unilluminating," "malleable," and "broad-ranging" as the language they seek to clarify. *See Yost*, 2024 WL 555904, at *13-14 (eleven-factor test did not cure issues of vagueness). Some of the factors are mere tautology—*i.e.*, to determine whether there is a representation for muscle building or weight loss, courts should consider whether there is a representation for muscle building or weight loss. *See* § 391-oo(6)(c),(d)(iii). Others direct courts to apply even more subjective criteria that only broaden the Act's scope, such as whether an "image" or "statement" "implies" an effect on "the process by which nutrients are metabolized"—language that could implicate any number of communications wholly unrelated to weight loss and muscle building, as nutrient metabolism refers to a host of life-sustaining chemical processes. Another factor hinges on unconstrained assessments of proximity as to other "weight loss or muscle building supplements," which remains an undefined phrase that eludes common understanding or consistent application. *Id.* § 391-oo(6).

These enumerated factors also raise far more questions than the Act purports to answer. Is a product represented for a proscribed purpose because of the physique of a company spokesperson a public-facing CEO? When and under what conditions does an image imply an effect on muscle growth or weight loss? What type of statement impermissibly suggests an effect on the process by which nutrients are metabolized and how are these statements even related to weight loss? What threshold of closeness renders products grouped together? Does the Act ban the sale of any product containing an ingredient identified in the Act's factors? "That questions of this nature so readily come to mind means that it is not sufficiently clear to a manufacturer or distributor of ordinary intelligence, what exactly the statute prohibits." *See Ass'n of Nat. Advertisers, Inc. v. Lungren*, 809 F. Supp. 747, 762 (N.D. Cal. 1992), *aff'd*, 44 F.3d 726 (9th Cir. 1994).

Nor do the enumerated factors provide any meaningful guidelines for enforcement. The factors are not only "vague," "pliable," and subjective themselves, but they are "*non-exclusive*." *See Amidon v. Student Ass'n of State Univ. of New York at Albany*, 508 F.3d 94, 104 (2d Cir. 2007). The list makes clear that it sets forth *some*, but not *all*, of the factors a court should consider when deciding whether a product falls within the Act's prohibitions. This non-exhaustive list of factors necessarily provides the government with substantial discretion to justify its application of the Act "through post-hoc reliance on unspecified criteria." *See id.*; *see also People v. New York Trap Rock Corp.*, 442 N.E.2d 1222 (N.Y. 1982) (statute was unconstitutionally vague where guidelines did not set forth an ascertainable standard and, "[p]erhaps worst of all, since the [guidelines] to be applied are 'not limited' to the listed ones, where does the defendant-to-be go from there?").

The net result of these vague and ambiguous guidelines for enforcement is that the sale of *any* dietary supplement *may* violate the Act unless the government, *in its unfettered discretion*, decides that it does not. By failing to provide "explicit standards" for such determinations, the

only means by which the government is empowered to enforce the law is through impermissible "resolution on an *ad hoc* and subjective basis, with the attendant dangers of arbitrary and discriminatory enforcement." *See Cunney*, 660 F.3d at 621 (cleaned up). This is unconstitutional. *See, e.g.*, *Sessions v. Dimaya*, 584 U.S. 148, 175 (2018) ("Vague laws invite arbitrary power," as "leaving people in the dark about what the law demands" "allow[s] prosecutors and courts to make it up.") (Gorsuch, J., concurring); *Police Benevolent Ass'n of City of New York, Inc. v. City of New York*, 224 N.E.3d 522, 531 (N.Y. 2023) (statute is facially vague where it "permits those enforcing it to exercise unfettered discretion in every single case.").

The State should not force CRN's members to preemptively divine the Act's potential scope when its own sponsor was unable to do so. And worst of all, there is no assurance that even CRN members' best, speech-curtailing efforts will be enough to avoid liability, as the government has unfettered discretion under the clear language of the Act and may impose civil penalties based on any number of unenumerated factors, including potentially the actions and perceptions of independent third parties. For these reasons, the Act is vague on its face and cannot survive constitutional scrutiny. CRN is thus substantially likely to prevail on Count I of its Complaint.

B. The Act Violates the First Amendment Because it Infringes Upon Protected Commercial Speech

CRN is also substantially likely to prevail on the merits of Count II of its Complaint, which alleges a violation of the First Amendment, because the Act unconstitutionally restricts protected commercial speech. The Act does not impose restrictions based on anything inherent to a product itself. Instead, it imposes restrictions based on what has been *said* about the product or its ingredients. Statements made by CRN members in labeling, marketing, or advertising a commercial good are protected First Amendment speech. *See, e.g.*, *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996); *Rubin*, 514 U.S. at 480. As the Supreme Court has explained:

> Advertising . . . is [] dissemination of information as to who is producing and selling what product, for what reason, and at what price. So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable.

Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 765 (1976) (cleaned up). It is this "free flow of information" that the Act regulates, penalizes, and chills. *See id.* This restriction is improper and renders the Act unconstitutional.

As the "party seeking to uphold a restriction on commercial speech," the State "carries the burden of justifying it." *See Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002) (cleaned up). To do so, it must satisfy the four-part test articulated in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980). This test examines whether the regulated "expression is protected by the First Amendment," and, if so, whether the "the asserted government interest is substantial," "the regulation directly advances the governmental interest," and the regulation "is not more extensive than necessary to serve that interest." *See id.* at 567.

The State cannot plausibly deny that the Act regulates speech "protected by the First Amendment." *See id.* at 567. The First Amendment protects commercial speech so long as it "concerns lawful activity" and "is not misleading." *See id.* The speech at issue here easily meets this standard: it does not propose unlawful activity, and the structure/function claims that may give rise to liability under the Act are the same exact statements that the FDA has considered legally permissible for dietary supplements and which meet its standard, along with that of the Federal Trade Commission ("FTC"), that such statements are accurate and not misleading.

The State's burden in justifying its encroachment on speech is far more exacting. It "must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *See Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995). "[M]ere speculation

or conjecture" are not enough, yet, that is all the State provides here. *See id.* The State cannot meet this burden, and the dearth of evidence regarding the regulation's direct and narrow advancement of a substantial interest precludes the State from satisfying the *Central Hudson* test.

1. The State Does Not Have Any Interest in Depriving Citizens of Truthful Information Relevant to Their Health

The Act is unconstitutional because it is fundamentally premised on suppressing truthful information. CRN does not contest that the State has a substantial government interest in protecting public health and regulating misleading information. But 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.

Indeed, "[t]he First Amendment directs [courts] to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good." *44 Liquormart, Inc.*, 517 U.S. at 503. The Supreme Court has thus "rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 374 (2002). As Justice Blackmun explained in his concurring opinion in *Central Hudson*:

> The Court recognizes that we have never held that commercial speech may be suppressed in order to further the State's interest in discouraging purchases of the underlying product that is advertised.
>
> I seriously doubt [] suppression of information concerning . . . a legally offered product is ever a permissible way for the State to "dampen" demand for or use of the product. Even though "commercial" speech is involved, such a regulatory measure strikes at the heart of the First Amendment.

Central Hudson, 447 U.S. at 574-75 (Blackmun, J., concurring); *see also Bates v. State Bar of Arizona*, 433 U.S. 350, 375 (1977) ("We view as dubious any justification that is based on the benefits of public ignorance.").

The Act does precisely what the Supreme Court has routinely and forcefully warned states they may not do. The proscriptions in the Act are not premised on public health and safety; if that were the primary motive, the Act would have directly regulated the sale of dietary supplements that are unsafe, dangerous, which cause unhealthy weight loss or muscle gain in minors, or that have a known causal connection to eating disorders. It did no such thing. Instead, the Act *discourages* disclosure of information to the consumer. The danger it regulates is not in the product itself or its ingredients, but in the truthful information conveyed about the product.

The State's misguided fears as to what minors will do with accurate information about dietary supplements are not a valid basis for legislation. There is no scientific basis for this concern, and the mere fact that the State believes the structure/function claims are "too persuasive does not permit it to quiet the speech or to burden its messengers." *See Sorrell v. IMS Health Inc.*, 564 U.S. 552, 578 (2011). That is, nevertheless, what the State has done. Because of the State's overreaching, CRN's members are faced with nothing but untenable conditions in this new regulatory matrix. This Court should not require CRN's members to refrain from engaging in accurate speech and still face the risk of civil penalties and reputational harm, or incur substantial compliance costs and lost sales in an attempt to comply with what they think the Act may require.

2. The Act Does Not Directly Advance Any Substantial Government Interest

Even if the Court accepts the State's proffered interest of combating eating disorders in minors, the Act does not advance that interest. A statute violates the First Amendment where, instead of regulating conduct, it restricts speech based on the belief that "disfavored speech has

adverse effects." *See Sorrell*, 564 U.S. at 578. That is what the State has done. The Act accordingly fails to "directly" advance an substantial government interests. *See id.*

While this should end the inquiry, the Act also fails the third prong of *Central Hudson* well beyond the compelling basis articulated in *Sorrell*. *See id.* The State must demonstrate that the harm that it seeks to redress—undefined eating disorders caused by dietary supplements—is "real" and directly mitigated by the Act. *See Rubin*, 514 U.S. at 487. "[T]his requirement is critical; otherwise, a State could with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression." *Id.* (cleaned up).

Eating disorders in minors is an unquestionably a real harm, but it is a harm that is wholly unconnected to the restrictions the Act imposes on dietary supplements. The State has not proffered any evidence otherwise. At best, it advances what can only be described as a gut feeling derived from stacking unwarranted inferences that dietary supplements cause eating disorders. Its failure to adduce such evidence is unsurprising, as "[t]he evidence to date does not support a causative role for dietary supplements in eating disorders." *See* Nutrients Paper.

It is precisely because there is no evidentiary support for the Act that it cites irrelevant materials masquerading as genuine evidence. The Act cites to four authorities in support of its stated purpose (and the subsequent imposition on First Amendment rights). But not one concerns a link between dietary supplements and eating disorders. In fact, the disclosed scientific bases on which the Legislature based the Act do not concern legally marketed dietary supplements at all. They address other conduct, *i.e.*, the dangers of consuming diet *drugs* (as opposed to dietary supplements) and the dangers of illicit products laced with pharmaceutical or other dangerous ingredients that the FDA has prohibited and worked to remove from the market. And not only does the scientific research not support a causal relationship between dietary supplements and

eating disorders, there is nothing in the Act or its legislative history that demonstrates a nexus between how a supplement is *marketed* (the only basis on which products are designated as subject to the Act) and the potential for eating disorders in minors.

The New York State Legislature should have demanded to see the "body of research on the causal link between these types of supplements and" eating disorders that the Act's sponsor, Assemblywoman Rozic, claimed supported the Act. *See* Ex. A, Tr., at p. 111. Instead, legislators decided to "trust that it's probably out there"—despite admitting that they have not seen it themselves. *See id.* This blind faith falls far short of the "credible evidence" necessary to justify a restriction on the First Amendment. *See Rubin*, 514 U.S. at 489.

Even assuming such evidence existed, the State cannot establish that the Act's restrictions will meaningfully address its stated purpose of addressing adolescent eating disorders. That alone renders the Act unconstitutional. The Supreme Court's opinion in *Liquormart, Inc.* is instructive. *See* 517 U.S. at 505-07. While "common sense" supported the notion that restrictions on price advertising may decrease consumption of alcohol, the state failed to provide sufficient "evidentiary support" demonstrating that the ban directly and meaningfully advanced that interest. *See id.* at 505. As it explained, the state could not quantify its results, and alcoholics would continue to suffer with their affliction regardless of the censorship. *See id.* at 506-07. The Court found that the regulation did not directly advance the state's interest in temperance absent impermissible surmise, which "certainty does not suffice when the State takes aim at accurate commercial information for paternalistic ends." *See id.* at 507. Under those circumstances, the Court found the statute unconstitutional based on its restriction of speech.

This same reasoning necessitates a finding that the Act is unconstitutional. The Act fails to make more than a half-hearted attempt to connect eating disorders—which are complicated

conditions with innumerable variables—and dietary supplements, and the evidence already put forward by the government can barely be strung together with even common sense. *Cf. id.* at 505. The science shows the contrary: that any theoretical role of dietary supplements is statistically de minimis.[15] And, like in *Liquormart*, a disease is just that—a disease—such that restricting dietary supplements from minors would not mitigate against the underlying condition.

To that end, the Act does not directly advance the interest of protecting against minors' eating disorders because the net it casts fails to include problematic conduct and instead, includes perfectly appropriate conduct. Products that are frequently misused by those with eating disorders, such as laxatives and diuretics (products commonly available as over-the-counter drugs), remain readily accessible to minors. But at the same time, the Act will prohibit the sale of a number of perfectly safe and beneficial products—such as those including calcium, vitamin D, fiber, vitamin B12, folic acid, and a number of other common and essential nutrients—including those with no discernable connection to weight loss or muscle building. This overbreadth, which is compounded by the vagueness of the statute, chills substantially more speech than necessary. *See, e.g.*, *Am. Booksellers Found. v. Dean*, 342 F.3d 96, 104 (2d Cir. 2003) ("When a court finds that a statute suffers from such substantial overbreadth, all enforcement of the statute is generally precluded.").

Moreover, the potential loopholes in the Act simultaneously threaten to swallow the efficacy of the whole regulation. Construing "representation" as broadly as the Act allows yields the counterproductive results described above. However, limiting "representation" to the

[15] As data from the Center for Disease Control demonstrates, the use of dietary supplements amongst individuals under the age of 19 is "low," but nearly *all* of those users consumed dietary supplements for the betterment of their health rather than an aesthetic goal. *See* Nutrient Trends. Only a few individuals surveyed identified weight loss, weight gain, or muscle gain as a motivation. *See id.* Even still, there is still no evidence that this subfraction of a subfraction of total adolescents surveyed abused the supplement, had an eating disorder, or developed one.

statements made by the person against whom the Act is enforced prevents the Act from accomplishing any of its stated aims. If a manufacturer advertises a product as aiding in a proscribed purpose, a teenager will simply find the same ingredient online, but in a product unencumbered by any such a representation. Far from solving a problem, the Act will just redirect sales from one entity to another. *See, e.g.*, *Greater New Orleans*, 527 U.S. at 189 (regulation on casino advertising failed third prong of *Central Hudson* where, *inter alia*, it was "reasonable to assume that" regulation would "merely channel gamblers form one casino rather than another.").

At best, then, the Act provides only "ineffective or remote support for the government's purpose." *See Central Hudson*, 447 U.S. at 564. That is simply not enough to warrant the restrictions on speech under the heavy weight of Supreme Court authority. The Court should find that CRN is likely to succeed on the merits of its First Amendment claim for this reason alone.

3. The State Did Not Appreciate the Extent to Which the Act Burdened Significant Interests in Speech, the Dissemination of Information, and the Public Wellbeing Before Passing the Act

The Act also fails the final *Central Hudson* criteria for justifying an imposition on speech because the State cannot demonstrate a reasonable fit between the Act and the harm it seeks to regulate. "The fourth part of the [*Central Hudson*] test complements the direct-advancement inquiry of the third, asking whether the speech restriction is not more extensive than necessary to serve the interests that support it." *Greater New Orleans Broad. Ass'n, Inc.*, 527 U.S. at 188. The State "must demonstrate narrow tailoring of the challenged regulation to the asserted interest[.]" *See id.* "[T]he challenged regulation should indicate that its proponent carefully calculated the costs and benefits associated with the burden on speech imposed by its prohibition." *Id.*

"[A] speech regulation cannot unduly impinge on the speaker's ability to propose a commercial transaction and the adult listener's opportunity to obtain information about products." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 566 (2001). In *Reilly*, the Court considered a ban

on the advertisement of tobacco products within a certain proximity to schools and playgrounds. *See id.* at 556. The government had a significant interest in preventing underage tobacco use, and it provided concrete evidence that "advertising and labeling play a significant and important contributory role in a young person's decision" to consume tobacco products. *See id.* at 558, 561-65. Yet the Supreme Court still held the regulation violated the First Amendment. As it explained, the government failed to consider all of the costs involved, explaining:

> [T]obacco retailers and manufacturers have an interest in conveying truthful information about their products to adults, and adults have a corresponding interest in receiving truthful information about tobacco products.

Id. at 564. A finding otherwise would run afoul of years of Supreme Court precedent holding that "the governmental interest in protecting children from harmful materials does not justify an unnecessarily broad suppression of speech addressed to adults." *Id.* (cleaned up).

Any attenuated effect the Act could have on eating disorders in minors is outweighed by the certain harms that the Act inflicts on First Amendment speech, private businesses, and all citizens in the State of New York. The Act imposes even more significant burdens than in *Lorillard*—its reach is nationwide and affects multi-jurisdictional business operations. The Act also deprives adults of information to which they are not only legally entitled, as in *Lorillard*, but scientifically substantiated information designed to assist all consumers in making informed decisions concerning their health based on their individualized needs. *See U.S. v. Caronia*, 703 F.3d 149, 167 (2d Cir. 2012) (in the context of public health "barriers to information . . . could inhibit, to the public's detriment, informed and intelligent treatment decisions.").

The fact that the State's first attempt to achieve its stated purpose did not involve speech demonstrates the existence of less burdensome alternatives. *See Thompson*, 535 U.S. at 373 ("If the First Amendment means anything, it means that regulating speech must be a last—not first—resort."). Another alternative to the State's "highly paternalistic approach . . is to assume that []

information is not itself harmful, that people will perceive their own best interests only if they are well informed enough, and that the best means to that end is to open the channels of communication rather than to close them." *Va. State Bd. of Pharm.*, 425 U.S. at 770. Instead of stifling speech, then, the State could have also inserted its own with outreach or educational programs. *See, e.g.*, *Linmark Assocs., Inc. v. Willingboro*, 431 U.S. 85, 97 (1977) (invalidating law and noting government could devote resources to educating the public and "widespread publicity" on issue).

CRN does not mean to suggest that this is how the State must pursue its interests. That decision is for the State alone. But the First Amendment firmly instructs that it may not do so by "keeping the public in ignorance of [] entirely lawful information." *See Va. State Bd. of Pharm.*, 425 U.S. at 770. "It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us." *Id.* The State thus erred in making a choice foreclosed by the Constitution, and cannot meet its burden of justifying its improper imposition on speech.

C. The Act is an Excessive Imposition of the State's Police Powers

For substantially the same reasons, CRN is likely to succeed on the merits of its policy powers claim in Count III. The State has authority under its police powers to enact laws protecting the "health," "safety," and "well-being" of its citizens. *See* N.Y. Const. Art. IX, § 2(c)(1). But legislation "must bear a reasonable relationship to" the State's objectives with respect to those interests. *See, e.g.*, *DoorDash, Inc. v. City of New York*, No. 1:21-CV-7564-GHW, 2023 WL 6118229, at *20 (S.D.N.Y. Sept. 19, 2023) (applying New York law). A law regulating private business defies this requirement where it is "arbitrary, capricious[,] unreasonable, or where the remedy proposed is unduly oppressive[.]" *Louhal Properties, Inc. v. Strada*, 743 N.Y.S.2d 810, 815 (Sup. Ct. 2002), *aff'd and remanded*, 307 A.D.2d 1029 (2003) (cleaned up).

The Act does not meet these requirements, as its roundabout regulations accomplish nothing but burdening private businesses and constitutional rights. There is no evidence, whatsoever, that demonstrates that the harm the State seeks to regulate—that dietary supplements cause eating disorders—is real. *See DoorDash*, 2023 WL 6118229, at *20 (government may exceed police power by acting without "empirical data"). That is, perhaps, why New York is the first state to enact legislation of this kind. *See, e.g.*, *Vermont Ry., Inc. v. Town of Shelburne*, 918 F.3d 82, 88 (2d Cir. 2019) (finding law was invalid exercise of police power where law was first of its kind and there was insufficient evidence substantiating danger).

New York law makes clear that a state exceeds its police power where the Act "operate[s] illogically, especially where it does so at the expense of private business owners." *Strada*, 743 N.Y.S.2d at 815, 817. The Act is toothless in addressing eating disorders, but bites sharply into the rights and operations of private businesses for conduct that has not been demonstrated to be harmful, at all. The Act may prohibit minors from purchasing wholly innocuous products—including pediatric supplements aiding children with bone and muscle growth—while simultaneously allowing for the sale of far more dangerous products that are not categorized as dietary supplements or for which there are no problematic "representations" suggesting muscle building or weight loss. In "mak[ing] punishable conduct that poses no threat at all to the health and welfare of its residents," the Act is illogical, burdensome, and an excessive imposition of the State's police power. *See id.* at 815.

D. The Act is Preempted by Federal Law and the Comprehensive Federal Policy Governing Dietary Supplements and their Labeling

Plaintiff is also likely to succeed on the merits of its claim that the Act is preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Dietary Supplement Health and Education Act of 1994 ("DSHEA"). The FDCA, as amended, contains an express preemption

clause, whereby Congress explicitly preempted any labeling requirements for dietary supplements which differ from those in the FDCA. In barring the sale of dietary supplements to minors based solely on the statements made in their labeling, the New York legislature has overridden the informed judgments of Congress and the FDA, who have expressly blessed the type of labeling claims New York now seeks to prohibit.

The relevant federal regulatory scheme here includes the FDCA, NLEA, and DSHEA. The FDCA "is designed to protect consumers from harmful products." *Ferrari v. Vitamin Shoppe Indus. LLC*, 70 F.4th 64, 67 (1st Cir. 2023). Congress amended the FDCA with the NLEA in 1993 for the purpose of establishing "the circumstances under which claims may be made about the nutrients in food." *See Nutritional Health All. v. Shalala*, 144 F.3d 220, 223 (2d Cir. 1998). It amended the FDCA again in 1994 with DSHEA "to establish a uniform framework to regulate dietary supplements." *See Ferrari*, 70 F.4th at 67.

The DSHEA expressly regulates a dietary supplement company's ability to make claims about "the role of a nutrient or dietary ingredient with respect to the structure or function of the human body," referred to as structure/function claims. *See Shalala*, 144 F.3d at 224. As the First Circuit has recently explained:

> A structure/function claim "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans" or "characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function." 21 U.S.C. § 343(r)(6)(A). That a nutrient, for example, "helps promote digestion" or "supports the immune system" is a structure/function claim.

Ferrari, 70 F.4th at 68 (cleaned up). To make such a claim a dietary supplement manufacturer must provide substantiation that the assertion is truthful and non-misleading, and, *inter alia*, notify the FDA of the claim "within 30 days of the first marketing of the product that bears the claim." *See* 21 U.S.C. § 343(r)(6).

The FDCA, through the NLEA, contains an express preemption provision. *See* 21 U.S.C. § 343-1(a). "That provision preempts any state requirement that is different than the FDCA's regulation in Section 343(r)(1)." *Jovel v. i-Health, Inc.*, No. 12-CV-5614 JG, 2013 WL 5437065, at *5 (E.D.N.Y. Sept. 27, 2013). "Structure/function claims under § 343(r)(6) fall within § 343(r)(1)'s ambit." *Ferrari*, 70 F.4th at 68. "Thus, 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 id.*

The Supremacy Clause permits Congress to preempt any state law that conflicts with the exercise of federal power. *See, e.g.*, *Murphy v. Nat'l Collegiate Athletic Ass'n*, 584 U.S. 453, 477 (2018). "Pre-emption fundamentally is a question of congressional intent and when Congress has made its intent known through explicit statutory language, the courts' task is an easy one." *English v. General Elec. Co.*, 496 U.S. 72, 78-79 (1990) (cleaned up). In such circumstances, courts "focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *See Puerto Rico v. Franklin California Tax-Free Tr.*, 579 U.S. 115, 125 (2016) (cleaned up). The relevant provision here preempts "any state requirement that is different than the FDCA's regulation in Section 343(r)(1)." *Ackerman v. Coca-Cola Co.*, No. CV-09-0395 (JG), 2010 WL 2925955, at *6 (E.D.N.Y. July 21, 2010). As a result, there "are only two ways" in which the State "may escape its preemptive force." *Id.* Specifically, the Act is preempted unless it: (1) imposes "requirements that are identical to those imposed by the FDCA;" or (2) if the Act's requirements "are not with respect to claims of the sort described in Section 343(r)(1)." *See id.*

The Act does not fall into those exceptions, and it runs directly afoul of the NLEA's express preemption provision by regulating the labeling of dietary products in a manner that conflicts with federal law. The Act regulates the labeling of dietary supplements—it expressly applies to such

products based on how they are "labeled, marketed, or otherwise represented[.]" *See* § 391-oo(1)(a)-(b). Federal regulation of labeling encompasses all such terms, and it extends to any statement "part of an integrated scheme to promote the product, with a readily discernable nexus between product sales and the matter[.]" *See Ackerman*, 2010 WL 2925955, at *6 n.12.

Both DSHEA and the Act operate to regulate structure/function claims. The Act regulates structure/function claims based on weight loss or muscle building. *See* § 391-oo(1). For instance, it bans the sale of a dietary supplement to a minor upon a claim that the product will help "maintain or increase muscle or strength." *See id.* at (6)(b)(ii). Those are the same precise statements that the FDA has expressly "blessed" as permissible structure/function claims. *See Ferrari*, 70 F.4th at 70 (permissible structure/function claims include statements that product "helps increase muscle size," "enhance muscle tone," and "helps support muscle growth"). The Act, therefore, impermissibly usurps the federal regulatory scheme by outright restricting the sale of otherwise compliant products based solely upon permissible structure/function claims. This is a requirement imposed on structure/function claims in New York that is now different from the federal scheme.

Ultimately, "the purpose of Congress is the ultimate touchstone in every pre-emption case." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009). By substituting the Attorney General's ad hoc determinations with the informed-decision making of the FDA, the State has upended the core purposes of the FDCA. For instance, the Act requires vastly different marketing of products in New York, even though the FDCA was designed to promote "national uniformity in certain aspects of food labeling, so that the food industry can market its products efficiently in all 50 states in a cost-effective manner." *See State Petitions Requesting Exemption from Federal Preemption*, 58 Fed Reg. 2462, 2462 (Jan. 6, 1993).

Another key purpose behind DSHEA was to eliminate the erection of "barriers that impede the ability of consumers to improve their nutrition through the free choice of safe dietary supplements and to clarify that dietary supplements are not drugs ... and should not be regulated as drugs." *Ferrari*, 70 F.4th at 73 (cleaned up). The Act defies both such purposes. It indiscriminately lumps together dietary supplements with diet pills (which are defined by the Act as a type of drug), makes it more difficult for adults to purchase dietary supplements, obstructs the free-flow of accurate information about dietary supplements which the federal government already comprehensively regulates, wholly bars minors from purchasing otherwise available products, and in some ways regulates dietary supplements to a greater extent than drugs, which minors may purchase in many circumstances without restriction.

The federal government fully and adequately ensures that dietary supplements offered to the public are safe for use and labeled appropriately. There is no room in the regulatory landscape for the Act's contrary requirements. CRN is thus likely to succeed on the merits of its preemption claim in Count IV of its Complaint.

II. CRN WILL SUFFER IRREPARABLE HARM ABSENT INJUNCTIVE RELIEF

CRN will suffer irreparable harm if this Court does not issue an injunction. "To establish irreparable harm, the movant must demonstrate an injury that is neither remote nor speculative, but actual and imminent and that cannot be remedied by an award of monetary damages." *Shapiro v. Cadman Towers, Inc.*, 51 F.3d 328, 332 (2d Cir. 1995) (cleaned up). CRN meets this requirement for three independent reasons.[16]

[16] That the Act is not yet in effect does not alter CRN's right to injunctive relief. "The standard for preliminary injunctive relief requires a *threat* of irreparable harm, not that irreparable harm already have occurred." *Mullins v. City of New York*, 626 F.3d 47, 55 (2d Cir. 2010) (emphasis in original). That threat is all but certain here, as the Act was passed into law and the Attorney General will begin enforcing its unintelligible requirements in April.

First, CRN's likelihood of success on the merits demonstrates the fact of irreparable harm. Deprivations of constitutional rights constitute *per se* irreparable harm. *See, e.g.*, *Deide v. Day*, No. 23-CV-3954 (NSR), 2023 WL 3842694, at *24 (S.D.N.Y. June 6, 2023) ("In the Second Circuit, it is well-settled that an alleged constitutional violation constitutes irreparable harm" and "presumption of irreparable harm follows" likelihood of success on the merits) (aggregating authority). Indeed, "[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Elrod v. Burns*, 427 U.S. 347, 373 (1976).

Second, CRN and its members will suffer irreparable injury absent an injunction because the Eleventh Amendment may bar it from obtaining any monetary damages from the State of New York. The Second Circuit routinely finds irreparable injury in such circumstances. *See, e.g.*, *U.S. v. State of N.Y.*, 708 F.2d 92, 93 (2d Cir. 1983); *Entergy Nuclear Vermont Yankee, LLC v. Shumlin*, 733 F.3d 393, 423 (2d Cir. 2013); *see also, e.g.*, *Chamber of Com. of the U.S. 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.").

Third, CRN's members would suffer irreparable harm because the Act fundamentally changes the economic landscape of the dietary supplement industry. As a threshold matter, "[c]omplying with a regulation later held invalid almost *always* produces the irreparable harm of nonrecoverable compliance costs." *See Book People, Inc. v. Wong*, 91 F.4th 318, 341 (5th Cir. 2024) (emphasis in original); *accord Commonwealth v. Biden*, 57 F.4th 545, 556 (6th Cir. 2023); *see also Nat'l Fed'n of Indep. Bus. v. Dep't of Lab., Occupational Safety & Health Admin.*, 595 U.S. 109, 120 (2022) (granting relief based on, *inter alia*, non-recoverable compliance costs); *New York v. U.S. Dep't of Homeland Sec.*, 969 F.3d 42, 86 (2d Cir. 2020) (finding irreparable harm based on costly revisions to existing system). And here, the Declarations to CRN's Motion

establish that the compliance costs necessitated by the Act do not merely tweak existing practices, but require the upheaval of longstanding operations. Aside from the traditional time and cost of reviewing the law and training employees accordingly, CRN members must self-censor their legal speech, thereby surrendering their ability to market their products, and implement new age verification procedures that prevent the sale of their product in many cases, including to lawful consumers, and increase the sale of every dietary supplement sold using such procedures.

CRN members are also certain to lose revenue and business opportunities as a result, which constitutes separate irreparable harm. *See, e.g.*, *Register.com, Inc. v. Verio, Inc.*, 356 F.3d 393, 404 (2d Cir. 2004); *Regeneron Pharms., Inc. v. U.S. Dep't of Health & Hum. Servs.*, 510 F. Supp. 3d 29, 38-41 (S.D.N.Y. 2020). In fact, that was the precise purpose of the Act, as the Legislature reasoned: "[b]y implementing age based restrictions on sales" of dietary supplements, the Act is intended to "draw attention to the health risks of using these products and reduce the incidents of use[.]" *See* Bill 5601. In addition to lost revenue due to the age restrictions itself, CRN members will lose revenue from consumers between the ages of 18 and 21 because of limitations in age verification procedures and from adults lacking sufficient government identification or disincentivized by increased costs and decreased accessibility.

The combination of increased potential for liability met with decreased revenue and demand creates a ripple effect that affects the relationship between CRN members and third parties. Retailers will not want to take risks given the uncertainty with which products are subject to the Act. They will certainly err on the side of not carrying a product that *may* be subject to the Act—and as set forth in detail herein, that category may be limitless. Retailers have already begun changing the terms of their relationships with CRN members. Others are likely to exit the

relationship altogether. These conditions, mixed with hornbook economics, will also decrease the revenue of other CRN members that operate as contract manufacturers and ingredient suppliers.

III. THE PUBLIC INTEREST AND BALANCING OF THE EQUITIES SUPPORT AN INJUNCTION

The last factor this Court must consider in evaluating CRN's Motion is the public interest and the balance of the equities, which merge for purposes of this analysis. *See, e.g., 725 Eatery Corp. v. City of New York*, 408 F. Supp. 3d 424, 469 (S.D.N.Y. 2019). These factors weigh conclusively in CRN's favor. Simply enough, the government "does not have an interest in the enforcement of an unconstitutional law," and "securing [constitutional] rights is in the public interest." *See id.* (cleaned up). The public interest necessitates relief well beyond that as well. Any speech concerning a product sold by a CRN member throughout the United States may create liability in New York, even where that speech was not made in or directed to this forum. Thus, CRN's members must restrict their speech on a nationwide basis, depriving *all* citizens in the United States of the information necessary to make educated decisions about their individualized care. *See Caronia*, 703 F.3d at 167 (recognizing public health is furthered by dissemination of information that empowers "intelligent and well-informed decision-making").

Additionally, while the Act will not meaningfully reduce the occurrence of eating disorders in minors, it is certain to: (1) disrupt the business operations of CRN's members; (2) deprive minors in New York and adults lacking sufficient government identification of dietary supplements that may be beneficial to their health; (3) render dietary supplements more expensive and less accessible for all adult consumers in New York; and (4) in the short and long term, reduce competition in the market, the existence of which inures to the benefit of the consumers with respect to product safety, quality, and price. *See, e.g., Nat'l Soc. of Prof'l Engineers v. U.S.*, 435

U.S. 679, 695 (1978) ("The heart of our national economy has been faith in the value of competition," which "will produce not only lower prices, but also better goods[.]")

This Court should fully resolve the Act's substantial constitutional defects before causing businesses to alter their key operations and burdening consumers' ability to purchase helpful and healthful dietary supplements. Any harm the government could muster pales in comparison to these concerns. And even if the State could articulate some non-trivial cost, that "is a cost that the [New York Legislature] chose to bear" when it enacted an overbroad and constitutionally suspect law. *See Yang v. Kosinski*, 960 F.3d 119, 136 (2d Cir. 2020) (weighing public interest and balance of equities factors in favor of injunction). CRN is thus entitled to injunctive relief.

IV. THIS COURT SHOULD NOT REQUIRE CRN TO POST BOND

While Federal Rule of Civil Procedure 65(c) contemplates a bond as a condition precedent to the issuance of a preliminary injunction, this Court should decline to order such security here. "It is well-settled that a district court has wide discretion in the matter of security" and may waive the bond requirement where "there has been no proof of likelihood of harm to the non-movant." *725 Eatery Corp*, 408 F. Supp. 3d at 470 (cleaned up). Such is the case where, for instance, a preliminary injunction restrains enforcement of an unconstitutional law that is not yet in effect. *See id.* That is the precise situation here, as Defendant will not sustain any harm from the continuance of the status quo. As a result, this Court should not require CRN to post bond.

CONCLUSION

As set forth above, all relevant factors weigh in favor of granting injunctive relief. CRN thus respectfully requests that the Court grant its Motion for Preliminary Injunction and enjoin Defendant from enforcing the Act until this litigation is resolved.

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Respectfully submitted,

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