

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

-----	X	
COUNCIL FOR RESPONSIBLE NUTRITION,	:	
	:	
Plaintiff,	:	24-cv-1881 (ALC)
	:	
-against-	:	<u>OPINION & ORDER</u>
	:	
LETITIA JAMES.,	:	
	:	
Defendant.	:	
	:	
-----	X	

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

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

BACKGROUND

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

I. STATUTORY FRAMEWORK

Beginning in 2020, members of the New York State Legislature sought to address the growing prevalence of the “serious public health problem” of eating disorders “affecting youth

and adults of all races, ages, and genders.” Sponsor’s Mem. in Support for A10138 (2020), at 1; *accord* Sponsor’s Mem. in Support, in Bill Jacket for ch. 558 (2023), at 1-2. One central concern for the Legislature was that studies showed that eating disorders are mental health condition that may be identified and diagnosed based on “the presence of what clinicians call unhealthy weight control behaviors.” *See id.* One of these signals is misusing dietary aids to try to lose weight or build muscle. *See id.* Legislators were also concerned that dietary supplements used for weight loss or muscle building were readily available “alongside multivitamins and other supplements largely regarded as safe,” even though there had been a number of reported instances of deaths and serious harms resulting from the largely unregulated use of dietary supplements. *Id.* Modeled after longstanding age restrictions for alcohol and tobacco, which “have been demonstrated to reduce . . . consumption” of those products by adolescents, the Legislature sought to implement an age restriction for the purchase of dietary supplements used for losing weight or building muscle, to reduce the unsupervised use of these products by minors and, more broadly, to “draw attention to the life-threatening risks that come along with these widely used products.” Sponsor’s Mem. in Supp. for A10138 (2020), at 2.

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

such assessments, it was “not equipped to create a list of restricted products.” *Id.* For these reasons she was “constrained to veto this bill.” (*Id.*).

On October 25, 2023, the Legislature enacted A5610, the subject of this action. Ch. 558, 2023 N.Y. Laws. Consistent with the original versions of the law, the Statute provides that no person, company “or other entity shall sell or offer to sell or give away, as either a retail or wholesale promotion, . . . [a] dietary supplement¹ for weight loss or muscle building within this state to any person under eighteen years of age.” Ch. 558, § 1, 2023 N.Y. Laws (to be codified at N.Y. Gen. Bus. Law § 391-oo(2)). As enacted, the Statute defines “dietary supplement for weight loss or muscle building” as “a class of dietary supplement as defined in section three hundred ninety-one-o of this article¹ that is labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building.” Gen. Bus. Law § 391- oo(1)(a). Exempted from the age-based sales restriction are “protein powders, protein drinks and foods marketed as containing protein unless the protein powder, protein drink or food . . . contains an ingredient other than protein which would, considered alone, constitute a dietary supplement for weight loss or muscle building.” *Id.* The Statute also contains a number of provisions clarifying its scope and guiding enforcement. In particular, the Statute states that a supplement is “labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building” where its “labeling or marketing bears statements or images that express or imply that the product will help . . . modify, maintain, or reduce body weight, fat, appetite, overall metabolism, or the

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

process by which nutrients are metabolized” or “maintain or increase muscle or strength.” *Id.* § 391-oo(6)(b)(i)-(ii).

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

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

Plaintiff, Council for Responsible Nutrition, is a nonprofit trade organization that represents various dietary supplement manufacturers and distributors. (AC, ECF No. 44 ¶ 12.) CRN brings this action against Attorney General Leticia James in her official capacity, seeking declaratory and injunctive relief to prevent enforcement of the Statute.

PROCEDURAL HISTORY

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

STANDARD OF REVIEW

Where, as here, "a preliminary injunction will affect government action taken in the public interest pursuant to a statute or regulatory scheme, the moving party must demonstrate (1) irreparable harm absent injunctive relief, (2) a likelihood of success on the merits, and (3) public interest weighing in favor of granting the injunction." *L.T. v. Zucker*, 2021 U.S. Dist. LEXIS 196906, *7 (N.D.N.Y., Oct. 13, 2021) (quoting *Friends of the E. Hampton Airport, Inc. v. Town of E. Hampton*, 841 F.3d 133, 143 (2d Cir. 2016)).

"[A] preliminary injunction is an extraordinary and drastic remedy, one that should not be granted unless the movant, by a clear showing, carries the burden of persuasion." *Sussman v.*

Crawford, 488 F.3d 136, 139 (2d Cir. 2007); *see also Anwar v. Fairfield Greenwich Ltd.*, 728 F. Supp. 2d 462, 472 (S.D.N.Y. 2010) ("Temporary restraining orders and preliminary injunctions are among the most drastic tools in the arsenal of judicial remedies, and must be used with great care.") (internal citations omitted).

DISCUSSION

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

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

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

An injury sufficient to satisfy Article III must be "concrete and particularized" and "actual or imminent, not 'conjectural' or 'hypothetical.'" *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560, 112 S. Ct. 2130, 119 L. Ed. 2d 351 (1992) (citations omitted). An allegation of future injury may suffice if the threatened injury is "certainly impending," or there is a "'substantial risk' that the harm will occur." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409, 414 n.5, 133 S. Ct. 1138,

185 L. Ed. 2d 264 (2013) (emphasis and internal quotation marks omitted). "Pre-enforcement challenges to criminal statutes are cognizable under Article III," as it is well established that a "plaintiff need not first expose [her]self to liability before bringing suit to challenge . . . the constitutionality of a law threatened to be enforced." *Picard*, 42 F.4th at 97 (internal quotation marks and citations omitted). Courts apply a three-prong test to assess the existence of a cognizable injury in fact in the context of pre-enforcement challenges, which requires a plaintiff to demonstrate: (1) "an intention to engage in a course of conduct arguably affected with a constitutional interest"; (2) that the intended conduct is "proscribed by" the challenged law; and (3) that "there exists a credible threat of prosecution thereunder." *Susan B. Anthony List*, 573 U.S. at 159 (internal quotation marks and citation omitted). *See Nastri v. Dykes*, 2024 U.S. App. LEXIS 7445, *2-3 (2d Cir., Mar. 29, 2024) (noting that "[w]hile many pre-enforcement cases involve a threat of *criminal* prosecution, the fear of civil penalties can likewise be sufficient.") (internal citation and quotation marks omitted). CRN has satisfied all three elements to establish that it has suffered an injury in fact related to the prospect of the State's enforcement of the Statute.

Defendant argues, inter alia, that CRN fails to allege that its members have any concrete "intention to engage in a course of conduct" prohibited by law, *Vitagliano v. County of Westchester*, 71 F.4th 130, 137-38 (2d Cir. 2023), that would subject them to a "credible threat" of enforcement, *Cayuga Nation*, 824 F.3d at 331-32. (Def. Memo. at 6-7). Defendant also suggests that Plaintiff's seller members have not identified factually specific details to nudge their injuries from the constitutionally impermissible speculative realm to concrete and particularized injuries in fact. (*Id.*). These claims are without merit. At least one of CRN's seller

members, XYMOGEN, has alleged a certainly impending injury that could very well expose the company to the threat of enforcement. (ECF No. 23 ¶¶ 19-21). XYMOGEN manufactures dietary supplements, and notes that at least six of its products will be impacted by the Statute. (*Id.* at 17). If XYMOGEN voluntarily redesigns labels for impacted products, it must temporarily age-restrict the products in New York until the new labels are available or halt the sale of the affected products until all existing inventory is out. (*Id.*) The question of how to handle inventory in stock with current label claims if age verification protocols are not implemented before the Statute takes effect is sufficient to demonstrate injury in fact. CRN also claims that compliance costs that its members have already incurred to assess which products are affected and to implement age verification are also sufficient to demonstrate standing. (ECF No. 22, ¶ 15; ECF No. 24, ¶ 14; ECF No. 3, ¶¶ 12-13, 16- 17, 21, 24-29; Compl. ¶¶ 165-180). This Court agrees. *See, e.g., Grand River Enters. Six Nations v. Boughton*, 988 F.3d 114, 121 (2d Cir. 2021) (“[a] regulated entity may plead an ‘injury in fact’ by plausibly alleging compliance costs associated with an increased regulatory burden.”); *see also Clementine Co., LLC v. Adams*, 74 F.4th 77, 86 (2d Cir. 2023) (finding that Plaintiffs plausibly alleged injury in fact because of compliance costs associated with hiring additional staff to check proof of vaccination requirement). “Any monetary loss suffered by the plaintiff satisfies this element; even a small financial loss suffices.” *Carter v. HealthPort Techs., LLC*, 822 F.3d 47, 55 (2d Cir. 2016) (internal citation and quotation marks omitted).

Finally, CRN’s fear of enforcement is not contrived. Presuming that the State will immediately begin enforcement after the Statute takes effect, officials could plausibly use the “Dietary Supplement Label Explorer” as created by Strategic Training Initiative for the

Prevention of Eating Disorders (“STRIPED”) to begin identifying and categorizing products and issuing penalties accordingly. (ECF No. 15 ¶¶ 75, 78, 80).

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

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

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

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

i. The First Amendment’s Doctrinal Regime

CRN locates its purported First Amendment injury as an unconstitutional restriction on protected commercial speech. Speech is commercial when it “does no more than propose a commercial transaction.” *Conn. Bar Ass’n v. United States*, 620 F.3d 81, 93 (2d Cir. 2010) (quoting *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66, 103 S. Ct. 2875, 77 L. Ed. 2d 469 (1983)). Moreover, “commercial speech [constitutes] ‘expression related solely to the economic interests of the speaker and its audience.’” *Id.* at 94 (quoting *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of New York*, 447 U.S. 557, 561, 100 S. Ct. 2343, 65 L. Ed. 2d 341 (1980)). The Supreme Court elucidated that “the Constitution presumes that attempts to regulate

speech are more dangerous than attempts to regulate conduct.” *44 Liquormart v. R.I.*, 517 U.S. 484, 512 (1996). Consequently, the First Amendment “directs that government may not suppress speech as easily as it may suppress conduct and that speech restrictions cannot be treated as simply another means that the government may use to achieve its ends.” *Id.* Finally, the Court elaborated that “these basic First Amendment principles clearly apply to commercial speech.” *Id.*

ii. Whether the Statute Implicates the First Amendment

Defendant argues that the Statute does not regulate speech, rather it is directed solely toward conduct: namely, restricting the sale of certain dietary supplements to a particular class of consumers. Returning to the plain text of the Statute, the Legislature explicitly states that “[n]o person, firm, corporation, partnership, association, limited liability company, or other entity shall sell or offer to sell or give away, as either a retail or wholesale promotion, an over-the-counter diet pill or dietary supplement for weight loss or muscle building within this state to any person under eighteen years of age.” N.Y. Gen. Bus. Law § 391-oo(2). Standing alone, this provision is a cabined, conduct-based age restriction that “simply regulates business behavior.” *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 492-93, 496 (1982) (finding that an ordinance that prohibited the sale of certain items “designed or marketed for use” with drugs did not infringe on First Amendment rights, and even if a commercial speech interest was implicated it was only the “attenuated interest in displaying and marketing merchandise in the manner that the retailer desires.”); *see also Art & Antique Dealers League of Am., Inc. v. Seggos*, 523 F. Supp. 3d 641, 646 (S.D.N.Y. 2021) (holding that statutory prohibition of in-store display of product was an “ordinary economic regulation of commercial activity” that “impose[d] and incidental burden on ‘speech.’”).

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

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

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

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

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

compliance costs, or lose the percentage of sales that targeted youth. Again, the Statute regulates conduct not speech. It affects what sellers “must do,” require proof of legal age to purchase over-the-counter dietary pills or dietary supplements for weight loss or muscle building. The Statute does not regulate what these sellers “may or may not say.” *Id.* at 86 (citing *FAIR*, 547 U.S. at 60).

CRN Member sellers are free to market, describe, or label their products however they so choose in accordance with federal and state statutory requirements regarding advertising. XYMOGEN can continue to label, market, and sell its product “Appe-Curb” and represent that it “combats cravings naturally” and “supports healthy weight”. (Ex. G, ECF No.37-7 at 2-3). Nature’s Bounty can maintain that its “Metabolism Booster” product “promote[s] abdominal fat loss and boost[s] fat metabolism.” (*Id.* at 3). Nutrilite can target its “Slimmetry Dietary Supplement” to “anyone looking to support their weight-loss efforts with a convenient supplement” by “help[ing] you maintain a healthy waistline.” (*Id.* at 6). The Statute does not prohibit these statements, alter them in any way, nor *say* anything about them. It only requires that customers over the age of eighteen verify their age before purchasing these products. And “[b]ecause 'every civil and criminal remedy imposes some conceivable burden on First Amendment protected activities,' a conduct-regulating statute of general application that imposes an incidental burden on the exercise of free speech rights does not implicate the First Amendment.” *Clementine Co., LLC*, 74 F.4th at 87 (quoting *Arcara*, 478 U.S. at 706).

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

iii. Whether the Statute Survives Intermediate Scrutiny

The Court need not undertake a levels of scrutiny analysis because the Statute does not implicate the First Amendment. But Plaintiff still fails to demonstrate a likelihood of success on this claim because—in all probability—the statute survives intermediate scrutiny. To determine whether a regulation of commercial speech is constitutionally permissible, courts must determine whether (1) the expression is protected by the First Amendment, concerns lawful conduct, and is not misleading; (2) the asserted governmental interest is substantial; (3) the regulation directly advances the asserted government interest; (4) and the regulation is no more extensive than necessary to serve that interest. *Central Hudson Gas & Elec. Corp. v. Public Svs. Comm.*, 447 U.S. 557, 566 (1980). It is well established that "the party seeking to uphold a restriction on commercial speech carries the burden of justifying it." *Edenfield v. Fane*, 507 U.S. 761, 770 (1993) (internal citations omitted). Plaintiff has conceded that the State has a substantial government interest in protecting public health and regulating misleading information. (Pl. Memo. at 19). CRN has also admitted that eating disorders in minors are unquestionably real harms. (*Id.* at 21). The Court therefore focuses its analysis on the third and fourth prongs of the *Central Hudson* inquiry.

1. The Third *Central Hudson* Prong

The third *Central Hudson* prong requires that the speech restriction directly and materially advance the asserted governmental interest. "This burden is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Lorillard Tobacco Co.*, 533 U.S. at 556 (internal

citation omitted). “New York is not required to produce ‘empirical data come . . . accompanied by a surfeit of background information’ in order to satisfy intermediate scrutiny.” *Art & Antique Dealers*, 523 F. Supp. 3d at 647 (quoting *Lorillard Tobacco Co.*, 533 U.S. at 555) (citations and internal quotation marks omitted).

CRN claims that the State has not proffered any evidence to suggest that the harms it seeks to address—the prevalence of eating disorders and the health harms from the unregulated use of dietary supplements used for weight loss and muscle building—are directly mitigated by the Statute. Further, Plaintiff argues that the Act cites to “irrelevant materials masquerading as genuine evidence” and that the Legislature “should have demanded to see the body of research on the causal link between these types of supplements and” eating disorders.” (Pl. Memo. at 21-22). These arguments are without merit. The Supreme Court has recognized that state laws may be justified “by reference to studies and anecdotes . . . or even based solely on history, consensus, and ‘simple common sense.’” *Lorillard Tobacco Co.*, 533 U.S. at 555 (quoting *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 628 (1995)).

Given the ample evidence in the legislative record and public health discourse, the State has sufficiently met its burden—at this stage in the litigation—to demonstrate that the Statute directly and materially advances the harms it seeks to address. For example, in his testimony submitted to the Legislature in support of the Statute, Dr. Joseph Nagata cited several different studies to demonstrate this causal connection: (1) The U.S. weight-loss and muscle-building supplement industry generates over \$2.5 billion in annual revenue and youth are prominent consumers of these products; (2) a recent study found that youth using weight-loss supplements were three times more likely than those using ordinary vitamins to experience severe medical

harm, including hospitalization, disability, and even death; (3) The American Academy of Pediatrics recently issued two reports strongly cautioning against teens using these products for any reason; (4) Youth who use over-the-counter diet pills are six times more likely to be diagnosed with an eating disorder compared to nonusers; (5) Use of muscle-building supplements has also been linked to eating disorders. This evidence suggests that this Statute provides substantial rather than ineffective or remote support for the government's intended purpose. (Ex. E, ECF No. 37-5 at 2-3. *See L.T. v. Zucker*, 2021 U.S. Dist. LEXIS 196906 *17-20 (N.D.N.Y., Oct. 13, 2021) (upholding mask mandate for children in school as surviving intermediate scrutiny and relying in part on Defendant New York government official's cite to third-party reports and studies to demonstrate the rising threat of COVID-19 which the government had an important interest in stopping).

2. The Fourth *Central Hudson* Prong

The fourth *Central Hudson* prong asks "whether the speech restriction is not more extensive than necessary to serve the interests that support it." *Lorillard Tobacco Co.*, 533 U.S. at 556 (citing *Greater New Orleans, supra*, at 188). The Supreme Court has made it clear that "the least restrictive means" is not the standard; instead, the case law requires a reasonable "'fit between the legislature's ends and the means chosen to accomplish those ends, . . . a means narrowly tailored to achieve the desired objective.'" *Went For It, Inc., supra*, at 632 (internal citation omitted). That fit "is not necessarily perfect, but reasonable" and "represents not necessarily the single best disposition but one whose scope is in proportion to the interest served; that employs not necessarily the least restrictive means but . . . a means narrowly tailored to achieve the desired objective." *Art & Antique Dealers League of Am., Inc.*, 523 F. Supp. 3d at

646-47 (citing *Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480, 109 S. Ct. 3028, 106 L. Ed. 2d 388 (1989)) (internal quotations and citation omitted). Essentially, "the regulation [may] not burden substantially more speech than is necessary to further the government's legitimate interests." *Safelite Grp., Inc. v. Jepsen*, 764 F.3d 258, 265 (2d Cir. 2014).

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

weight loss or muscle building.” N.Y. Gen. Bus. Law § 391-oo(1). In fact, the Statute carves out protein powders, protein drinks and foods marketed as containing protein (unless the product contains an ingredient that in isolation would constitute a dietary supplement for weight loss or muscle building). *Id.* at § 391-oo(1)(a). Because the Statute also leaves “open alternative avenues for vendors to convey information about products” the restriction is not more extensive than necessary to serve the government’s interest. *Lorillard Tobacco Co.*, 533 U.S. at 570.²

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

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

This Statute falls well within the ambit of the Legislature’s broad police powers to enact laws aimed at protecting health and safety. *Lyn v. Inc. Vill. Of Hempstead*, 308 F. App’x 461, 464 (2d Cir. 2009) (quoting *City of Erie v. Pap’s A.M.*, 529 U.S. 277, 296 (2000)), including that of its children. *See Ginsberg v. New York*, 390 U.S. 629, 639 (1968) (noting that “[t]he well-being of its children is of course a subject within the State's constitutional power to regulate.”). Challenges to a State’s exercise of its police powers are reviewed for reasonableness. *Jacobson v. Massachusetts*, 197 U.S. 11, 35 (1905). Under rational basis review, laws have a “strong

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

presumption of validity” such that attacks to rationality “must discredit any conceivable basis which could be advanced to support the challenged provision, regardless of whether that basis has a foundation in the record, or actually motivated the legislature.” *United States v. Amalfi*, 47 F.4th 114, 124-25 (2d Cir. 2022). Given that this Statute survives the more demanding level of intermediate scrutiny, *supra*, it easily satisfies rational basis review. A restriction preventing minors from directly purchasing certain dietary supplements is a rational means of reducing the unsupervised use of those products, often by youth who struggle with eating disorders. CRN fails to prove that it will likely succeed on a claim of excessive imposition of police powers.

B. The Act is Not Preempted by Federal Law

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

As the Court has already determined, the Statute does not mandate any alterations to the labeling of dietary products, it merely institutes an age restriction. Because there is no basis for

preemption, Plaintiff fails to establish that it will succeed on the merits of this claim. There exists no such violation of the Supremacy Clause.

C. The Statute is Not Unconstitutionally Vague on its Face

A statute is void for vagueness where it fails to provide: (1) “people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits;” or (2) “explicit standards for those who apply,” thereby risking “resolution on an ad hoc and subjective basis[.]” *See Cunney v. Bd. of Trustees of Vill. of Grand View, N.Y.*, 660 F.3d 612, 621 (2d Cir. 2011) (internal citations omitted). “Animating this first vagueness ground is the constitutional principle that individuals should receive fair notice or warning when the state has prohibited specific behavior or acts.” *Thibodeau v. Portuondo*, 486 F.3d 61, 65 (2d Cir. 2007). “In reviewing the ordinance's language for vagueness, “we are relegated . . . to the words of the ordinance itself, to the interpretations the court below has given to analogous statutes, and, perhaps to some degree, to the interpretation of the statute given by those charged with enforcing it.” *Cunney*, 660 F.3d at 621 (citing *Grayned v. City of Rockford*, 408 U.S. 104, 110 (1972)). To succeed on a facial challenge, as CRN asserts here, the plaintiff “must demonstrate that the law is impermissibly vague in all of its applications.” *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 497-98 (1982).

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

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

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

III. CRN Has Failed to Prove Irreparable Harm

CRN asserts that it will suffer irreparable harm absent injunctive relief, namely the infringement on First Amendment freedoms and economic injury because of compliance costs and lost revenue due to the age restriction. “Where a plaintiff alleges injury from a rule or regulation that directly limits speech, the irreparable nature of the harm may be presumed.” *Bronx Household of Faith v. Bd. of Educ.*, 331 F.3d 342, 349 (2d Cir. 2003). Although “[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury,” *Elrod v. Burns*, 427 U.S. 347, 373, 49 L. Ed. 2d 547, 96 S. Ct. 2673 (1976), in “instances where a plaintiff alleges injury from a rule or regulation that may only potentially affect speech, the plaintiff must establish a causal link between the injunction sought and the alleged injury, that is, the plaintiff must demonstrate that the injunction will prevent the feared deprivation of free speech rights.” *Bronx Household of Faith v. Bd. of Educ.*, 331 F.3d 342, 350 (2d. Cir. 2003).

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

Furthermore, Plaintiff's substantial and inexcusable delay in moving for preliminary relief five months after the State was enacted in October 2023, erodes its claims of immediate, irreparable, and impending injury. When determining whether a moving party faces irreparable harm without a preliminary injunction, district courts "should generally consider [any] delay" on the movant's part in seeking the injunctive relief. *Tom Doherty Assocs., Inc. v. Saban Ent., Inc.*, 60 F.3d 27, 39 (2d Cir. 1995)); see also *Tough Traveler, Ltd. v. Outbound Prod.*, 60 F.3d 964, 968 (2d Cir. 1995) (months-long delay in bringing suit and moving for preliminary injunction negates presumption of irreparable harm. These delays undermine the theory justifying preliminary injunctions, namely "that there is an urgent need for speedy action to protect the plaintiff's rights." *Central Point Software, Inc. v. Glob. Software & Accessories, Inc.*, 859 F. Supp. 640, 644-45 (E.D.N.Y. 1994). Although a delay in seeking a preliminary injunction "does not always undermine an alleged need for preliminary relief, months-long delays in seeking preliminary injunctions have repeatedly been held by courts in the Second Circuit to undercut the sense of urgency accompanying a motion for preliminary relief." *Silber v. Barbara's Bakery*, 950 F. Supp. 2d 432, 439 (E.D.N.Y. 2013).

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

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

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

CRN has admitted that eating disorders in minors are unquestionably real harms. (Pl. Memo. at 21). Enjoining the Statute, which seeks to protect minors from the physical and mental health harms associated with the use of dietary supplements for weight loss and muscle building, would deprive New York residents of the protections of the law. *See, e.g., L.T.*, 2021 U.S. Dist. LEXIS 196906, *29-31 (evidence that demonstrated the rise of COVID-19 may imperil thousands of lives, endanger children, and cause schools to shutdown weighed heavily against enjoining enforcement of the mask mandate); *see also N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health*, 545 F. Supp. 2d 363, 368 (S.D.N.Y. 2008) ("The public interest . . . in enforcement of legislation enacted in the public interest, weigh[s] heavily against granting a stay of enforcement.").

A Center for Disease Control study found that five percent of teens have used diet pills, powders, or liquid in the past month without a doctor's approval in order to lose weight or prevent weight gain.³ (Def. Opp. at n.6). Another study from the Journal of Adolescent Health found that supplements sold for weight loss, muscle building, and energy were associated with almost three times the risk for severe medical outcomes compared to vitamins.⁴ (*Id.*) Curbing these incidences of eating disorders in youth is a serious public health problem. CRN's pecuniary interests, fear of the enforcement of civil penalties, and speculative loss of revenue and sales pale in comparison to the State's goal of protecting youth from products that unfettered access to dietary supplements present. It would be unquestionably against the public interest to impede enforcement of N.Y. Gen. Bus. Law § 391-oo. The Court denies the emergency injunctive relief that Plaintiff seeks.

CONCLUSION

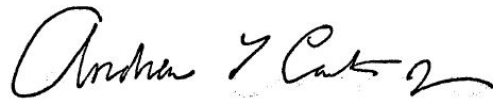
For the reasons set forth above, Plaintiff's emergency request for a preliminary injunction is hereby **DENIED**. The Clerk of the Court is directed to close the open motion at ECF No. 14.

SO ORDERED.

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

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

Dated: April 19, 2024
New York, New York

A handwritten signature in black ink, appearing to read "Andrew L. Carter, Jr.", written in a cursive style.

ANDREW L. CARTER, JR.
United States District Judge