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.	JURY DEMANDED Case No. 1:24-cv-01881-ALC

AMENDED VERIFIED COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF

Plaintiff, Council for Responsible Nutrition, by and through the undersigned counsel, hereby files this Amended Verified Complaint for Declaratory Judgment and Injunctive Relief against Defendant, New York Attorney General Letitia James, in her official capacity, respectfully showing the Court as follows:

INTRODUCTION

1. Council for Responsible Nutrition ("CRN") brings this facial challenge to enjoin, preliminarily and permanently, the enforcement of N.Y. Gen. Bus. Law 391-oo (the "Act").

2. On October 25, 2023, New York Governor Kathy Hochul signed the Act into law.

3. The Act purports to bar minors from purchasing dietary supplements or diet pills that have been marketed or represented at some point, by seemingly anyone, as intended for muscle building or weight loss.

4. The Act also appears to apply the same restrictions for products containing any *ingredient*, where the ingredient alone has been marketed or represented somehow as intended for

muscle building or weight loss—even if the actual product makes no such claims and the product's marketer or retailer are not aware of such claims being made elsewhere.

5. The purported legislative intent for the Act is to prevent unidentified eating disorders in minors. While a noble and worthwhile goal, there is absolutely *no evidence* demonstrating a causal link between dietary supplements and eating disorders—and there is certainly no evidence that such products are unsafe for minors based solely on their label claims or how they are marketed or otherwise represented. In fact, the current scientific evidence belies any causal relationship between dietary supplements and eating disorders in minors.

6. The Act's indirect method of achieving this objective also makes scant sense. The Act does not target the consumption of products with dangerous ingredients or potential for misuse in connection with eating disorders. Instead, the Act focuses on whether a product is *labeled* or *marketed* as a product meant for "achieving weight loss or muscle building," relying solely upon any representations communicated for that product, irrespective of any actual dangers, potential for misuse, or demonstrable causal relationship to disordered eating.

7. This, in turn, presents numerous nonsensical loopholes. For instance, the Act would bar a minor from purchasing a product whose label touts its weight loss potential, even though the minor could legally purchase a product with the exact same formulation so long as the label or other marketing did not advance such a representation.

8. Put simply, the Act does not actually address the problem it seeks to solve, and instead punishes truthful, and otherwise lawful communications.

9. Finally, the Act offers no meaningful guidelines for compliance. The only guidance provided to a party interested in complying is that the Act applies to products with certain representations about weight loss or muscle building. But the Act does not specify ***which***

representations are relevant or ***whose*** representations are relevant for purposes of complying with the statute.

10. As far as a manufacturer or retailer of dietary supplements would know, any representations, made at anytime, anywhere, by anyone (including unaffiliated third-parties) can subject a dietary supplement to the age restrictions of the Act. Such is the case even where the entity subject to penalties was not aware that the representation was made or viewed by a minor. In fact, the Act itself just requires that the representation was made, even if there was no evidence that the representation was made *to* or understood *by* a minor.

11. So the Act appears to draw into its reach all kinds of conduct that has absolutely nothing to do with its purported goal of protecting minors; and the Act imposes sanctions on otherwise lawful behavior and protected commercial speech.

12. Plaintiff, CRN, is a nonprofit trade organization that counts many dietary supplement manufacturers and distributers as members. They have the same concerns as the government in ensuring that the purposes underlying the statute are furthered. But the disconnect between the Act's purpose and what it appears to prohibit renders the Act unconstitutional.

13. In creating age-based restrictions on dietary supplements based on extraordinarily broad and undefined criteria, the Act runs afoul of the federal and New York constitutions. For example, it is impossible for a product's manufacturer, distributer, retailer—*or even the regulator*—to know, from the text of the Act alone, whether a particular product falls under its ambit and therefore may not be sold to minors. The Act lacks objective, understandable criteria for the products that are subject to the age-based restrictions and produces seemingly illogical results of restricting products that are not marketed for weight loss or muscle building and are

widely recognized as safe. Parties who *want* to comply will be left guessing as to which products are covered under the Act, thus rendering compliance functionally impossible.

14. Without any guidance from the State, but substantial financial penalties for violations, the Act compels retailers and marketers to err on the side of restricting sales of products with lawful claims thereby chilling their right to sell and make lawful claims for these dietary supplements, and restricting New York consumers' (of all ages) rights to access these products and to receive truthful communications about their benefits.

15. Moreover, even if the Act's purpose was supported by the scientific literature (and it is not), prohibiting minors from purchasing products based solely on their labeling and marketing is simply not a direct way to achieve that stated purpose. Neither a restriction on commercial speech nor an exercise of the state's police powers is justified where there is such an attenuated link between the conduct prohibited and the alleged purpose of the restriction.

16. For these reasons and more, this Court should enjoin Defendant from enforcing the Act against Plaintiff's members and declare the Act unconstitutional.

PARTIES AND STANDING

17. Plaintiff Council for Responsible Nutrition ("CRN") is a nonprofit 501(c)(6) trade association representing dietary supplement and functional food manufacturers and ingredient suppliers for these products.[1]

18. CRN, which was founded in 1973, is the leading trade association representing such manufacturers and suppliers.

[1] CRN's members are listed at CRN, About Us, https://www.crnusa.org/membership/responsible-its-our-middle-name.

19. Its mission is to protect and advance a climate for its members to responsibly develop, source, manufacture, and market science-backed dietary supplements, functional food, and their ingredients, for better health and nutrition.

20. Many of CRN's members are manufacturers or suppliers of dietary supplements that sell finished dietary supplements in the State of New York, including through retail operations and other online platforms. These members, including those described in this Complaint, are governed by the Act.

21. Some of CRN's members have individual standing to sue in their own right, as those members are subject to the Act, challenging the Act is germane to CRN's purpose, and members' individual participation in this matter is unnecessary as it is a purely legal, facial challenge.

22. CRN has also incurred costs and will continue to divert finite resources to address the Act's implications and compliance costs for dietary supplement manufacturers and suppliers.

23. CRN incorporates by reference the factual averments contained in ECF Nos. 15-24 as if alleged fully herein.

24. Defendant Letitia James is the New York Attorney General. The Act provides that enforcement under the Act must be initiated by "an application" "made by the attorney general in the name of the people of the state of New York." GBL § 391-oo(5).

25. CRN sues Attorney General James in her official capacity.

JURISDICTION AND VENUE

26. This Court has subject-matter jurisdiction under 28 U.S.C. §§ 1331 and 1343(a). This Court has authority to grant legal and equitable relief under 42 U.S.C. § 1983, injunctive relief under 28 U.S.C. § 1651, and declaratory relief under 28 U.S.C. § 2201(a).

27. This Court has personal jurisdiction over Defendant pursuant to Fed. R. Civ. P. 4(k)(1), because the New York Attorney General resides in and/or conducts a substantial proportion of her official business in New York.

28. Venue is proper in this District under 28 U.S.C. § 1391(b) because the defendant resides in and performs her official duties in this District and the events giving rise to this civil action occurred in this District.

BACKGROUND

I. A General Primer on Dietary Supplements and Their Benefits

29. A dietary supplement is, simply enough, a product that adds to or supplements a person's diet with a dietary ingredient. *See FDA 101: Dietary Supplements*, U.S. FOOD AND DRUG ADMIN. (June 2, 2022), https://www.fda.gov/consumers/consumer-updates/fda-101-dietary-supplements ("*FDA 101*").

30. Common "[d]ietary ingredients" include: "[v]itamins (such as multivitamins or individual vitamins like vitamin D and biotin), [m]inerals (such as calcium, magnesium, and iron), [b]otanicals or herbs (such as echinacea and ginger), [b]otanical compounds (such as caffeine and curcumin), [a]mino acids (such as tryptophan and glutamine), [l]ive microbials (commonly referred to as "probiotics")." *Id.* This list is not exhaustive and simply illustrates the wide variety of ingredients that can be legally included in dietary supplement products.

31. "Dietary supplements play a role in the comprehensive care plan for many Americans," as "some dietary supplements can help improve or maintain overall health and help provide adequate amounts of essential nutrients that the body needs to function." *See Information for Consumers on Using Dietary Supplements*, U.S. FOOD AND DRUG ADMIN. (Oct. 21, 2022), https://www.fda.gov/food/dietary-supplements/information-consumers-using-dietary-supplements ("*Information for Consumers on Using Dietary Supplements*").

32. By way of example, the United States Federal Food and Drug Administration ("FDA") advises consumers that "calcium and vitamin D can help build strong bones, and fiber can help to maintain bowel regularity." *See FDA 101*.

33. That guidance makes sense, as the general U.S. population, including children and adolescents, do not receive enough of these key nutrients. *See* U.S. Department of Agriculture and U.S. Department of Health and Human Services, *Dietary Guidelines for Americans, 2020-2025*, 9th Ed., Dec. 2020, https://www.dietaryguidelines.gov/sites/default/files/2021 03/Dietary_Guidelines_for_Americans-2020-2025.pdf. In fact, the 2020-2025 Dietary Guidelines for Americans indicate that calcium, vitamin D, and fiber are considered dietary components of public health concern because low intakes are associated with health concerns. *See id.* at

34. Calcium, vitamin D, fiber, and many other nutrients may also ultimately assist maintaining a healthy weight and/or support a strong muscular build.[2] Those effects similarly contribute to the wellbeing of everyone, including children and adolescents given the dangers of adolescent obesity.

35. Indeed, childhood obesity rates "have reached epidemic levels in the United States," with "about 17 percent of US children" presenting obesity as of 2019.[3] These rates in the United States have *tripled* over the past three decades, such that "one out of six children is obese,

[2] Bonetti G, et al., *Dietary supplements for obesity*, J PREV MED HYG. 2022 Oct 17;63(2 Suppl 3):E160-E168, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9710396/#:~:text=Calcium%2Dvitamin%20D%20supplementation&text=Combined%20supplementation%20of%20calcium%20and,metabolism%2C%20and%20reduce%20body%20weight; Kimm SYS. *The Role of Dietary Fiber in the Development and Treatment of Childhood Obesity*, PEDIATRICS. 1995;96:1010-1014, https://pubmed.ncbi.nlm.nih.gov/7494672/.

[3] *See, e.g.,* Sanyaolu A, et al, *Childhood and Adolescent Obesity in the United States: A Public Health Concern,* GLOB PEDIATR HEALTH. 2019 Dec 1;6:2333794X19891305. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6887808/.

and one out of three children is overweight or obese."[4] That is cause for substantial concern as adolescent obesity increases the risk for a slew of serious health complications.[5]

36. Dietary supplements may support healthy weight management without the need for intensive pharmacological treatments or surgery. For instance, prebiotic fiber supplements may be a "simple and inexpensive new tool in the fight against childhood obesity," and are "very safe" and "very easy" to use.[6] In a study, overweight children given a placebo "continued to gain weight almost three times faster than they should have for a child of their age and gender," while overweight children taking the supplement "obtained an almost normal rate of growth" that "you would see in a healthy child," such that the children were able to continue to grow while simultaneously losing abdominal fat, which increases the risks for type 2 diabetes and heart disease.[7]

37. As a result, dietary supplements assist the public in advancing their health goals, whether those goals are to simply receive sufficient amounts of a key nutrient absent in their diet, or to target more substantial health concerns like weight management without the risks and costs associated with pharmaceutical treatments.

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[4] *Child Obesity,* HARVARD SCHOOL OF PUBLIC HEALTH, https://www.hsph.harvard.edu/obesity-prevention-source/obesity-trends-original/global-obesity-trends-in-children/ ("*Child Obesity*").

[5] *See Consequences of Obesity,* CENTER FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/obesity/basics/consequences.html.

[6] *See* Alissa Nicolucci, et al., *Prebiotics Reduce Body Fat and Alter Intestinal Microbiota in Children Who Are Overweight or With Obesity,* GASTROENTEROLOGY. 2017 Sep;153(3):711-722, https://pubmed.ncbi.nlm.nih.gov/28596023/; *A little fibre a day can help pounds fly away for overweight kids, Calgary study suggests*, CBC NEWS (June 8, 2017), https://www.cbc.ca/news/canada/calgary/childhood-obesity-study-university-calgary-fibre-supplement-research-nutrition-gut-bacteria-reimer-1.4151742.

[7] *See id.*

II. The Federal Regulatory Scheme Requires Truthful, Accurate, and Scientifically-Supported Representations Relating to Dietary Supplements

38. The FDA is a federal agency in the Department of Health and Human Services, which regulates dietary supplements through the Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Dietary Supplement Health and Education Act ("DSHEA"), and the Nutrition Labeling and Education Act ("NLEA").

39. In regulating dietary supplements, the FDA protects "the public by identifying and removing unsafe and illegal [dietary supplements] from the market," "ensuring that the dietary supplements are safe, well-manufactured, and accurately labeled," and requiring "those who manufacture, package, or hold dietary supplements to follow current good manufacturing practices that help ensure the identity, purity, quality, strength, and composition of dietary supplements."[8]

40. Both the FDA and the Federal Trade Commission ("FTC") work closely together to oversee and enforce federal requirements for the labeling and advertising of dietary supplements, with the FDA responsible for product labels and labeling (like packaging, inserts, and other promotional materials distributed when the product is sold), and the FTC responsible for advertising (whether in print, online, or broadcast).

41. Under this regulatory scheme, an entity cannot market a dietary supplement with a claim relating to how the supplement effects a structure or function of the human body, "a structure/function claim," or otherwise claim the product promotes general well-being, *unless* the company demonstrates that the claim is truthful, not misleading—requiring that any disclaimers

[8] *See Information for Consumers on Using Dietary Supplements,* U.S. FOOD AND DRUG ADMIN. (Oct. 21, 2022), https://www.fda.gov/food/dietary-supplements/information-consumers-using-dietary-supplements; *Questions and Answers on Dietary Supplements,* U.S. FOOD AND DRUG ADMIN. (Feb. 21, 2024), https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements.

or qualifying information are clearly and prominently displayed—and substantiated. *See* 21 U.S.C. § 343(r)(6).

42. Substantiation requires competent and reliable scientific evidence—meaning tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results—evaluated against the claim made, the relationship between the evidence to the claim, and the quality and totality of the evidence.

43. As a result, the marketing, labeling, and advertising of dietary supplements provides consumers with truthful information that may assist the consumer in making educated decisions regarding the consumption of dietary supplements for the betterment of their health.

III. The New York Legislature Passed the Act as a Workaround to a Vetoed Bill

A. New York Governor Kathy Hochul Vetoed the Prior Iteration of the Act

44. In 2022, the New York State Legislature ("Legislature") passed a prior iteration of the Act, which barred the sale of dietary supplements and diet pills to minors. *See* Assembly Bill Number 431-C.

45. This bill would have "prohibited the sale of diet pills and supplements to minors," and defined dietary pills and supplements "based on a list of ingredients" that would be determined by the New York State Department of Health ("DOH"). *See* NYS Assembly Transcript, NYS Representative Nily Rozic, June 1, 2023, ("NYS Assembly Tr."), p. 104.

46. On December 23, 2022, New York Governor Kathy Hochul vetoed this prior version of the Act, reasoning that the "DOH does not have the expertise necessary to analyze ingredients used in countless products, a role that is traditionally played by the FDA." *See* Veto #122, December 23, 2022.

47. Governor Hochul further reasoned that it would "be unfair to expect retailers to determine which products they can and cannot sell over the counter to minors, particularly while facing the threat of civil penalties." *See id.*

B. The Legislature Works Around the Veto by Using Marketing as a Proxy for Identifying Dangerous Ingredients in the Act

48. Following this veto, Senator Shelley B. Mayer and Assemblyperson Nily Rozic introduced the current version of the Act before the New York Assembly.

49. To distinguish the Act from its prior iteration, the Legislature intentionally decided to target "the way in which products are labeled or marketed, rather than what the actual products are within the diet pill." *See* NYS Assembly Tr., at p. 104.

50. Its sponsors explained the difference between the vetoed bill and the Act as follows:

> This legislation takes a new approach, focused on the way products are marketed, regardless of their ingredients . . . This approach will target drugs[9] based on their marketing - and associated harmful effects - rather than relying on a list of covered ingredients that the industry will soon work around.

See New York Assembly Bill No. 5610, New York Two Hundred Forty-Sixth Legislative Session ("Bill No. 5610").

51. Much like the vetoed bill, the Act was similarly justified on the purported ground that dietary supplements "often contain unlisted, illegal pharmaceutical ingredients that pose serious risks." *See id.*

52. But the Act did not target, or even identify, those supposed illegal ingredients.

53. Rather, the Act, Assembly Bill A5610, defines "over-the counter diet pills" as "a class of drugs labeled, marketed, or otherwise represented for the purpose of achieving weight loss

[9] Notwithstanding this colloquial description, drugs and dietary supplements are not one in the same. Drugs are a separate and distinct legal and regulatory category than dietary supplements under the FDCA.

that are lawfully sold, transferred, or furnished over-the-counter with or without a prescription pursuant to the federal food, drug, and cosmetic act, 21 U.S.C. section 301 et seq., or regulations adopted thereunder." *See* § 391-oo(1)(b).

54. The Act defines "dietary supplements for weight loss or muscle building" as "a class of dietary supplement as defined in section three hundred ninety-one-o of this article that is labeled, marketed, ***or otherwise represented*** for the purpose of achieving weight loss or muscle building, but shall not include protein powders, protein drinks and foods marketed as containing protein unless the protein powder, protein drink or food marketed as containing protein contains an ingredient other than protein which would, considered alone, constitute a dietary supplement for weight loss or muscle building." *Id.* § 391-oo(1)(a) (emphasis added).

55. Without explanation, the Act excludes dietary supplements containing protein powder despite it being one of the most commonly marketed ingredients for promoting, building and preserving muscle.

56. The Act provides that in "determining whether an over-the-counter diet pill or dietary supplement is labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building," "the court shall consider, ***but is not limited to***, the following factors:"

> (a) Whether the product contains:
>
> (i) an ingredient approved by the federal Food and Drug Administration for weight loss or muscle building;
>
> (ii) a steroid; or
>
> (iii) creatine, green tea extract, raspberry ketone, garcinia cambogia, green coffee bean extract;
>
> (b) whether the product's labeling or marketing bears statements or images that express or imply that the product will help:

> (i) modify, maintain, or reduce body weight, fat, appetite, overall metabolism, or the process by which nutrients are metabolized; or
>
> (ii) maintain or increase muscle or strength;
>
> (c) whether the product or its ingredients are otherwise represented for the purpose of achieving weight loss or building muscle; or
>
> (d) whether the retailer has categorized the dietary supplement for weight loss or muscle building by:
>
> (i) placing signs, categorizing, or tagging the supplement with statements described in paragraph (b) of this subdivision;
>
> (ii) grouping the supplements with other weight loss or muscle building products in a display, advertisements, webpage, or area of the store; or
>
> (iii) otherwise representing that the product is for weight loss or muscle building.

Id. § 391-oo(6) (emphasis added).

57. The Act does not define "weight loss" or "muscle building," or explain whose representations are relevant in assessing the scope of the Act. *See generally id.* § 391-oo.

58. Several of the factors similarly hinge on undefined broad-ranging terms that demand subjective application, such as "imply," "process by which nutrients are metabolized," "categorized," and "grouping," to name a few.

59. The Act then bars anyone from selling, offering to sell, or giving away a product that meets these criteria to anyone under the age of eighteen. *See id.* § 391-oo(2).

60. It also imposes age verification requirements on both retail establishments and "delivery seller[s], including an online retailer, who mail[] or ship[] . . . dietary supplements for weight loss or muscle building to consumers" *See id.* 391-oo(2)-(4).

61. Specifically, the Act regulates a "delivery seller . . . who mails or ships dietary supplements for weight loss or muscle building to consumers," as follows:

> (a) shall not sell, deliver, or cause to be delivered any over-the-counter diet pills or dietary supplements for weight loss or muscle building to a person under eighteen years of age; and
>
> (b) shall use a method of mailing or shipping:
>
> (i) that requires the purchaser placing the delivery sale order, or an adult who is at least eighteen years of age to sign to accept delivery of the shipping container at the delivery address; and
>
> (ii) that requires the person who signs to accept delivery of the shipping container to provide proof, in the form of a valid, government-issued identification bearing a photograph of the individual, that the person is at least eighteen years of age.

Id. 391-oo(4).

62. Thus, whenever an online retailer sells a dietary supplement covered by the Act in the State of New York, they must ship the dietary supplement using an age verification shipping service. *See id.*

63. Each violation of the Act may result in a civil penalty of up to $500. *See id.* §391-oo(5).

C. The Sponsors of the Act Fail to Substantiate the Act's Stated Purpose of Addressing the Prevalence of Eating Disorders in Teenagers

64. The articulated intent of the Act was to address eating disorders in minors. *See* NYS Assembly Tr. At p. 106.

65. As the "JUSTIFICATION" for the Act provides:

> Eating disorders are a serious public health problem affecting youth and adults of all races, ages, and genders. The most common eating disorder, anorexia nervosa, has the second highest mortality rate of all mental health conditions. Eating disorders are diagnosed based on a number of criteria, including the presence of what clinicians call unhealthy weight control behaviors (UWCBs). One UWCB of particular concern is the use of pills or powders to lose weight or build muscle, which are often sold as dietary supplements.

See Bill No. 5610.

66. New York State legislators were concerned that diet pills and dietary supplements are used by minors "specifically for weight loss," and that such use "eventually leads to eating disorders" and body dysmorphia. *See* NYS Assembly Tr., at p. 106.

67. The Act's sponsor noted that there are "specific studies" which purport to document this "causal relationship" between diet pills and dietary supplements intended for weight loss, on the one hand, and these harmful effects on minors, on the other. *See id*.

68. But when pressed on whether there were "any cases or specific studies where supplements are directly tied to body dysmorphia" or reflect a "a causal relationship" between the two, Assemblywoman Rozic was unable to identify any specific research and, instead, offered to "follow up" with such research. *See id.* She did not.

69. Other assemblypersons opted to simply "trust" that "there is a body of research on the causal link between these types of supplements and substances and dysmorphia and anorexia but, explaining, "you know, I haven't seen it but I – I trust that it's probably out there." *Id.* at 111.

70. Ultimately, the Act's sponsors did not substantiate the claimed "causal relationship" anywhere in the record, including in the Bill's footnotes, which cites to four inapposite authorities. *See* Bill No. 5610, at nn.1-4.

71. The first authority cited merely discusses the presence of pharmaceutical *ingredients* discovered in products that are illegally marketed as dietary supplements following FDA recalls for such adulteration. *See id.* at n.1 (citing Cohen PA, et al., *Presence of banned drugs in dietary supplements following FDA recalls*. J AM MED ASSOC. 2014;312(16): 1691-1693. Doi:10.1001/jama.2014.10308).

72. The second citation was limited to the risks associated with *since-banned* prescription-grade diet pills adulterated with multiple pharmaceutical agents, such as benzodiazepines, beta-blockers, and amphetamine. *See id.* at n.2 (citing Cohen PA, Goday A, Swann JP. The Return of Rainbow Diet Pills. Am J. Public Health. 2012;102(9):1676-1686).

73. The third cited authority is an online article concerning the death of a woman in the United Kingdom after taking a diet drug that she ordered online, which contained dinitrophenol[10]—a highly toxic industrial chemical that FDA declared to be "extremely dangerous and not fit for human consumption" in 1938 and therefore is *not* a dietary supplement.[11] *See id.* at n.3 (citing Morris S. Woman died after accidental overdose of highly toxic diet pills. The Guardian. https://www.theguardian.com/society/2015/jul/23/womandiedaccidentaloverdose-highly-toxicdietpillselo ise-parry. Published July 23, 2015).

74. The final cited authority discusses a tragic death following the consumption of a diet pill containing an ingredient known as dimethylamylamine, which FDA does not consider to be a *dietary supplement*, and has worked to remove from the market.[12] *See id.* at n.4 (citing Singer

[10] This drug is banned in both the United States and the United Kingdom for use in weight loss. *See, e.g.,* Johann Grundlight, et al., *2,4-Dinitrophenol (DNP): A Weight Loss Agent with Significant Acute Toxicity and Risk of Death*, J MED TOXICOL. 2011 Sep; 7(3): 205–212 (Jul. 8, 2011), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3550200/.*

[11] Department of Justice, *Texas Woman Sentenced to 6 Months in Federal Prison for Selling Deadly Weight Loss Drug to Consumers,* U.S. FOOD AND DRUG ADMIN., (Oct. 6, 2021), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/texas-woman-sentenced-6-months-federal-prison-selling-deadly-weight-loss-drug-consumers; *see also* FDA News Release, *FDA NEWS RELEASE FDA targets unlawful internet sales of illegal prescription medicines during International Operation Pangea IX*, U.S. FOOD AND DRUG ADMIN., (June 9, 2016), https://www.fda.gov/news-events/press-announcements/fda-targets-unlawful-internet-sales-illegal-prescription-medicines-during-international-operation ("DNP is most often used as a dye, wood preserver, and herbicide and has never been approved by the FDA for use as a drug.").

[12] *DMAA in Products Marketed as Dietary Supplements DMAA in Products Marketed as Dietary Supplements,* U.S. FOOD AND DRUG ADMIN., (current as of Feb. 22, 2023), https://www.fda.gov/food/information-select-dietary-supplement-ingredients-and-other-substances/dmaa-products-marketed-dietary-

N, Lattman P. A Workout Booster, and a Lawsuit. The New York Times. http://www.nytimes.com/2013/02/14/business/death-after-use-ofjack3dshowsgap-inregulation.html. Published February 14, 2013.).

75. In other words, none of the four cited authorities by the Legislature discuss the marketing or labeling of dietary supplements, the relationship between dietary supplements and eating disorders, or the prevalence of eating disorders in adolescents that consume dietary supplements.

76. To date, the New York Legislature has not offered any explanation as to how dietary supplements cause eating disorders in teenagers or even which specific disorders purportedly result from such use.

77. During the time the legislature was debating the merits of the Act, CRN made legislators aware of that fact that "***[t]he evidence to date does not support a causative role for dietary supplements in eating disorders***." *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 (emphasis added).[13]

D. Critical Questions Regarding the Act's Application and Requirements Went Unanswered in the New York Assembly June 1, 2023, Meeting on the Act

78. The New York Assembly convened on June 1, 2023, to discuss, *inter alia*, the Act proposed by Assemblywoman Rozic. *See generally* NYS Assembly Tr.

supplements#:~:text=Taking%20DMAA%20can%20raise%20blood,the%20health%20risks%20they%20present.

[13] This research was funded by a restricted grant from CRN.

79. One of the first questions asked was simple: is the Act regulating products "that are being marketed *specifically* to teens," "to teens or adults," or, more broadly, "when looking at marketing, . . . what . . . *specifically*" does the Act consider? *See id.* at p. 105 (emphasis added).

80. Assemblywoman Rozic did not provide a straightforward answer to that question, instead referring to "those definitions" of "over-the-counter diet pill" and "supplement for weight loss or muscle building" in the Act. *See id.*

81. Assemblywoman Rozic's response failed to address the substantial confusion over those precise terms, as one assemblywoman poignantly remarked:

> [R]etailers are going to have to try to figure out whether what they're selling in their store is something that they're going to have to age check now. So I just want -- for the legislative record I'm just trying to make it really clear for them in trying to interpret this because there -- they certainly don't want to be held liable and fined.

See id. at 110.

82. Assemblywoman Rozic provided business owners with the following limited guidance in response: the Act "doesn't include protein drinks" and "we are trying to protect minors at the end of the day and this is specifically tailored for someone under the age of 18 trying to buy these pills or supplements." *See id.*

83. An assemblyman later attempted to probe this same topic, directly asking "what products are considered within the bill that [stores, online retailers, brick and mortar stores] cannot sell over the counter if you're under 18?" *See* NYS Assembly Tr., at 115.

84. Assemblywoman Rozic *could not answer this threshold question about the Act*, instead stating: "[t]hat's a great question and I'll follow up with you on that." *See id.*

85. In a final attempt to gain some clarity on the scope of the Act, another assemblyman raised the example of "popular" beverages such as Celsius or Bang Energy, which are marketed as "having either strength-building properties or weight loss and fat-burning properties," and are

"sold in supermarkets," in the New York State Assembly's "vending machines," and are even sold "pretty much everywhere nowadays." *See id.* a pp. 109, 116-118.

86. Assemblywoman Rozic responded, "I'm going to read the definition of what a dietary supplement is according to this bill and I hope that answers your question." *See id.* at 117.

87. When pressed further on that unsatisfactory answer, Assemblywoman Rozic made clear that the answer lies not within the statute but should be left to be decided in future litigation by future courts:

> The court would have to consider whether the product contains an ingredient approved by the FDA for weight loss or muscle-building…It would also have to consider whether the products labeled or marketed bear statements that express or imply the product will modify, maintain or reduce body weight, fat, appetite or metabolism or maintain or increase muscle or strength. They would have to consider whether the product or its ingredients are otherwise represented for the purpose of achieving weight loss or building muscle, and they would also have to consider whether the retailer has categorized the dietary supplement for weight loss or muscle-building.

See id. at pp. 117-118.

88. Those subject to civil penalties up to $500 per violation are therefore left on their own to come up with their own preemptive interpretations of the Act to determine which products and claims the Act might (or might not) cover. They must then make further predictions about which products it can, or cannot, sell to minors. This is a textbook example of bad legislation.

89. Not only was there ambiguity as to *which* products the Act governed and based on *what* marketing, several assemblypersons expressed uncertainty as to the mechanics of the age verification requirement identified in the Act, the noncompliance with which could subject businesses to fines and other liability.

90. One assemblyperson sought clarification as to the age verification procedure in the context of mail order items—specifically, whether *anyone* at the house could sign for the package in order for the minor to obtain the prohibited item. *See id.* at 107.

91. Other concerns raised in the assembly were left wholly unacknowledged, including the inconsistency in the New York Legislature's treatment "of those who are under 18 for some—in some respects when it comes to operating an ATV to take yesterday's example—to receive birth control—we're just treating young people differently depending on what the topic is, and I do think that there is a disparity there." *See id.* at 111.

92. Notwithstanding all this uncertainty, Assemblywoman Rozic provided her own conclusive explanation regarding the enforcement of the Act, which will be driven by "consumers calling in" suspected violations to the Attorney General, who would then investigate "on report only." *See id.* at 108. The text of the Act makes no such assurance to retailers in the state who must ensure their compliance with the law.

E. Governor Kathy Hochul Signs the Act into Law

93. Despite the multiple ambiguities and unanswered questions on these fundamental aspects of the Act, on October 25, 2023, New York Governor Kathy Hochul signed Assembly Bill A5610 into law.

94. The Act is set to take effect on April 22, 2024.

95. New York will be the first and only jurisdiction in the United States that prohibits the sale of dietary supplements to minors.

IV. There is No Valid Basis for the Act Because Actual Evidence Disproves the Causal Link Suggested in Passing this Legislation

96. In passing the Act, the Legislature emphasized the "prolific increase" in eating disorders amongst teenagers and the purported causal relationship between certain kinds of dietary supplements and eating disorders in minors. *See* NYS Assembly Tr., at p. 106.

97. A recent paper published in the peer-reviewed journal Nutrients debunks the purported scientific premise on which the Act was offered.

98. According to the paper, the Legislature has advanced this "suggest[ion] that the use of dietary supplements may lead to eating disorders, despite a lack of evidence to support this conjecture." *See* Nutrients Paper, at p. 1.

99. The Nutrients Paper addresses this disconnect by "elucidat[ing] the lack of support in the scientific literature for dietary supplements as an etiologic factor in eating disorders," which is flatly debunked by empirical studies and meta-analyses, and by explaining, "somewhat paradoxically . . . the beneficial role of dietary supplements in the treatment of eating disorders." *See id.* at p. 2.

100. Several points from the Nutrients Paper are particularly relevant when considering the stated purpose, and potential effect, of the Act.

101. *First*, the Legislature's theory that the recent increase in eating disorders was caused by an increase in dietary supplement usage is belied by empirical data.

102. The Center for Disease Control and Prevention's National Center for Health Statistics ("CDC") conducted research on supplement use in children 19 years and younger between 1999 and 2016. *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/ ("*Trends in Dietary Supplement Use*"). The CDC expressly found that dietary supplement use in adolescents "remains relatively low overall[.]" *See id.* at Conclusions.[14]

[14] The CDC also found that dietary supplement "use was higher in boys than in girls (3.9% vs 3.3%)[.] *See Trends in Dietary Supplement Use*, at Results. Yet the Act aims to decrease the prevalence of eating disorders in teenagers, which are *twice* as common in females—only 3.3% of which use dietary supplements for any purpose—than in males, reflecting a mismatch between the goal that the New York Legislature seeks to resolve and their construct for meaningfully doing so. *Compare id.; with* Eating Disorders, NAT'L INST. OF MENTAL HEALTH, available at https://www.nimh.nih.gov/health/statistics/eating-disorders#:~:text=Prevalence%20of%20Eating%20Disorders%20in%20Adolescents,-

103. This finding is fundamentally inconsistent with the reasoning underlying the Act, as a "relatively low overall use" of dietary supplements, *see id.*, cannot give rise to the "prolific increase" in eating disorders that the Legislature points to as justification for the Act, *See* NYS Assembly Transcript, NYS Representative Nily Rozic, June 1, 2023, p. 106.

104. The Legislature's justification is also flatly contradicted by scientific observation of the "marked decline in the use of 'diet pills' by high-school aged students," which is now at "the lowest level ever recorded." *See Nutrients Paper,* at pp. 3-4.

105. This finding is supported by an epidemiological study conducted by researchers from the University of Michigan's Institute for Social Research and published in June of 2023. *See* Richard A. Mietch, Ph.D, *et al.*, *National Survey Results on Drug Use, 1975-2022: Secondary School Students*, MONITORING THE FUTURE (June 2023), https://monitoringthefuture.org/wp-content/uploads/2022/12/mtf2022.pdf. This longitudinal study—which assessed 12th grade students since 1975, and 8th and 10th grade students since 1990—found that the use of diet pills is "at the lowest level ever recorded by the survey in 2022 for lifetime, past 12-month, and past 30-day use." *See id.* at 103. Indeed, according to the study, "[t]oday's levels of past 12-month use are more than five times *lower* than their peak of 21% in 1982[.]" *Id.*

106. *Second*, the data shows that teenagers are using dietary supplements for increasing muscle mass and improving overall health, belying the Legislature's assumption that this demographic uses dietary supplements for "weight loss," *see* NYS Assembly Tr., at p. 106, as. *See Nutrients Paper* at p. 4. These uses are "recommended as a means to enhance health and fitness as well as to optimize performance and recovery in sports." *Id.*

Based%20on%20diagnostic&text=Eating%20disorders%20were%20more%20than,nervosa%2C%20and%20binge%20eating%20disorder.

107. Indeed, the results from a number of studies demonstrate that "the major motivations for dietary supplement use in adolescents are to maintain or improve overall health, as well as for positive performance gains, as opposed to diet and weight loss." *See id.* at 4.

108. For instance, the CDC study noted above found that the most common motivations for use of dietary supplements were, in order of prevalence: to maintain health, improve overall health, prevent health problems, relaxation and stress, boosting immunity, supplementing the diet, mental health, bowel/colon health, improving digestion, heart health, healthy skin, hair, and nails, for more energy, and for bone health. *See Trends in Dietary Supplement Use*, at Table 3.

109. Not even 1% of the study participants used dietary supplements for "weight loss" or "build[ing] muscle/weight gain," neither of which were listed within the top ten most common motivations for the use of dietary supplements. *See id.*

110. *Third,* studies that have attempted to link dietary supplements to eating disorders have been debunked for their "faulty designs with conclusions based on unsupported data." *See Nutrients Paper* at p. 4. These studies were also inconsistent in how they defined "dietary supplement" or "diet pills," and often used definitions entirely unmoored from the definitions in the Act or those used by the FDCA. *See id.* at pp. 4-7.

111. By way of example, one prospective study purported to examine the association between diet pills/laxative use and eating disorders in *adult* women. *See id.* at 5. Yet in defining "diet pill," the study failed to distinguish between dietary supplements and other over-the-counter medications, like laxatives or diuretics. *See id.* As a result, "the amount of dietary supplement use by participants could not be determined in the study." *Id.* Setting aside this methodological flaw, the study did not demonstrate "causality" between dietary supplement use and eating

disorders—indeed, dietary supplement use could not be "characterized as causal, or even a contributing factor, to the subsequent diagnosis" of an eating disorder. *See id.*

112. As another example, a cross-sectional study sought to examine the connection between ergogenic supplement use and eating attitudes and behaviors in college athletes between the ages of 18 and 26. *See id.* But ergogenic supplements were defined to include "illegal substances and prescription drugs such as anabolic steroids, human growth hormone, and androstenedione" along with dietary supplements. *See id.* But these "are not dietary supplements and are not sold under this regulatory classification." *Id.*[15] And again, no causality was demonstrated. *See id.*

113. These methodological flaws, false presumptions, and skewed motives pervade the scientific studies on which the Legislature presumably relied in structuring the Act. Without relying on these flawed studies, there is no scientific support for the proposition that regulating dietary supplements will reduce the prevalence of eating disorders in minors.

114. Indeed, well-respected resources, including the Diagnostic and Statistical Manual of Mental Disorders, *see Nutrients Paper* at p. 1, do not identify dietary supplement use as a cause, contributing factor, risk factor, or even symptom of eating disorders. Nor are dietary supplements considered a "trigger" of eating disorders "[a]ccording to major professional organizations such as the Academy of Nutrition and Dietetics," in contrast to "frequently used or abused substances" of

[15] Indeed, the Act itself recognizes that diet pills and dietary supplements are a specific regulatory classification under the FDCA (GBL § 391-oo(1)(a)-(b)), and definitionally do not contain any illegal substances. Nonetheless, in arguing for the Act, the New York State Legislature made the same mistake as this faulty cross-sectional study, wrongly contending that dietary supplements "often contain unlisted, illegal pharmaceutical ingredients." *See* New York State Assembly, A05610 Memorandum in Support of Legislation, submitted in accordance with Assembly Rule III, Sec 1(f).

those with eating disorders, such as "alcohol, laxatives, emetics, diuretics, [and] amphetamines/stimulants[.]" *See id.* at 3.

115. And so, the Legislature has banned teenage consumption of dietary supplements—for which there is no evidence of substantiated danger—while simultaneously allowing a portion of that same class to operate an ATV—a device that has been involved in countless deaths and other incidents.[16]

V. The Act May Exacerbate the Problem of Eating Disorders it Seeks to Mitigate and Otherwise Negatively Impair Adolescent Health

116. While reducing the occurrence of eating disorders in minors is a meritorious concern, the Act does nothing to advance its stated purpose and, if anything, may reduce the welfare of the very class of citizens it aims to protect.

117. "One of the greatest concerns related to restricting access to dietary supplements of any type is that they support health for many individuals and are often included as part of care plans for many conditions." *Nutrients Paper*, at p. 8.

118. Restricting minors' access to dietary supplements is "incongruent with the advice of authoritative health professional organizations that play a key role in eating disorder treatment guidelines," as dietary supplements "are routinely used in the *treatment* of eating disorders," and are recommended by organizations like the Academy of Nutrition and Dietetics as "standards of care" in treating eating disorders. *See id.* at p. 7.

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[16] *See* OHV and ATV Safety, U.S. CONSUMER PRODUCT SAFETY COMMISSION, https://www.cpsc.gov/Safety-Education/Safety-Education-Centers/ATV-Safety-Information-Center#:~:text=ATVs%20accounted%20for%20nearly%20three,percent%20of%20the%20OHV%20injuries ("[F]rom 2016 through 2018, there were 2,211 deaths in the United States associated with OHVs, which includes all-terrain vehicles, recreational off-highway vehicles and utility-terrain vehicles. ATVs accounted for nearly three-quarters of the deaths. Nearly 300 deaths were among children under the age of 16).

119. To that end, the Act conflates dietary supplements for "weight loss" and for "muscle building" and places age restrictions on both equally, even though muscle building supplements may combat the loss of muscle mass that accompanies unhealthy weight loss.

120. "Dietary supplements are used as part of recovery for an individual to support health and recovery" beyond eating disorders as well, as a number of "major professional organizations" use dietary supplements "to prevent and treat many conditions including sarcopenia, frailty," and for managing other "clinical concerns, including inborn errors of metabolism." *See Nutrient Paper*, at p. 6.

121. The Legislature further ignores that *less than one percent* of teenagers are taking dietary supplements for weight loss or muscle gain, while the *vast majority* of adolescents consuming such substances do so for the *betterment* of their physical health and mental wellbeing. *See id.* at 4; *see also See Trends in Dietary Supplement Use*, at Table 3.

122. Prohibiting dietary supplements based on such *de minimis* numbers—and their disproven causal relationship to eating disorders and unsubstantiated and highly theoretical correlative relationship with eating disorders—threatens the wellbeing of a larger group of adolescents in the United States that may benefit from such products.

123. Indeed, the Act could very-well prohibit the sale of fiber, calcium, and vitamin D to minors, even though—as discussed—those are all vital nutrients that many children do not receive enough of and offer potential healthy weight management benefits in the one in three children in the United States that are overweight.

124. Dietary supplements—including those containing green tea extract, which is regulated by the Act—are also considered to have a multitude of other health benefits, which teenagers may wish to avail themselves of for reasons wholly unrelated to body image. *See, e.g.*,

10 Benefits of Green Tea Extract, medically reviewed by Jerlyn Jones, MS MPA RDN LD CLT, Arlene Semeco, MS, RN, Alyssa Northrop, MPH, RD, LMT, HEALTHLINE (last updated May 31, 2023), https://www.healthline.com/nutrition/10-benefits-of-green-tea-extract (observing green tea is high in antioxidants, may promote heart health, protects brain cells from oxidative stress, might benefit liver function, and may benefit exercise performance and recovery).

125. Similarly, creatine, another ingredient regulated by the Act, plays a role in energy metabolism and is widely recognized for a range of health benefits for people of all ages. Its well-established health effects include countering sarcopenia and age-related declines in skeletal muscle and bone mineral density, boosting cognitive function, reducing dehydration and muscle cramping, as well as improving exercise performance. See https://www.mayoclinic.org/drugs-supplements-creatine/art-20347591.

126. Given the breadth of the Act's potential reach, the same demographic the Act seeks to protect will be deprived of products that may assist them in *bettering* their health.

VI. The Act Imposes Burdens on all United States Consumers Because it Deprives the Public of Access to and Information Regarding Dietary Supplements, and Otherwise Implicates Privacy and Data-Security Concerns

127. The Act also threatens to harm *all* citizens in the United States for a number of reasons that the Legislature made no attempt to consider.

128. *First*, the Act will necessarily increase the cost of vital dietary supplements that a number of consumers rely upon, the Act fundamentally changes the economic landscape for the production, manufacture, distribution, and sale of dietary supplements. Companies must now incur additional oversight and compliance costs with respect to the formulation, distribution, and marketing of dietary supplements across an innumerable amount of forums *and* with respect to the new age verification requirements. And, in response to the civil penalties, retailers are already beginning to impose additional requirements on dietary supplement manufacturers—further

increasing costs—and requiring indemnification plus the payment of an additional fee for any violation of the Act asserted against the retailer.

129. The consequences of these added costs are obvious: in order to stay in business, many companies may need to pass some of their costs onto the consumer, thereby making dietary supplements more expensive for all citizens.

130. *Second*, and in light of these costs and the infinite events that may give rise to liability under the Act, some manufacturers, distributors, and retailers may simply decide to exit the dietary supplement industry entirely, cease distribution in New York, or decrease the number of products they offer. Yet marketplace competition, which the Act will decrease, inures to the benefit of the consumer with respect to cost, quality, safety, and innovation of an offered product.

131. *Third*, the Act will deprive consumers of truthful, accurate, and FDA/FTC-regulated communications about products and ingredients that may aid them in addressing specific health concerns. In response to the new law—but without ensuring non-liability thereunder—some companies may remove any labeling or marketing that suggests that a dietary supplement has a scientifically-proven benefit that a consumer could interpret as aiding in weight loss or muscle building, including but not limited to representations about metabolism, energy, muscle strength, or even adequate sleep, which similarly promotes weight loss efforts. As a result, consumers will no longer have access to protected commercial speech that may aid them in addressing specific health concerns.

132. *Fourth*, the Act will make it more difficult for adults with every legal right to purchase and consume dietary supplements to do so. As retailers are required to ensure that underage consumers do not have access to these products, the unavoidable consequence is that retailers will limit self-service availability of those products to consumers of all ages. This renders

the purchase of dietary supplements in store less accessible, more time-consuming, and more conspicuous—a potential concern given the sometimes sensitive or private nature of a product's use.

133. *Fifth*, the age-verification requirement may prevent adults from purchasing dietary supplements.

134. It is a simple fact that not all adults have the government-issued identification required by the Act. The Act may therefore bar that class of citizens from the lawful purchase of dietary supplements.

135. Even the adults with the requisite identification may no longer purchase dietary supplements once unable to do so without disclosing personal information, including their name, address, date of birth, and driver's license number or non-driver identification number. Some consumers may have a sensitive health issue, which the dietary supplement discloses or suggests, which the adult will only purchase under conditions of anonymity.

136. Other consumers may opt against the purchase of dietary supplements because of privacy and data security concerns.

137. Additionally, the new procedures may simply render the purchase of dietary supplements too inconvenient for some adult purchasers, including those that are not home during the day to tender their identification and accept the package.

VII. The Act is so Vague and Ambiguous that it is Impossible for CRN's Members to Ensure Their Compliance With its Requirements

138. Even assuming *arguendo* a scientific nexus between dietary supplements and eating disorders in minors, the Act is so vague and ambiguous that proper compliance is impossible.

139. The Act does not bar products based on some objective standard of danger, such as by their ingredients or known side effects. Instead, the Act bars sales to minors of certain products

based only on how they are labeled, marketed, or "otherwise represented." *See* GBL § 391-oo(1), (6). This facially covers a limitless world of representations, including those made by undefined persons, including any unaffiliated third-parties such as social media influencers, online reviewers, retailer staff such as in-store pharmacists, or undefined media, seemingly including text messages, statements on the Internet, and even oral communications. Such representations could also include information in published scientific studies regardless of whether the studies are used to market a product or ingredient.

140. Further, the Act compounds its vagueness by providing a non-exhaustive nine-factor test to be used in determining whether a product is covered by the Act, while providing no guidance at all as to whether a product is covered even if it meets just one or two of the nine factors identified.

141. Worse, these enumerated factors are themselves vague and subjective. The enumerated factors include, for instance, "whether the product or its ingredients are ***otherwise represented*** for the purpose of achieving weight loss or building muscle." GBL § 391-oo(6)(c) (emphasis added).

142. The phrase "otherwise represented" is not defined in the statute, but presumably means something beyond the mere "labeling" or "marketing" that is specifically identified as a way to determine if a product falls under the ambit of the Act.

143. "Otherwise represented" might even include some nebulous web of representations, potentially including social media posts, flyers, pamphlets, and even oral representations. Indeed, the Act expressly considers how a retailer groups its supplements in a "display, advertisement, ***webpage***, or area of the store," bringing the limitless world of the Internet into the determination,

which might invite complex analyses of how a product is displayed on, for example, Amazon or social media. § 391-oo(6)(d)(ii) (emphasis added).

144. The Act also asks those subject to its scope to consider how a product's "***ingredients*** are otherwise represented" for purposes of complying with its restrictions. Thus, the Act's obligations may theoretically extend to oral communications made about some trace ingredient in the product.

145. Further, the Act calls out five specific ingredients—creatine, green tea extract, raspberry ketone, garcinia cambogia, and green coffee bean extract—as subject to the age restriction with no finding that these ingredients either pose any health risk or that they are labeled, marketed or otherwise represented for the purpose of achieving "weight loss" or "muscle building." These ingredients are lawful for use in dietary supplements under federal law, have a history of safe use, and often have health benefits beyond "weight loss" or "muscle building."

146. Perhaps worst of all, the Act's nine factors are only the beginning—courts will be asked to consider these nine factors, but will not be limited to them in deciding whether a product is (or is not) covered by the Act.

147. In contemplating the possibility of unlimited considerations beyond even the nine factors identified, the Act fails to provide CRN's members with certainty as to which products are covered and how courts and the Attorney General's office will apply the Act.

148. That the Act's sponsor was unable to apply these definitions and criteria to popular drinks like Celsius and Bang Energy only demonstrates the Act's failure to clearly define what, precisely, it prohibits.

149. Assemblywoman Rozic's explanation as to the Act's application to Celsius also begs far more questions than it purports to answer. What does it mean to "imply" a product will

aid in muscle building or weight loss, and is there any limit to such implication in the context of modern day social media?

150. If a TikTok creator films a video in the gym where they discuss their weight loss while holding a can of Brand XYZ—a fictitious drink that is not marketed as a weight loss solution—is the influencer representing Brand XYZ as a weight loss product even without expressly stating so?

151. Alternatively, is muscle building "implied" if a bodybuilder posts on a Reddit bodybuilding thread that Brand XYZ gives them the energy they need to complete a difficult lifting session?

152. And, in either scenario, is that single isolated video or post enough to require Brand XYZ to comply with the Act when it did not authorize the video, and may not have even been aware of it? Was Brand XYZ required to affirmatively police all corners of the world wide web to ensure that no third party—over which it has no control—did not "imply" it may aid in weight loss?

153. Even beyond social media, the Act ignores the existence and popularity of dozens of health and science podcasts that discuss methods for weight loss. For instance, Huberman Lab—one of the most popular podcasts in the United States hosted by Andrew Huberman, an Associate Professor of Neurobiology and of Ophthalmology at Stanford—has discussed the role of Omega-3 fish oil in the context of losing fat.[17] Does the Act thus prohibit the provision of Omega 3 supplements to minors even though they have a number of critical benefits and may fill in a nutritional-gap created by a fish-averse diet?

[17] *How to Lose Fat with Science-Based Tools*, HUBERMAN LABS (May 23, 2021), available at https://www.hubermanlab.com/episode/how-to-lose-fat-with-science-based-tools.

154. This lack of objective criterion for compliance and endless spiral of unanswered questions is precisely why Governor Hochul vetoed the prior iteration of the Act. As Governor Hochul explained, it would "be unfair to expect retailers to determine which products they can and cannot sell over the counter to minors, particularly while facing the threat of civil penalties." *See* Veto #122, December 23, 2022.

155. Additionally, the Act's prior iteration was specifically vetoed because the DOH "does not have the expertise necessary" to analyze which products constituted covered dietary supplements and diet pills. *Id.* That required "expertise" was premised on the review of the safety of the ingredients; this version of the legislation seeks far more expertise to divine from express or implied representations the purpose of the product. The DOH is an agency comprised of public health experts. If they cannot make this determination, it is simply absurd to expect courts, and certainly, CRN's members, and the retailers who sell CRN members' products, to possess such expertise.

VIII. The Act Does Not Achieve its Stated Objective

156. CRN does not doubt the New York Legislature's desire to reduce the incidence of eating disorders and to prevent adolescent consumption of harmful products, and shares the same goals. The Act, however, does not accomplish those objectives.

157. Restricting teenagers' ability to purchase dietary supplements does not logically reduce the occurrence of eating disorders in that demographic. The Act will not prevent the onset of new eating disorders because it defies both science and common sense. Indeed, if a teenager is motivated to purchase a dietary supplement as a result of an eating disorder, the prohibition of the dietary supplement does absolutely nothing to treat the underlying condition.

158. Beyond that broader point, the Act regulates activity that could not possibly contribute to disordered eating, even accepting the premise of a causal relationship with dietary

supplements. The Act applies where there is a suggestion—regardless of who makes it or where they do so—that a product or ingredient will aid in weight loss or building muscle. But the Act does not require that *any* minor in New York is even aware of that representation. It defies logic that the prohibition of a product would prevent the minor from abusing that product for a purpose for which the minor was completely unaware.

159. The Act also creates an absurd paradigm in which teenagers may freely consume products outside the restricted categories of the Act that may very-well facilitate certain eating disorders, while simultaneously and irrationally prohibiting the sale of products that do not—so long as the marketing or labeling does not include mention of weight loss or muscle building.

160. For instance, one recent TikTok "weight-loss" trend involved consuming water with lemon juice[18]—a weight-loss method substantiated by the fact that water is known to suppress appetite and aid in weight loss.[19] As water and lemon are ingredients now represented for a weight loss purpose, the Act could require age verification for dietary supplements containing those ingredients. At the same time, however, a minor could continue to purchase laxatives and diuretics—which are not marketed for weight loss but are frequently abused for those purposes[20]—without issue, along with other products containing dangerous ingredients that are not marketed for a proscribed purpose.

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[18]*See* Toby Amidor, M.S., R.D., C.D.N., F.A.N.D., *Skip or Try These 5 Nutrition Tiktok Trends, According to a Registered Dietitian*, FORBES (Jan. 9, 2024), https://www.forbes.com/health/nutrition/tik-tok-nutrition-trends/.

[19]*See, e.g., Yes, drinking more water may help you lose weight*, JOHNS HOPKINS HUB (Jan. 15, 2020), https://hub.jhu.edu/at-work/2020/01/15/focus-on-wellness-drinking-more-water/.

[20]*See, e.g.,* Dr. Dennis Gibson, MD, *Complications from the Misuse of Laxatives and Diuretics*, ACUTE CENTER FOR EATING DISORDERS AND SEVERE MALNUTRITION (Nov. 9, 2022), https://www.acute.org/blog/complications-misuse-laxatives-and-diuretics (stating "75% of those with anorexia and bulimia misusing laxatives and approximately 33% misusing diuretics.").

161. This hypothetical is not as far-fetched as it may seem. Teenagers (as it turns out) are chronically online, as a recent Pew Study reflects that nearly all teenagers have access to a smartphone, 95% of teenagers are on YouTube and 67% use TikTok.[21] Those platforms are, in turn, home to more than 50 million social media influencers and a total creator market economy of approximately $104 billion.[22] This reality, in conjunction with the Act's overbreadth and vague drafting, present nearly infinite absurd applications of the Act that do nothing to advance its stated objectives.

162. Finally, the Act allows for the delivery of a prohibited dietary supplement so long as a person over the age of 18 signs for the package, regardless of whether they purchased the product. As a result, underage consumers could simply ask a parent or friend to sign on their behalf, as the Act does not actually prohibit *consumption* of such substances—just the sale thereof absent age verification.

IX. The Act Would Impose Undue Burdens on CRN and its Members

163. The Act's illogical and ill-defined regulations impose tremendous burdens and threaten to cripple the dietary supplement industry—a massive, $6.83 billion industry in New York state alone, which creates tens of thousands of jobs and generates over $783 million in state taxes. These jobs and state revenue would all be negatively affected by the Act.

164. The Act would not only deprive the industry of sales to minors of products that are not harmful to them, but would necessarily limit access to these products for all consumer resulting in loss of sales to CRN's members. Ensuring compliance with the age restriction will inevitably

[21] *See* Emily A. Vogels, et al, Teens, Social Media and Technology, PEW RESEARCH CENTER (Aug. 10, 2022), https://www.pewresearch.org/internet/2022/08/10/teens-social-media-and-technology-2022/.

[22] *See* Joe Gagliese, The Rise of the Influencer: Predictions for Ways They'll Changes the World, FORBES.COM (Jul. 8, 2022), https://www.forbes.com/sites/theyec/2022/07/08/the-rise-of-the-influencer-predictions-for-ways-theyll-change-the-world/?sh=600aecab43a7.

lead many retailers to removing the effected products from self-service displays entirely to effectively police their sales.

165. It would also require significant compliance costs. It would require CRN members and their retailers to make costly assessments of which products are covered by the Act, a nebulous determination which could not be resolved with any certainty. It would require enacting corporate policies to ensure compliance with the Act, and training key personnel accordingly.

166. CRN members would be required to remove label claims and discontinue advertising and marketing programs to communicate otherwise truthful and lawful information to consumers about the health benefits of their products in order to avoid the restrictions. As a result, and as discussed, consumers in New York would likewise be deprived of receiving this truthful information. As retailers err on the side of conservatively avoiding even questionable representations that could result in sanctions, otherwise lawful speech would be chilled because of the vague and ambiguous extent of the restricted class of goods.

167. CRN members that sell directly to consumers through online or catalogue sales would face a particularly daunting challenge. There are no commercial services readily available in New York to verify delivery to purchasers who are at least 18 years old, as the only services available are targeted for 21 year olds. This is because the vast majority of age-restricted products offered online for home delivery in New York, including alcohol and tobacco products, are restricted to consumers 21 years of age and older. Shipping using such an age-verification service also increases shipping and delivery costs by about $10, which CRN members will either incur as compliance costs or pass along to consumers.

168. Delivery services (like Door Dash, Uber Connect, InstaCart) that provide home delivery from retail locations are similarly unprepared to conduct age verification for purposes of healthcare products available only to consumers 18 years of age and older.

169. As a result, the existing infrastructure—without additional costly development—would preclude companies from selling dietary supplements to *legal adults* between the ages of 18 and 21.

170. As to products that are often purchased by minors, the Act may force retailers and CRN members to discontinue those products or incur the expense of rebranding those products to remove truthful claims on their labels about the uses of the products. Accordingly, it might force them to forgo certain business opportunities or sever ties with its business partners. The Act may even force certain retailers, suppliers, and manufacturers to cease operations altogether.

171. These are not just hypothetical challenges to a theoretical company: the Act poses real, serious, and imminent harms to CRN's current members.

172. One CRN member, Doctor's Best, Inc., markets a dietary supplement that contains the dietary ingredient benfotiamine, a fat-soluble form of vitamin B1 (thiamine), and makes a label claim that the product "helps support healthy glucose metabolism." This is a lawful and truthful structure/function claim that is permitted by federal law. Doctor's Best has no ability to determine whether this accurate representation "express[es] or impl[ies] that the product will help modify, maintain, or reduce *overall metabolism*, or *the process by which nutrients are metabolized*." *See* § 391-oo(6)(b)(i) (emphasis added).

173. Out of concern that its benfotiamine product would be identified by retailers that it is subject to the age restrictions of the Act, Doctor's Best must immediately determine whether to remove that claim from its labeling—at great expense, and thus denying consumers access to that

accurate health information—or to face the reduced sales that will accompany the restricted access imposed by retailers.

174. The company also sells dietary supplements directly to consumers through its website, https://www.doctorsbest.com/, and through other third-party retail platforms. In the face of the vagueness of the law, and without guidance from the State, the company also risks being removed from these third-party platforms, who may not want to incur the risk of civil penalties as a result of good faith, but incorrect, interpretations of the Act. On its own website, the company must determine whether to remove the lawful claim from its product, thereby denying consumers of access to that truthful health information, or incur the considerable expense of implementing an age verification delivery program for deliveries to New York addresses, or risk fines for alleged noncompliance with the Act.

175. CRN also has members that market and sell dietary supplements containing an ingredient known as berberine, which assists with blood sugar regulation and provides cardiovascular support. Those companies do not market their products as a supplement that aids in weight loss. Nevertheless, unaffiliated social media influencers have touted the weight loss potential of berberine, as have other manufacturers. It is unclear whether the Act now applies to every dietary supplement containing berberine as an ingredient.

176. CRN also has members that market products containing specific ingredients listed in the Act, *see* § 391-oo(6)(a)(iii), unaccompanied by any weight loss or muscle building claims. These members do not know whether the Act applies to their products.

177. One CRN member markets a product containing green tea, an ingredient listed in the Act, *see* § 391-oo(6)(a)(iii), but does not make any weight loss or muscle building claims for the product and believes the product is not a "weight loss" or "muscle building" dietary supplement

that would be age restricted under the Act. Nevertheless, because of the vagueness of the Act, and without any guidance from the State, some New York retailers may believe the inclusion of green tea extract on the enumerated list of ingredients is dispositive regardless of the label. Other retailers may believe that because some products that contain green tea extract are marketed for weight loss that this product is too. In both cases, those New York retailers are likely to identify the product as subject to the age restriction and remove it from their self-service assortment to prevent sale of the product to minors. One retailer has already notified the company it must indemnify them for any fines they incur if the company's assessment is incorrect. This creates potential lost sales and the uncertainty of potential liability for the company.

178. Other CRN members sell dietary supplements containing creatine, which assists muscular development, and which may be truthfully marketed as such. These companies must now decide whether to: (1) continue selling their product in New York, despite significant lost sales, and the additional cost of implementing age verification procedures; or (2) discontinue the creatine products from their portfolio or from the New York market.

179. Other CRN members cannot decipher what it means to "imply that" their product "will help modify, maintain, or reduce . . . overall metabolism, or the process by which nutrients are metabolized." *See* § 391-oo(6)(b)(i). Yet, these members must preemptively determine whether to remove any claim they make which could theoretically fall under that direction—at great expense and to the detriment of consumers relying on companies to provide them with useful and helpful information regarding the supplement—or face future uncertainty.

180. Other CRN members are not willing to curb their lawful commercial speech based on a guess as to the Act's application. While their products are demonstrably safe for minor consumption and there is no science to support their connection to eating disorders, these members

are developing age verification protocols. The development, application, and maintenance of these procedures are costly and logistically difficult.

COUNT I
42 U.S.C. § 1983
VOID FOR VAGUENESS UNDER THE FIRST AND FOURTEENTH AMENDMENTS OF THE UNITED STATES CONSTITUTION AND ARTICLE 1, § 6 OF THE NEW YORK CONSTITION

181. CRN incorporates all prior paragraphs as though fully set forth herein.

182. The Fourteenth Amendment of the United States Constitution provides that a State shall not "deprive any person of life, liberty, or property without due process of law[.]" US CONST. amend. XIV, § 1. The New York Constitution similarly provides that "[n]o person shall be deprived with life, liberty, or property without due process of law." *See* N.Y. CONST. Art. I, § 6.

183. A governmental enactment like the Act is unconstitutionally vague if it fails to provide a person of ordinary intelligence fair notice of what is prohibited or is so standardless that it authorizes or encourages discriminatory enforcement.

184. As set forth above, the Act includes undefined and subjective terms that lend themselves to conflicting interpretations and fails to provide adequate notice as to which products require compliance with the Act and in which circumstances.

185. Because of this vagueness, it is impossible for CRN's members, and the retailers that sell CRN's members' products to New York consumers, to identify which of their activities are governed by the Act, and CRN's members are justifiably fearful of engaging in any speech or conduct that the Act may penalize.

186. Truthful, legal claims that are permitted under federal law are being chilled because companies don't know how the Act will be construed.

187. Given the lack of objective, certain criteria for enforcement and compliance, the Act violates the First Amendment and Due Process Clause of the Fourteenth Amendment to the

United States Constitution and its equivalent in the New York Constitution, and thereby gives rise to both declaratory and injunctive remedies under 28 U.S.C. §§ 2201 and 2202.00.

188. CRN has no adequate remedy at law for the harm caused by the Act, which deprives CRN, its members, and dietary supplement manufacturers, and suppliers of enforceable rights. Unless the Court enjoins the enforcement of the Act, CRN, its members, and dietary supplement manufacturers will suffer irreparable harm.

COUNT II
42 U.S.C. § 1983
VIOLATION OF THE FIRST AMENDMENT, AS INCORPORATED AGAINST THE STATES BY THE FOURTEENTH AMENDMENT AND ARTICLE I, § 8 OF THE NEW YORK CONSTITION

189. Plaintiff incorporates all prior paragraphs as though fully set forth herein.

190. As incorporated against the States, the First Amendment's Free Speech Clause provides that government "shall make no Law…abridging the Freedom of Speech." U.S. CONST. amend. I. The New York Constitution similarly mandates that "no law shall be passed to restrain or abridge the liberty of speech." *See* N.Y. CONST. Art. I, § 8

191. The Act restricts and regulates labeling, marketing and other representations concerning covered products. It therefore abridges commercial speech of lawful activity, namely, the consumption of dietary supplements and/or diet pills.

192. There is no suggestion in the Act that the commercial speech it is curtailing is misleading, as the Act targets all representations concerning covered products, regardless of their accuracy.

193. Nor is it limited to speech that is directed toward minors; truthful and lawful claims directed toward adults over 18 can also implicate the product for age restriction and the loss of sales.

194. The government's stated interest in regulating commercial speech concerning dietary supplements is the premise that use of dietary supplements leads to eating disorders in minors, even though the Legislature has never substantiated such a causal relationship and less than 1% of minors in the United States use dietary supplements for weight loss and/or muscle building—uses that may lack any relationship, whatsoever, with the onset or facilitation of an eating disorder as no causal link has been established.

195. Even if the Legislature's purpose is construed broadly to address adolescent eating disorders in a general sense, the Legislature's purported reasoning for the Act is not directly advanced by its terms, as there is insufficient evidence that adolescent access to or consumption of dietary supplements causes, gives rise to, encourages, or enables eating disorders in that same demographic based on the product's labeling or marketing as a weight loss or muscle building product.

196. The harm suggested by the Legislature in passing the Act is not substantiated, nor will the restriction alleviate this harm to a material degree, as adolescents may easily bypass the requirements of the Act with a few simple clicks on their computer, and otherwise consume products with dangerous ingredients or that facilitate disordered eating.

197. Further, the Act does not target the consumption of dietary supplements or diet pills themselves. Instead, it directly targets commercial speech which falls squarely within the ambit of the First Amendment. Specifically, under the Act, a product can be legally sold to and consumed by a minor in one instance, while in another instance, the identical product may not be sold to a minor because of how it is labeled, marketed, or otherwise represented.

198. Moreover, the Act is violated once a sale of a covered product is made to a minor—it does not matter whether the product is ever consumed. Thus, the Act fails to address any inherent

danger in a particular product but rather the protected commercial speech surrounding the products.

199. In light of this attenuated connection between the Act and the governmental interest it supposedly advances, it is clear that the Act does not directly advance its purported interest.

200. Finally, even if the Act did directly advance its purported interest, its commercial speech burden would still need to be no more extensive than necessary to survive First Amendment scrutiny.

201. The regulation does not meet this constitutional requirement. The purported connection between eating disorders and dietary supplements has been debunked with recent scientific scholarship. And the Act covers *all* marketing, labeling and other representations of the product, regardless of where such representations occur. It is not narrowly tailored to address only that commercial speech which is untruthful, or misleading or contributes to a demonstrated societal harm. In restricting such limitless modes of communication, all while failing to advance, and worse, exacerbating the problem it purports to address, the Act is substantially overbroad and constitutes an impermissible abridgement of commercial speech.

202. For the reasons provided above, the Act violates the First Amendment to the United States Constitution and its equivalent in the New York Constitution and thereby deprives Plaintiff, its members, and dietary supplement manufacturers and suppliers of enforceable rights, causing them irreparable harm.

COUNT III
42 U.S.C. § 1983
EXCESSIVE IMPOSITION OF THE STATE'S POLICE POWERS

203. Plaintiff incorporates all prior paragraphs as though fully set forth herein.

204. The Act is an impermissible exercise of the State's police powers. Specifically, the Act unduly restricts the conduct of a private business without a showing of real or substantial evil

the Act is designed to cure, as well as no showing of a reasonable relation between this evil and the remedy proposed through the Act.

205. Here, there is no evidence of a causal link between dietary supplement usage and eating disorders, such that there is no relation between the Act and the problem it is designed to address.

206. Further, the Act does not directly target the consumption of dietary supplements, but rather, broadly targets commercial speech in a roundabout way of attempting to limit youth exposure to such supplements. The Act also only restricts sales of covered products, thus facially permitting their consumption. And the Act does not even bar the sale of a dietary supplement where it is not labeled, marketed, or otherwise represented as such.

207. Thus, even if there were a causal link between dietary supplement usage and eating disorders, there is a frayed and attenuated connection between dietary supplement usage and the Act. This attenuated connection constitutes an excessive imposition of New York State's police power.

208. Additionally, on its face, the Act provides that an otherwise harmless product cannot be sold to minors based on representations made by third-parties, such as by Yelp reviewers or social media influencers. The Act does not even require that the customer must have seen such representations in order for the product to be rendered unsafe.

209. Where, as here, no evidence supports a causal link between state legislation and the harm it intends to prevent, even the slightest restriction constitutes an undue exercise of police powers.

210. Yet the Act, despite having no rational basis, imposes tremendous burdens, threatening to cripple the dietary supplement industry. The compliance, training, and technology

costs thrust upon CRN's members may yield job reductions, severed business relations, and discontinued products, which, in turn, reduces competition in the market.

211. Additionally, the Act burdens these entities' First Amendment rights, chilling commercial speech and causing these entities to avoid making any representations concerning its products in an abundance of caution. These First Amendment burdens necessitate a compelling governmental interest and clear criteria for enforcement of that interest, both of which are entirely absent here.

212. In light of the Act's baseless, irrational nature, its failure to target the harms it purports to prevent, its substantial overbreadth, and its tremendous burdens on the dietary supplement industry, the Act constitutes an excessive imposition of New York State's police powers, and thereby deprives Plaintiff, its members, and dietary supplement manufacturers and suppliers of enforceable rights—causing them irreparable harm.

COUNT IV
42 U.S.C. § 1983
VIOLATION OF THE SUPREMACY CLAUSE

213. Plaintiff incorporates all prior paragraphs as though fully set forth herein.

214. The Supremacy Clause is the source of the preemption doctrine which invalidates state laws that are contrary to federal statutes.

215. The FDA regulates dietary supplements through the FDCA, as amended by DSHEA and the NLEA. The FDCA, in turn, expressly sets forth the definition of what is legally considered a dietary supplement and the labeling requirements for the same. *See* 21 U.S.C § 321(ff) and 21 U.S.C. § 343(r).

216. The FDCA expressly preempts any state law that establishes "any requirement respecting any claim of the type described in § 343(r)(1)…made in the label or labeling of food that is not identical to the requirements of § 343(r) of this title." 21 U.S.C. § 343-1(a)(5).

217. The Act bars the sale of dietary supplements to those under 18 years old depending on how they are labeled, and unavoidably restricts access to these products for everyone else. As such, the Act both concerns a labeling claim of the type described in § 343(r)(1), and imposes additional requirements beyond those imposed by the FDCA.

218. The Act's restrictions on a product's labeling, marketing and other representations all fall within the ambit of a labeling claim under the FDCA.

219. Structure/function claims fall within § 343(r)(1)'s ambit. 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).

220. The Act purports to target similarly prototypical structure/function claims and thereby intrudes on the ambit of the FDCA. The FDA has specifically permitted statements that a product helps "preserve muscle," "increase muscle size" and "enhance muscle tone" (*id.*)—these closely track those contemplated by the Act, which is intended to cover products labeled, marketed, or otherwise represented "for the purpose of achieving weight loss or muscle building." Act, § 391-oo(6). Similarly, the FDA permits statements about weight loss as appropriate structure/function claims.

221. Additionally, the Act targets the same intended purpose of the FDCA.

222. The FDCA's main purpose was to further its underlying goal of ensuring that products sold in the marketplace are safe.

223. This is precisely the intended purpose of the Act, which targets dietary supplements it deems unsafe for minors. In so legislating, the Act entirely overrides the FDCA's intentional legislative scheme, instead outright barring the sale of certain dietary supplements to minors. In

some sense, the Act treats certain dietary supplements as being even more dangerous and subject to greater regulation than many drugs, which may be sold to minors with a prescription.

224. The Act entirely supersedes the informed judgment of the FDA, which found that dietary supplements making structure/function claims regarding muscle building or weight loss are permissible for all consumers so long as such claims are substantiated as truthful, are not misleading, do not purport to make disease claims, and are accompanied by a disclosure that the "product is not intended to diagnose, treat, cure, or prevent any disease." § 343(r)(6)(C).

225. In attempting to overrule the FDA's decision and instead deem dietary supplements unsafe for minors, New York has intruded into the federal regulatory scheme and the Act is preempted.

226. Indeed, New York Governor Kathy Hochul acknowledged as much when she vetoed the prior iteration of the Act, reasoning that evaluating the safety of dietary supplements is "a role that is traditionally played by the FDA." *See* Veto #122, December 23, 2022.

227. Governor Hochul's reasoning applies with equal force here—it is the FDA's role to assess whether the dietary supplements covered by the Act are safe for minors, and neither the New York State Legislature nor Defendant should supersede those informed judgments.

228. For the reasons provided above, the Act violates the Supremacy Clause of the Constitution and thereby deprives Plaintiff, its members, and dietary supplement manufacturers and suppliers of enforceable rights, causing them irreparable harm.

COUNT V
42 U.S.C. § 1983 AND 28 U.S.C. § 2201
DECLARATORY RELIEF

229. Plaintiff incorporates all prior paragraphs as though fully set forth herein.

230. With exceptions not relevant here, in any "case of actual controversy within [their] jurisdiction," federal courts have the power to "declare the rights and other legal relations of any interested party seeking such declaration." 28 U.S.C. § 2201(a).

231. There is a present and justiciable dispute as to whether enforcement of the Act by Defendant violates CRN's rights under the United States Constitution and the New York Constitution, as stated in Counts I-IV.

232. The interests of the parties are real and adverse.

233. The unlawful portions of the Act are not severable from the rest of the Act. The entire Act is therefore unlawful and unenforceable.

234. Absent court intervention, which would resolve the dispute over the Act's lawfulness, Defendant will proceed to enforce the Act even though it is unconstitutional and void.

235. This Court can and should exercise its equitable power to enter a declaration that the entire Act is unconstitutional.

COUNT VI
EQUITABLE RELIEF

236. Plaintiff incorporates all prior paragraphs as though fully set forth herein.

237. The Act violates the United States Constitution and the New York Constitution, and deprives Plaintiff, its members, and its members' users of enforceable federal rights, causing them irreparable harm.

238. Federal courts have the power to enjoin unlawful actions by state officials.

239. This Court can and should exercise its equitable power to enter an injunction prohibiting Defendant from enforcing the Act and any of the challenged provisions of the Act against Plaintiff and its members.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court:

A. Declare that NY GBL § 391-oo is unlawful.

B. Declare that NY GBL § 391-oo is unconstitutionally vague in violation of the First Amendment and Due Process Clause of the Fourteenth Amendment to the Constitution and Article 1, § 6 of the New York Constitution.

C. Declare that NY GBL § 391-oo violates the First Amendment to the Constitution and Article 1, § 8 of the New York Constitution.

D. Declare that NY GBL § 391-oo constitutes an impermissible exercise of New York State's police powers.

E. Declare that NY GBL § 391-oo violates the Supremacy Clause of the Constitution.

F. Enjoin Defendant and her agents, employees, and all persons acting under her direction or control from taking any action to enforce the Act against Plaintiff or its members;

G. Enter judgment in favor of Plaintiff;

H. Award Plaintiff its attorneys' fees and costs incurred in bringing this action, including attorneys' fees and costs under 42 U.S.C. § 1988(b) for successful 42 U.S.C. § 1983 claims against state officials; and

I. Award Plaintiff all other such relief as the Court deems proper and just.

Dated: April 10, 2024

Respectfully submitted,

COZEN O'CONNOR

BY: _____

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Attorneys for Plaintiff Council for Responsible Nutrition

VERIFICATION

I, Megan Olsen, hereby verify as follows:

1. I am the Senior Vice President and General Counsel of Plaintiff Council for Responsible Nutrition ("CRN") and I am authorized by CRN to make this Verification on its behalf.

2. I have read the foregoing Amended Verified Complaint and based on my personal knowledge of CRN and information provided to me by CRN's members, I declare the facts therein to be true and correct.

Pursuant to 28 U.S.C. § 1746, I certify under penalty of perjury that the foregoing statements are true and correct.

Executed on April 10, 2024

MEGAN OLSEN

CERTIFICATE OF SERVICE

I, Sarah Krissoff, hereby certify that on this 11th day of April, 2024, I caused to be served the foregoing Amended Verified Complaint for Declaratory Judgment and Injunctive Relief, on the following, via the court's electronic filing system upon:

Linda Fang, NYS Office of The Attorney General,

Email – linda.fang@ag.ny.gov

and

Elizabeth Filatova, NYS Office of The Attorney General

Email – elizabeth.filatova@ag.ny.gov

Sarah Krissoff