

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

COUNCIL FOR RESPONSIBLE NUTRITION

Plaintiff,

v.

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

Defendant.

Case No. : 1:24-cv-01881

**DECLARATION OF STEVEN M. MISTER IN SUPPORT OF
PLAINTIFF'S MOTION FOR ORDER TO SHOW CAUSE FOR TEMPORARY
RESTRAINING ORDER AND PRELIMINARY INJUNCTION**

I, Steve Mister, declares as follows:

1. My name is Steven M. Mister, Esq., and I am the President and Chief Executive Officer ("CEO") of Plaintiff Council for Responsible Nutrition ("CRN").
2. I have been CRN's President and CEO since 2005. As President and CEO, I manage and set the strategic direction of this nonprofit trade association. I provide staff leadership and oversight of CRN's government relations, legal, regulatory, and public affairs operations and serve as the staff liaison for CRN's Retailer Relations Forum, a committee of CRN members who routinely interface with major retailers of dietary supplements who are our retail customers (e.g., Walmart, Walgreens, CVS, Target, Costco, etc.).
3. In total, I have been involved in the dietary supplement industry for over 19 years. I am well versed on the science and safety of dietary supplements, the relationships between various entities in the dietary supplement industry, including but not limited to manufacturers, suppliers, retailers, and distributors, and the general economics of the business.

4. I am aware that New York has passed legislation, N.Y. Gen. Bus. Law 391-oo (“the Act”), prohibiting the sale of dietary supplements to minors where the supplement or one of its ingredients is represented as assisting in weight loss or muscle building.

5. I have been asked to explain the effect the Act will have on CRN’s members, and I submit this Declaration in support of CRN’s Motion for Order to Show Cause.

6. I am over the age of 18 and am competent to make the statements herein. My Declaration is based on my personal knowledge and experience in the industry, and if called upon to do so, I could and would testify competently as to the matters set forth within.

I. CRN’s Mission of Bettering Health and Nutrition Through Safe, Legal, and Responsibly Developed Dietary Supplements and Ingredients

7. Many Americans do not receive sufficient amounts of critical vitamins and nutrients from their diet alone. Dietary supplements are products containing vitamins, minerals, botanicals, and other dietary ingredients intended to add to or supplement the diet. Common dietary supplements may include, but are certainly not limited to, vitamins (e.g., vitamin C, vitamin D, vitamins B-3, B-6, and B-12), minerals (e.g., calcium, magnesium), probiotics, and amino acids. Dietary supplements promote overall good health when used properly and in conjunction with a well-balanced diet and healthy lifestyle.

8. The dietary supplement industry generates over \$50 billion in annual revenue and includes dietary ingredient suppliers and dietary supplement manufacturers, and their retailers and distributors. The industry is regulated by the federal government, including through the Food and Drug Administration (“FDA”) and Federal Trade Commission (“FTC”).

9. CRN is the leading trade association representing the dietary supplement and functional food industry. Since 1973, CRN has advanced its mission of fostering a climate for responsible companies to improve consumers’ health and nutrition through the availability of safe,

legal, and responsibly developed, sourced, manufactured, and marketed science-based dietary supplements, functional food, and their ingredients.

10. CRN has historically carried out this mission through the provision of education, self-regulatory initiatives, fostering industry understanding and compliance with applicable laws and regulations, and advocating for appropriate laws and regulations of the industry.

11. **Education.** CRN prepares and disseminates educational information concerning dietary supplements and dietary ingredients to consumers, members, retailers, healthcare providers, researchers, and others in the dietary supplement industry. CRN provides a number of best practice guidelines for the sale of dietary supplements in certain circumstances (i.e., via e-commerce), or based on specific ingredients (like melatonin or protein), runs educational campaigns on certain dietary ingredients, and otherwise publicly discusses the specific uses and benefits of a variety of dietary ingredients to foster the safe and beneficial distribution, sale, and use thereof.

12. **Self-Regulatory Initiatives.** In an effort to promote transparency and accountability, CRN requires its members to publicly post their labels in a database, the Supplement OWL (www.SupplementOwl.org), which is accessible to the FDA as well as to consumers. CRN also encourages its members' participation with the National Advertising Division ("NAD") of the Council of Better Business Bureau to increase monitoring of dietary supplement advertisement to ensure the truthful and not misleading advertisement of dietary supplement products.¹

¹ By way of further explanation, CRN, through the CRN Foundation, partnered with the NAD for over ten years to expand the NAD's review of advertising claims for dietary supplements for truth and accuracy. Through this program, the CRN Foundation provided dedicated funding for an NAD attorney to bring and review supplement advertising cases, resulting in over 250 NAD decisions involving the truthfulness of supplement advertising and wide recognition from

13. ***Legal Compliance.*** CRN has historically advanced its mission by seeking to ensure and facilitate its members' compliance with applicable laws and regulations. CRN advises its members on how to comply with all federal and state laws and regulations concerning dietary supplements, dietary ingredients, and functional foods, through several industry education initiatives. CRN has co-hosted a two-day dietary supplement legal and regulatory conference for over a decade that provides legal education and compliance information on topics ranging from safe supplement manufacturing regulatory requirements to standards for truthful and accurate advertising practices. Federal legal and regulatory officials regularly address CRN members at these events, including speakers from the FDA, FTC, and the Department of Justice ("DOJ"). CRN regularly meets with federal agency leaders from the FDA and FTC and advises CRN members on legal and regulatory expectations raised in these meetings.

14. ***Advocacy of Laws Ensuring the Safe and Responsible Sale of Dietary Supplements.*** CRN takes a leadership role in advocating for public policy based on sound science and the ability for consumers to have access to a wide variety of high-quality, safe, and beneficial dietary supplement products. It was a key supporter of the Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006, which required dietary supplement companies to monitor and report important safety information about their products to the FDA.

15. CRN also supported the FDA's position when the law was enacted to make this adverse event data available to the public, demonstrating CRN's commitment to the safe and ethical sale of dietary supplements. Such was the case even though doing so could increase CRN members' risk of litigation if the data was not properly interpreted or put into context.

consumer protection regulators as a valuable complement to the FTC's own enforcement efforts to eliminate fraud in this industry.

16. More recently, CRN championed the Designer Anabolic Steroid Control Act (“DACSA”), which was enacted in 2014, that increased the authority of the Drug Enforcement Administration (“DEA”) over illegal ingredients and has subsequently supported additional legislation building on that law that would further limit the sale of selective androgen receptor modulators (SARMs) that mimic the effects of anabolic steroids.

II. CRN’s Members Share in CRN’s Mission and Produce Safe and Legal Dietary Supplements and Ingredients Intended to Better Consumer Health

17. CRN has more than 180 member companies, including ingredient suppliers and manufacturers in the dietary supplement and functional food industry, as well as companies providing services to those suppliers and manufacturers. A number of these members are manufacturers of dietary supplements and suppliers of dietary ingredients that conduct business in the State of New York.

18. All CRN members share CRN’s commitment to transparency, accountability, high ethics, safety, and responsibility.

19. CRN’s members comply with federal and state laws and regulations governing dietary supplements in the areas of manufacturing, marketing, quality control, and safety. To that end, nearly all facets of dietary supplement safety, manufacturing, labeling, and marketing are covered by extensive regulations issued and enforced by the FDA and FTC. Manufacturers are held accountable by these federal agencies for any statement they make concerning a product’s effect on the structure or function on the human body—a structure/function claim—as any such claim must be truthful, not misleading, and substantiated by competent scientific evidence.

20. CRN’s members also go above the requirements of law in complying with CRN’s self-regulating initiatives. All dietary supplement manufacturer members provide their product

labeling information to CRN's Supplement OWL, facilitating industry transparency for the FDA and consumers, and comply with CRN's best practices guidelines, discussed above.

21. Dietary supplement manufacturers and dietary ingredient suppliers who are members of CRN have also agreed to abide by CRN's Code of Ethics, which requires, among other things, that CRN's members market products that support the health and wellness of consumers, observe all applicable laws and regulations, use truthful and non-misleading labeling and advertising, take appropriate action to support the safety of their products, engage in self-regulation to foster consumer confidence in the quality of products and the truthfulness of advertising, and otherwise observe fair business practices in their dealings with consumers and the general public.

22. Our members take these commitments seriously. Many of our members utilize third-party certification programs, which independently review and test dietary supplement manufacturing processes and products for safety and quality. CRN members also champion self-regulatory initiatives to increase quality and safety throughout the dietary supplement supply chain through consortium groups of manufacturers, retailers, and other stakeholders that develop scientific, consensus-based standards to evaluate the manufacturing and testing of dietary supplements.

III. New York Passes the Act, Which Restricts the Sale of Dietary Supplements Based on Representations as to Weight Loss or Muscle Building

23. I have become familiar with the Act in the course of my employment with CRN, as it regulates the dietary supplement industry and conceivably covers or otherwise affects the actions of a large number of our members.

24. The Act restricts the sale of dietary supplements to minors where a dietary supplement is labeled, marketed, or "otherwise represented" for the purpose of weight loss or

muscle building. *See* § 391-oo(1). In determining whether a product falls within the Act's prohibition, the Act directs courts to consider, among other things, whether: (1) the dietary supplement contains an expressly identified ingredient; (2) the product's labeling bears statements or images implying the product will help with, *inter alia*, "the process by which nutrients are metabolized" or will maintain muscle or muscle strength; or (3) how a retailer or online seller has characterized the product, including its placement of the product in-store or on a website with respect to other products or information that falls within the ambit of the Act. *See* § 391-oo(6).

25. Notwithstanding my time and substantial experience in the dietary supplement industry, I cannot determine what products fall within the Act's ambit. I am not personally familiar with what it means to represent a product as aiding in weight loss or muscle building, nor am I aware of any common industry understanding as to what those terms mean. Any number of products or ingredients could play a role in a body's weight, muscle mass, or metabolism, either directly or indirectly, through a variety of known or unknown mechanisms of action. There is also no common legal practice, industry understanding, definition, or other mechanism to discern whether a product or ingredient is "represented for the purpose of achieving [the undefined terms of] weight loss or muscle building." *See id.*

26. The Act's factors also fail to provide additional guidance, as they similarly incorporate terms and phrases with no common meaning in the industry. I do not know how to begin to discern whether a product implies an effect on how the body metabolizes nutrients and how this demonstrates that a product is "represented for the purpose of achieving weight loss." *See id.* Similarly, I do not know what it means to imply that a product will maintain muscle or strength and how this relates to representing a product for the purpose of achieving muscle-building.

27. Based on my personal knowledge, CRN's half a century in the dietary supplement industry, conversations with members, and the practical applications of the Act, CRN has concluded that the Act will irreparably harm CRN, CRN's members, and the public at large.

IV. The Act Interferes with CRN's First Amendment Speech and Impedes its Ability to Carry Out its Mission

28. The Act chills CRN's protected First Amendment speech and materially frustrates CRN's core mission of bettering consumers' health and nutrition through the proliferation of safe, legal, and responsibly developed dietary supplements and ingredients.

29. CRN has historically advanced its mission through the dissemination of information concerning dietary supplements and ingredients. This core activity promotes public health and the availability of safe, responsibly developed products by: (1) empowering consumers to make educated and safe decisions concerning the betterment of their health; (2) informing healthcare professionals of appropriate uses of a dietary supplement or ingredient in certain healthcare settings; (3) and assisting retailers in selecting safe dietary supplements, better curating their offerings, improving their handling of dietary supplements, and educating their consumers on the responsible use and potential benefits of certain dietary supplements and ingredients.

30. However, the Act regulates the sales of dietary supplements to minors based on "representations" relating to weight loss or muscle building, including implications that a product or one of its ingredients could affect metabolism or muscle in the most abstract of ways. While it is clear that the Act tethers liability to speech, it is unclear in its requirements with respect to what constitutes a "representation" relating to "weight loss" or "muscle building," who must make the "representation," who must receive it, whose perception of the "representation" is relevant under the Act, and whether the "representation" must occur through a certain avenue of communication.

31. The Act's vagueness and the possibility for significant civil liability based on unbounded representations operate to materially impede CRN's ability to carry out its mission through its public informational speech. CRN reasonably fears that its truthful and substantiated statements as to certain dietary supplements and ingredients may unintentionally trigger the Act, thereby causing age verification requirements and potential liability for CRN's members where none would otherwise exist. Either result is antithetical to CRN's core mission.

32. By way of just one example, CRN runs educational campaigns on dietary ingredients. In 2021, it ran an informational campaign about the benefits and use of probiotics, a common dietary supplement, that was designed for consumers, retailers, dieticians, pharmacists, and other interested parties.² In connection with this campaign, CRN posted information online describing how different probiotic strains have unique bioactivities and provide varied health effects, which may affect different systems in the body.³ It describes two such genera as follows:

Bifidobacterium: Bifidobacterium are the most prevalent food-based probiotics in the digestive system, where they primarily occupy the colon. Bifidobacterium levels are highest during infancy but gradually decrease over time due to factors such as diet, stress, and antibiotics, providing supplemented probiotics ample opportunity to assist in maintaining ideal levels. Bifidobacterium species have been primarily studied for digestive and immune system health,[16] although research has shown benefits for glucose metabolism,[17] stress management,[18] weight management,[19] endurance,[20] and skin health.[21].

Bacillus: As a spore-forming bacteria, Bacillus spores act like a seed, protecting the bacteria's genetic makeup until they are provided with the proper conditions to germinate into a live cell. Because of this, Bacillus species are very stable and work well for gummies, chocolates, and other finished products that undergo harsh manufacturing or preparation conditions. While Bacillus are not known to colonize the intestine, they are a natural member of the gut microbiome, reproduce within the gut, and exert their effects as they travel through the digestive system. Bacillus

² See Educational Resources on Probiotics, CRN, <https://www.crnusa.org/probiotics>.

³ See 2021 Probiotics Education White Paper, CRN, www.crnusa.org/sites/default/files/Probiotics/Probiotics%20Retailer%20Education%20White%20Paper%205-13-21%20FINAL.pdf.

benefits are generally seen in digestive health,[22] immune health,[23] mood,[24] protein absorption,[25] oral health[26] and sports nutrition.[27].

33. The statements concerning metabolism, weight management, endurance, digestive health, protein absorption, and sports nutrition are accurate and supported by citation to scientific studies in the footnotes.

34. These statements are still publicly accessible through CRN's website.

35. CRN does not and did not intend to represent Bifidobacterium or Bacillus as ingredients designed for weight loss or muscle building. Nevertheless, it cannot rule out the possibility that a third party could construe its statements concerning glucose metabolism, weight management, endurance, digestive health, protein absorption, and/or sports nutrition as a representation relating to weight loss, muscle building, appetite, or metabolism.

36. In such a scenario, CRN reasonably fears that its accurate statements will trigger age restrictions on any products containing Bifidobacterium or Bacillus. CRN cannot risk the possibility of becoming the reason that a dietary ingredient is represented for weight loss or muscle building, as doing so would run afoul of CRN's mission of proliferating the availability of safe, responsibly developed dietary supplements.

37. Restrictions on CRN's protected speech will also fundamentally undermine another one of CRN's core activities. Specifically, CRN advanced its mission by assisting its members in understanding and complying with federal and state laws and regulations. CRN cannot fulfill that function due to the Act's vagueness, but, even worse, CRN is reasonably concerned that its lawful speech may become the reason its members are found in violation of the law. In the context of probiotics, CRN reasonably fears that its speech could form a basis for the Attorney General to prosecute one of CRN's members for the sale of a probiotic that is not marketed or advertised for

a proscribed purpose by the member, but which contains Bifidobacterium or Bacillus probiotic strains.

38. This new statutory paradigm has created an irresolvable tension where CRN cannot conduct a historical activity used to carry out its mission—the dissemination of accurate information concerning safe dietary ingredients and their benefits to consumers—without fundamentally harming its core mission and other key activities—the overall proliferation of responsibly manufactured dietary supplements and compliance with applicable laws and regulations.

39. Once the Act is in effect, CRN has no choice but to curtail and withhold its own protected First Amendment speech. Moreover, even when CRN's protected First Amendment speech is not directly chilled by the Act, CRN will have to expend ongoing time, effort, and legal costs carefully evaluating its protected First Amendment speech to ensure that it cannot form the basis for the Attorney General to prosecute one of CRN's members, even under the most expansive possible interpretation of the Act.

V. The Act's Effect on CRN's Members and the Public

40. The Act has and will continue to substantially burden CRN's Members and the public at large. It imposes a number of new and substantial compliance costs, is certain to reduce business revenue due to the new requirements and barriers to purchase, and provides CRN's members with no ability to guarantee their compliance with the law, a violation of which would result in litigation costs, potential civil penalties, and reputational harm.

41. In the wake of this new economic landscape, CRN members are determining whether they should cease selling dietary supplement products in the State of New York altogether or cease sales in certain outlets because of compliance challenges. These products are safe, legal, and truthfully labeled under all federal laws and regulations. However, because of the tremendous

burdens the Act imposes, if the Act goes into effect, it will no longer make economic sense for members to sell certain products in New York. As a result, adults in the State will no longer have the option to purchase these products.

42. Even if a member does not fully discontinue distribution of a product, at least one CRN member is considering limiting the sales channels through which certain products are sold, also reducing access for consumers.

43. I do not believe that these members are outliers. Based on my experience in the dietary supplement industry and understanding of the Act, I believe entities in the dietary supplement industry, both marketers of the products and retailers who sell them, will either exit the market, increase the costs of their products, and/or refrain from engaging in commercially protected speech.

44. In these instances, dietary supplements will become less accessible, more expensive, and consumers will be deprived of truthful information designed to assist the consumer in making educated decisions concerning their individualized healthcare needs.

A. The Act Imposes Substantial Compliance Costs on CRN Members and Chills Protected Commercial Speech

45. While CRN members are determining if they should remove certain products from the marketplace in New York, they also are currently attempting to wade through the quagmire of legal compliance. The Act imposes compliance costs on CRN's members with respect to the determination of whether the Act applies to their conduct, the necessity of revising marketing and advertising statements where appropriate, and with respect to the creation, implementation, and maintenance of age verification procedures that will affect not only their own distribution but how the product is distributed through third-party retailers.

46. The first step of compliance requires a time-intensive review of all applicable marketing, labeling, and advertising statements on a product-by-product basis. If the Act extends to third-party representations, which is currently unclear, CRN's members must scour the internet and other avenues of communication for any statement, by anyone, anywhere, concerning its products or the ingredients therein. This oversight is necessarily ongoing: it must continue so long as the CRN member continues to sell a product without age verification.

47. CRN members are also determining whether they need to steer clear of the Act by revising or removing any of their product names, logos, or structure/function claims. These assessments are far from straightforward. By way of just one example, it is unclear whether the Act would prohibit the sale of a product marketed with the word "metabolism," which may refer to any number of life-sustaining chemical reactions in the body's cells.

48. In any event, CRN's members do not limit their speech lightly. Marketing, labeling, and advertising are often the key ways in which CRN members communicate with consumers. For many products, the label is a consumer's first point of interaction with a product, and the accurate, scientifically supported, and not-misleading claims made thereon are how a CRN member conveys information to consumers that may assist the consumer in making decisions concerning their individualized healthcare needs.

49. While a member may believe that the name of their product or any structure/function claims do not constitute a representation as to weight loss or muscle building, a member that misestimates the Act's application faces civil penalties by the Attorney General, the cost of defending legal action by the Attorney General, and/or reputational harm resulting from the accusation that the member violated law or upon the unsubstantiated notion that the sale of their product contributes to or causes eating disorders in minors.

50. CRN has been advised that some of its members have decided to revise their labeling and are in the process of implementing those changes, while other members are still considering doing so. Members who opt to revise their statements lose the ability to effectively market their products and to provide consumers with helpful information concerning their health. Members who must change their name or logo, moreover, also lose the goodwill and name recognition associated with their historical marketing efforts.

51. These consequences reverberate far beyond New York. Because of the realities of the internet, CRN members who opt to change their labeling and marketing must do so on a nationwide basis. One CRN member is currently removing a number of substantiated structure/function claims from its website and from healthcare practitioner education information, both of which concern the members' speech throughout the United States.

52. From conversations with members and my experience in this industry, I also understand that the decision to change or remove labeling imposes additional costs. Employees must divert time and attention from their usual activities to reviewing claims concerning their product, revising the member's websites, redesigning the label, creating inventory of the product with the new label, and engaging in logistic arrangements for the unsold products bearing the previous label.

53. The Act also requires age verification procedures for products that fall within its amorphous ambit. All age verification procedures impose their own compliance and oversight costs with respect to employee training and the identification of age-restricted products.

54. However, these burdens are particularly steep in the context of online sales, in which many of CRN's members deal. In that context, the Act expressly requires the use of an age-verification shipping service to ensure that the recipient of the package is over the age of 18.

Logistically, I am not even aware of any common carrier or delivery service in New York that readily employs age-verification procedures for consumers between the ages of 18 and 21 years old, as existing services only provide age verification to those at least 21 years old.

55. If CRN members are required to use one of these providers, they would essentially forfeit the ability to make legal sales to consumers over the age of 18, but under the age of 21.

56. At best, it is possible that one or two discrete carriers may offer age verification services that check the requisite forms of government identification for consumers 18 years and older, but the use of these services would then restrict a CRN member's ability to utilize other common carrier services who may offer better shipping prices, speed, logistical convenience, or other competitive factors.

57. Even still, it is a fact that shipping products with age verification procedures—even those that are poorly suited to fulfill the Act's age verification requirement—costs more than shipping products without such a requirement. I have also been informed by a CRN member that they cannot use their existing common carrier's age verification procedure (which is designed for consumers over the age of 21) without renegotiating their current contract with that carrier, as shipping costs to consumers absent such renegotiation would be astronomically high.

58. The age verification shipping requirement also raises obstacles for delivery. Individuals are not always home to accept their packages, yet carriers will only attempt to deliver a package a certain amount of times before returning the package back to the sender. And, inevitably, some recipients will fail the age verification requirement—whether due to their biological age or their failure to locate or possess sufficient identification—that will similarly require the carrier to return the package to the sender. However, the return of consumable products poses the risks of tampering, damage, and mishandling. Some CRN members maintain policies

that, as a matter of consumer protection and quality control, require the destruction of the returned product so that it is not placed back into commerce. With the anticipated increase in returns, CRN members expect to incur more waste, less useable product, and increased logistics costs.

59. Given the possibility of liability under the Act, the certainty of lost sales, and increased operating costs due to additional age-restriction shipping logistics, one CRN member may cease selling certain products into New York using its own online sales platform, instead redirecting sales to other third-party retailers from the product landing page. In addition to the time spent recoding their website to redirect sales, the member will lose all direct online sales to consumers in New York, including those over the age of 21.

60. Other CRN members are going another route and attempting to deal with the uncertainty of the law by layering on additional verification procedures in an extreme abundance of caution. I am aware of a CRN member who is implementing age verification procedures at the point of sale. In addition to the cost of the age verification software, this member expended time and labor costs connecting the software to its multiple websites by building new web flows.

61. Even beyond the age verification procedures, CRN members must develop systems that aggregate and maintain their consumers' identifying information as a defense to any alleged violation of the Act. Because dietary supplements are akin to food—and, indeed, are considered a subset of food by the FDA—most CRN members do not currently have such systems in place. Developing a safe database of potentially private and/or sensitive consumer information is yet another cost necessitated by the Act.

62. For these reasons, the enforcement of the Act will require CRN members to incur a significant and never-ending commitment of resources and funds, all the while providing them

with no assurance of non-liability under the Act. CRN's members will suffer ongoing irreparable harm if forced to incur these costs and the statute is later invalidated or significantly altered.

63. The compliance efforts necessitated by the Act also have ripple effects that negatively impact consumers. By incentivizing CRN members to remove structure/function claims, adults in New York and elsewhere are deprived of valuable and truthful information concerning their health and well-being intended to facilitate their informed decision-making.

64. Additionally, given the onset of significant new compliance costs and the potential for liability, those in the dietary supplement industry will inevitably need to decide where to remove some products from sale in New York or to pass costs onto the end consumer in the form of higher prices. The prior approach reduces competition in the market and deprives adults of products they are entitled to purchase, and the latter makes dietary supplements more expensive for everyone.

65. The Act also makes it more difficult for adults to purchase dietary supplements. Adults no longer have the ability to purchase dietary supplements anonymously, as they always have in the past, and the Act entirely deprives supplement access to millions of adults who lack sufficient government-issued identification.

B. The Act Prevents CRN's Members From Selling Safe, Legal Products and Impairs Existing Business Relationships

66. Once the Act is in effect, CRN's members will sustain continuing lost sales revenue. It anticipates lost revenue from not only minors, but from lawful consumers between the ages of 18 and 21 who do not meet common carrier age verification requirements, and from adults who are less inclined to purchase dietary supplements due to the new barriers to purchase.

67. Putting aside the unsubstantiated nexus between dietary supplements and undefined eating disorders in minors, the Act's ban is not limited to only those products containing dangerous

ingredients. It instead prevents CRN members from recognizing revenue through the sale of products that are safe, beneficial for use by minors, not marketed for weight loss or muscle building, and which may even have been specifically designed to promote adolescent health.

68. In addition to the lost revenue, the Act is already impacting, and will continue to impact, CRN's existing business relationships with others in the dietary supplement supply chain. Because the Act imposes liability based on the actions or statements of third parties CRN's members must evaluate each of their supplier/retailer/distributor relationships.

69. CRN members may need to sever such relationships if they cannot control the third party's compliance with the Act, or where the retailer or supplier's actions pose too great a likelihood of liability.

70. One CRN member is considering asking retailers to limit the shelf placement of the member's products to minimize the risk of their product being "grouped" with any products that could be construed as weight loss or muscle building products. While necessary due to the Act, product placement in a store is an important driver of sales, and this CRN member understands that their request is likely to lead to reduced revenue, especially if their product is replaced in an unfavorable location, on a high shelf, or in an area with little foot traffic. Given the ambiguity in the Act over many of the elements necessary to determine what "grouping" would violate the Act, the member is risking reduced revenue with no guarantee that their actions will ensure compliance.

71. Doing so will harm that CRN member's sales not only in New York, but nationwide. Many retailers plan out store set-ups months in advance based on sales, marketing, consumer preference, and other data that can have a significant effect on the revenue generated by a product. National retailers that operate in New York often plan these store set-ups on a nationwide basis to promote uniformity and organization in their store layouts. If a retailer changes

the location of a product in one store, they may likely have to do so on a nationwide basis for consistency.

72. Conversely, based on my years of experience working with retailers to educate them about dietary supplement safety and benefits, and develop and promote a robust, responsible dietary supplement marketplace for CRN members, I believe some retailers and distributors may decide that the risks, compliance costs, and logistics associated with the Act outweigh the profit in selling certain dietary supplement products, and, therefore, decide to stop selling those products. In this scenario, CRN's members will lose their relationships with existing retailers and suffer a decrease in sales revenue.

73. While some retailer/manufacturers will stay intact, the Act is certain to change some of the economic underpinnings of those relationships in a manner that is detrimental to CRN's members. I am already aware of one retailer imposing new terms and conditions on its relationship with a CRN member as a direct result of the Act. This retailer is requiring the CRN member to agree to indemnify the retailer and pay an additional fee for any violation of the statute.

74. The Act is also certain to decrease CRN members' sales revenue while retailers adjust to the law. A sale of a dietary supplement may violate the statute based on where the retailer has placed the product in the store, although the Act provides no guidance on what it means to "group[] the supplements with other weight loss or muscle building products." *See* § 391-oo(6)(d)(2). Undefined criteria related to "grouping" is likely to cause retailers to rearrange the placement of products both in New York and nationwide or to remove a product from inventory altogether. These actions would cause significant harm to CRN's members in lost sales due to changes in which a product is replaced in a store or removed from a store entirely. Lost revenue may not be limited to just New York and, if a store mistakenly identifies a product as subject to

the Act or changes its location because of the Act, it could take a CRN member significant time to get the product returned to an appropriate location in a store.

75. There is also sufficient reason to believe that retailers are making these decisions upon inaccurate and misleading characterizations of certain dietary supplement products. While CRN and its members have struggled to determine when a product is age-restricted under the Act, an advocacy organization known as Strategic Training Initiative for the Prevention of Eating Disorders (“STRIPED”) has begun doing so for them, characterizing products as intended for “weight loss” or “muscle building” on its website.

76. STRIPED, which was formed in 2009, runs an advocacy campaign for the prohibition of “over-the-counter diet pills” and “muscle supplements.”⁴ STRIPED takes credit for informing the Act, which was plainly replicated from STRIPED’s “model legislation” in its “advocacy playbook.”⁵ STRIPED justifies the purpose of the Act with the following fiery rhetoric, uncoupled from citation to scientific evidence:

From social media influencers promoting unattainable body ideals to the corner pharmacy selling snake oil diet pills and muscle supplements, there is no shortage today of predatory companies trying to make a buck off of teens’ mental health struggles and body insecurities . . . Though we can’t legislate body confidence, we can change laws to make it harder for these companies to prey on kids.⁶

77. It would have been plainly inappropriate for the New York State Legislature to delegate to STRIPED—or any non-governmental interest group—the unilateral authority to decide when the Act applies on a product-by-product basis, especially given the STRIPED’s subjective biases, viewpoints, and interests.

⁴ See *Over-the-Counter Diet Pills & Muscle Supplements: Ban Sale to Children*, STRIPED, <https://www.hsph.harvard.edu/striped/over-the-counter-diet-pills-bill/>.

⁵ See *Model Legislation*, STRIPED, <https://www.hsph.harvard.edu/striped/wp-content/uploads/sites/1267/2023/09/STRIPED-Model-Legislation.pdf>.

⁶ See *New York bans sales of diet, muscle building supplements to minors*, STRIPED (Oct. 27, 2023), <https://www.hsph.harvard.edu/news/features/new-york-diet-supplements-ban/>.

78. Nevertheless, STRIPED recently updated its website with a “Dietary Supplement Label Explorer,” which categorizes dietary supplements as products for “weight loss,” “muscle building,” and “cleanse/detox,” based on the “manufacturer claims on the label” of the products.⁷

79. These categorizations are plainly misplaced—an unsurprising conclusion given that categorizing supplements for “weight loss” or “muscle building” eludes even the manufacturers of those products. Among other issues, STRIPED identifies immunity-supporting vitamin C and stress-reducing ashwagandha products as “muscle building” products for no discernable reason. It also labels products that are expressly designed for teenagers and adolescents, such as multivitamins, as seemingly dangerous products peddled by predatory companies (that, in reality, are just trying to better adolescent health with safe, affordable, and available multivitamins based on the adolescents’ needs). In another instance, STRIPED mischaracterizes an iron and vitamin supplement as a “muscle building” product for no apparent reason. This is especially concerning for adolescent health and access to these products because iron supplements could be particularly helpful for adolescents, with the Journal of the American Medical Association reporting that up to 40 percent of U.S. females from the ages of 12 to 21 could be iron deficient.⁸

⁷ See *Dietary Supplement Label Explorer*, STRIPED, <https://www.hsph.harvard.edu/striped/label-explorer/>. While originally public, STRIPED recently implemented password protection for the tool. It is unclear whether its doing so is temporary or permanent. However, ongoing password protection is itself particularly problematic, as STRIPED can ensure that certain demographics—such as retailers, government officials, and consumers—have access to their tool, while CRN’s members do not. In such an instance, CRN’s members have no opportunity to object to any misclassification with respect to their products, and must theoretically age restrict all of their products to ensure their compliance with the Act or risk liability from an unknown third-party representation. For the reasons discussed herein, doing so is not economically feasible, where age restriction substantially limits sales and revenue, and itself imposes additional costs.

⁸ See Angela C. Weyand, MD, et al., *Prevalence of Iron Deficiency and Iron-Deficiency Anemia in US Females Aged 12-21 Years, 2003-2020*, JAMA. 2023;329(24):2191–2193. doi:10.1001/jama.2023.8020.

80. It is unclear whether STRIPED's online tool constitutes a representation that could give rise to age restriction requirements and liability under the Act. However, given the absence of meaningful statutory direction and STRIPED's self-proclaimed proximity to the New York Legislature, STRIPED's categorizations will factor into CRN members and retailers deciding their compliance strategy with respect to the Act.

81. At a minimum, STRIPED's interjection makes the legal environment for selling or supplying dietary supplements even more uncertain. As noted, retailers and dietary manufacturers are likely to react to the combination of uncertainty, risk, and increased costs in the same way: by exiting the market in whole or in part. Doing so unquestionably harms consumers, who lose the benefits that inure to customers in a flourishing competitive environment.

VI. The Act Will Cause Irreparable Harm to CRN, CRN Members, and the Public

82. For these reasons described herein, if the Act takes effect on April 22, 2024, it will cause irreparable harm to CRN, CRN's members and dietary supplement consumers.

83. Once the Act is in effect, CRN's mission of bettering public health and well-being through the availability of safe and responsibly developed dietary supplements would be directly and substantially damaged.

84. CRN members are also suffering irreparable harm from the Act in the form of unrecoverable costs in connection with attempting to comply with the Act. Once the Act is in effect, CRN members face certain lost revenue and increased costs deriving from the new restrictions on the sale of perfectly safe and legal dietary supplement products. CRN members, all of whom are attempting to comply with the Act in the utmost good faith, also cannot ensure their compliance with the new statutory requirements, such that they risk enforcement by the Attorney General and attendant reputational harm, litigation costs, and potential civil penalties.

85. The public at large, both in and outside the State of New York, will suffer harm as well. The Act stifles speech and restricts the availability of dietary supplements on a nationwide basis, depriving all consumers of critical information concerning their health and the availability of dietary supplements that they have every legal right to purchase. However, adult consumers in New York will feel the brunt of these effects. In some instances, the Act will entirely deprive adult consumers lacking government identification of the ability to purchase a product they have every legal right to obtain and consume. Additionally, adults will lose the ability to purchase these supplements anonymously, with ease, and at the cost that they did before the Act.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 3rd day of April in 2024.



Steven M. Mister, Esq.