24-1343-cv

United States Court of Appeals

for the

Second Circuit

COUNCIL FOR RESPONSIBLE NUTRITION,

Plaintiff-Appellant,

– v. –

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

Defendant-Appellee.

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

BRIEF OF *AMICI CURIAE* PUBLIC HEALTH RESEARCHERS, HEALTHCARE PROVIDERS, AND ADVOCACY ORGANIZATIONS FOCUSED ON EATING DISORDERS IN SUPPORT OF DEFENDANT-APPELLEE

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CORPORATE DISCLOSURE STATEMENTS

Academy for Eating Disorders is a nonprofit organization. It has no parent corporations. It has no stock, and therefore no publicly held company owns 10% or more of its stock.

Be Real USA is a nonprofit organization. It has no parent corporations. It has no stock, and therefore no publicly held company owns 10% or more of its stock.

Eating Disorders Coalition for Research, Policy & Action is a nonprofit organization. It has no parent corporations. It has no stock, and therefore no publicly held company owns 10% or more of its stock.

Multi-Service Eating Disorders Association, Inc. is a nonprofit organization. It has no parent corporations. It has no stock, and therefore no publicly held company owns 10% or more of its stock.

Monte Nido Holdings, LLC is wholly owned by MN Acquisitions, Inc., which is wholly owned by MN Intermediate Holdings Corp., which is wholly owned by RCP MN Holdings, LLC. No publicly held corporation owns 10% or more of Monte Nido Holdings, LLC's stock.

National Alliance for Eating Disorders is a nonprofit organization. It has no parent corporations. It has no stock, and therefore no publicly held company owns 10% or more of its stock.

National Eating Disorders Association is a nonprofit organization. It has no parent corporations. It has no stock, and therefore no publicly held company owns 10% or more of its stock.

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INTERESTS OF AMICI CURIAE[1]

Amici are leading public health researchers and public interest organizations focused on combatting eating disorders. As a result of their research, direct patient contact, and deep involvement with public health solutions, they are intimately familiar with the harms that can result in children who consume weight-loss and muscle building supplements. Amici have an interest in New York General Business Law §391-oo(1)(a) (the "Act") as a measure to reduce those harms and improve public health outcomes. Amici submit this brief to (1) lay out for the Court the overwhelming evidence showing the harms posed by these supplements, especially to children; and (2) show that, contrary to Plaintiff-Appellant's assertions, such supplements are easily identified—including by the manufacturers of those products.

Dr. S. Bryn Austin is a Professor in the Department of Social and Behavioral Sciences at Harvard T.H. Chan School of Public Health, a Professor of Pediatrics at Harvard Medical School, a professor at Boston Children's Hospital, and a founding director of the Strategic Training Initiative for the Prevention of Eating Disorders; her research focuses on environmental influences on eating disorders risk and public health approaches to preventing and addressing eating disorders.

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[1] All parties have consented to the filing of this brief. *See* Fed. R. App. P. 29(a). No counsel for a party authored this brief in whole or in part; and no person other than amici and their counsel made a monetary contribution to fund the preparation or submission of the brief. Fed. R. App. P. 29(a)(4)(E); Local R. 29.1(b).

Dr. Pieter Cohen is an associate professor at Harvard Medical School and internist at the Cambridge Health Alliance; his research focuses on dietary supplements and patient safety, including analysis of dietary supplement labeling accuracy, the inclusion of unapproved or adulterated ingredients in supplements, and the efficacy of FDA warning letters and other enforcement action.

Academy for Eating Disorders works to advance eating disorder prevention, education, treatment, and research by expanding the global community of committed professionals.

Be Real USA is a non-profit organization dedicated to improving body image and body confidence for children.

Eating Disorders Coalition for Research, Policy & Action advances the recognition of eating disorders as a public health priority throughout the United States through federal legislation, awareness raising, and promotion of initiatives that advocate for those with these conditions.

Multi-Service Eating Disorders Association, Inc. ("MEDA") is a nonprofit organization that provides individual and group therapy services for individuals struggling with eating disorders; professional trainings to community-based organizations, academic institutions, and providers of all disciplines; and resources for

education and early detection. MEDA works closely with clinicians, physicians, dietitians, treatment centers and the general public in service of accessible, equitable care for all those who are impacted by eating disorders.

Monte Nido is a national mental healthcare provider committed to challenging harmful norms as it works to eradicate eating disorders. It offers industry-leading care to adults and adolescents of all genders. Monte Nido's evidence-based treatment in inpatient, residential, and day treatment settings shows exceptional outcomes, with significant improvements in depression, anxiety, and eating disorder-specific measures.

National Alliance for Eating Disorders provides referrals, education, and other support to people with eating disorders and their families and works to raise awareness and promote access to care for eating disorders.

National Eating Disorders Association is a national nonprofit that works to advance research, provide information, and raise awareness to support the nearly 30 million Americans who will experience an eating disorder in their lifetimes.

INTRODUCTION

The Act prohibits the sale of dietary supplements to children that are "labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building." It restricts sale of products to minors that, among other things: (1) contain ingredients approved by the Food and Drug Administration ("FDA") for weight loss or muscle building or that are commonly included in dietary supplements for weight loss or muscle growth; (2) according to their labeling or marketing, describe the product as for weight loss or muscle building; (3) are otherwise represented as achieving weight loss or muscle growth; or (4) are categorized by retailers as supplements for these same purposes. §391-oo(6). Physical and online retailers are required to implement age verification requirements, §391-00(2)-(4), and each violation of the Act may result in a civil penalty of up to $500, §391-00(5).

Amici strongly support the Act. In the past two decades, supplements for weight loss and muscle gain have become increasingly popular with U.S. consumers. A survey of 9,400 American adults found that an estimated 15.2% of adults (20.6% of women, 9.7% of men) have consumed at least one weight loss supplement,[2] and

[2] Heidi Michels Blanck et al., *Use of Nonprescription Dietary Supplements for Weight Loss is Common Among Americans*, 107 J. Am. Dietetic Ass'n 441, 441 (2007).

about one in twenty adolescents—including one in ten adolescent girls—have done so as well.[3]

Well-established medical science has found that weight loss and muscle building supplements have no demonstrated health benefit. To the contrary, they have been linked to numerous negative health effects, including short- and long-term health complications, increased hospitalizations, and death. These supplements may also contain prohibited or adulterated ingredients that can lead to additional adverse health effects. Section I, *infra*.

The risks of consuming weight loss and muscle building supplements are increased for children. Children face serious health effects from ingesting these products; leading hospitals and the American Academy of Pediatrics warn that they should not ingest them. Children are more likely to consume weight-loss and muscle-building dietary supplements in dangerous ways, as they are less likely than adults to understand or appreciate the risks that come with doing so. Beyond the health risks posed by the supplements themselves, taking those products as a child can lead to other long-term health effects, such as increased risk of eating disorders

[3] Natasha Yvonne Hall et al., *Global Prevalence of Adolescent Use of Nonprescription Weight-Loss Products: A Systematic Review and Meta-Analysis*, 7 JAMA Network Open, Jan. 2024 at 1, 7–8.

and steroid abuse. Children are at heightened risk of taking these supplements because these products are relentlessly marketed to them online and through social media. Section II, *infra*.

The Act seeks to restrict the sale of these products to children and—contrary to Plaintiff-Appellant's assertions—identifying those products is straightforward. Manufacturers routinely tell the FDA which of their products are purportedly designed to promote weight loss or muscle growth. A review of the FDA's public records shows that manufacturers self-identify hundreds of supplements for these purposes. Retailers and online sellers have already taken steps to identify and restrict access to such supplements, showing that there is no true confusion over which products are targeted by the Act. Section III, *infra*.

Amici urge this Court to affirm the District Court's denial of Plaintiff-Appellant's request for a preliminary injunction.

ARGUMENT

I. Weight Loss and Muscle Growth Supplements Are Harmful

Numerous research studies have found that consuming weight loss and muscle growth supplements is not associated with any health benefits, including the benefits touted by the supplements' manufacturers. To the contrary, studies link these supplements to serious side effects, emergency department visits, and long-term health

complications. Many of these supplements have also been found to contain adulterated, fraudulent, or toxic ingredients that can cause adverse health effects.

A. Weight Loss and Muscle Growth Supplements Have No Demonstrated Health Benefits

A broad body of research shows that weight loss supplements are not effective. In a literature review analyzing 48 articles published from 2006 to 2016 that evaluated the top nine most commonly-advertised weight loss supplements on Google and Amazon Canada, researchers found almost no evidence that those supplements contributed to weight loss. Sean Wharton et al., *The Safety and Effectiveness of Commonly-Marketed Natural Supplements for Weight Loss in Populations with Obesity: A Critical Review of the Literature from 2006 to 2016*, 60 Critical Revs. Food Sci. & Nutrition 1614, 1626 (2019). The study also found that none of the analyzed supplements demonstrated the clinical threshold for weight loss (the threshold required by the FDA for a product to be marketed as a weight loss drug) and so did not appear to offer any clinically significant benefits to consumers. *Id.* at 1626.

Other recent studies have similarly demonstrated that most weight loss supplements are ineffective or show negligible clinical benefits that barely surpass those provided by a placebo. Regina Ewa Wierzejska, *Dietary Supplements—For Whom? The Current State of Knowledge About the Health Effects of Selected Supplement Use*, 18 Int'l J. Env't Rsch. & Pub. Health, no.17, 2021 at 1, 17–18; Erica Bessell et

al., *Efficacy of Dietary Supplements Containing Isolated Organic Compounds for Weight Loss: A Systematic Review and Meta-Analysis of Randomised Placebo-Controlled Trials*, 45 Int'l J. Obesity 1631, 1631–43 (2021); Alireza Esteghamati et al., *Complementary and Alternative Medicine for the Treatment of Obesity: A Critical Review*, 13 Int'l J. Endocrinology & Metabolism, April 2015, at 1; Hongliang Tian et al., *Chromium Picolinate Supplementation for Overweight or Obese Adults*, Cochrane Database Systematic Revs., no. 11, 2013, at 1, 14–15.

Studies have similarly shown that muscle growth supplements are not effective. One study found that dietary supplements containing branched chain amino acids, a common muscle growth supplement, do not promote muscle anabolism and sometimes result in decreases in muscle protein synthesis. Robert R. Wolfe, *Branched-Chain Amino Acids and Muscle Protein Synthesis in Humans: Myth or Reality?*, 14 J. Int'l Soc'y Sports Nutrition, no. 1, 2017 at 1, 1, 6. Studies have shown that several other ingredients common in muscle growth supplements—chromium, vanadyl sulfate, boron, and dehydroepiandrosterone—are also ineffective. *See, e.g.*, Priscilla M. Clarkson and Eric S. Rawson, *Nutritional Supplements to Increase Muscle Mass*, 39 Critical Revs. Food Sci. & Nutrition 317, 317–23 (1999). While there is some evidence that creatine in its pure form may have beneficial effects for muscle growth in a laboratory setting, these benefits have not been established in common muscle growth supplements sold to consumers, which do not contain the same form

of creatine tested in laboratory settings. *See, e.g.*, Pieter Cohen et al., *Presence and Quantity of Botanical Ingredients with Purported Performance-Enhancing Properties in Sports Supplements*, 6 JAMA Network Open, July 2023, at 1, 3 (finding that of fifty-seven products purchased online for purported sports enhancing properties like muscle growth, 89% of products did not accurately declare ingredients in the products).

B. Weight Loss and Muscle Growth Supplements Are Associated with Serious Health Effects

Studies have linked consumption of weight loss and muscle building supplements to serious health effects, including stroke, testicular cancer, and liver or other organ damage. Flora Or et al., *Taking Stock of Dietary Supplements' Harmful Effects on Children, Adolescents, and Young Adults*, 65 J. Adolescent Health 455, 456 (2019); Sarah Y. Park et al., *Notes from the Field: Acute Hepatitis and Liver Failure Following the Use of a Dietary Supplement Intended for Weight Loss or Muscle Building*, 62 Morbidity & Mortality Wkly. Rep. 817 (2013). While some effects can be minor to moderate, consumption of weight loss supplements can result in liver and kidney failure. Wharton et al., *supra*, at 1616, 1624, 1626. One study found that over 15% of serious drug-included liver injury cases in the United States were attributed to patients having taken dietary supplements, mostly for weight loss and

muscle building. Victor Navarro et al., *Liver Injury from Herbals and Dietary Supplements in the U.S. Drug-Induced Liver Injury Network*, 60 Hepatology 1399, 1401–02 (2014).

Studies have also linked consumption of weight loss and muscle growth supplements to increased hospitalization and emergency room visits. One study estimated that on average, approximately 23,000 emergency department visits and approximately 2,150 hospitalizations in the United States each year from 2004 to 2013 were attributable to adverse events—adverse reactions, allergic reactions, excess doses, unsupervised ingestion by children, or other events (e.g., choking)—resulting from the consumption of dietary supplements. Andrew I. Geller et al., *Emergency Department Visits for Adverse Events Related to Dietary Supplements*, 373 New England J. Med. 16, 1531, 1533 (2015) (examining data from 63 emergency departments). Notably, 28% of these emergency department visits involved young adults between the ages of 20 and 34 and over 20% involved unsupervised children. *Id.* Of these emergency department visits, over a quarter were caused by weight loss products. *Id.* Studies have concluded that consumption of weight loss supplements is akin "to playing a game of 'Russian roulette,'" due to the dangers associated with ingesting them. Wierzejska, *supra*, at 14.

C. Weight Loss and Muscle Growth Supplements May Contain Adulterated, Fraudulent, or Toxic Ingredients

Studies have shown that many dietary supplements, including for weight loss and muscle building, contain microbial contamination, heavy metal contamination, prescription drug adulteration, substitution of active plant variety or enrichment product, and other fraudulent ingredients. C. Michael White, *Dietary Supplements Pose Real Dangers to Patients*, 54 Annals of Pharmacotherapy 815, 815–19 (2020).

The FDA has identified hundreds of weight loss supplements that it found to be tainted and which may cause serious side effects. The FDA maintains a list of hundreds of such potentially dangerous products on its website that are marketed to consumers for weight loss. *See Tainted Weight Loss Products*, FDA (Jan. 16, 2024), https://www.fda.gov/drugs/medication-health-fraud/tainted-weight-loss-products. The FDA also found that nearly 50 supplements sold on Amazon and eBay, including supplements for weight loss, contained active pharmaceutical ingredients not declared on the label that could pose health risks to consumers. *See* Ryan Felton, *FDA Finds Hidden Drugs in Nearly 50 Dietary Supplements Sold on Amazon, eBay*, Consumer Rep. (Dec. 18, 2020), https://www.consumerreports.org/health/fda-finds-hidden-drugs-in-weight-loss-sexual-enhancement-dietary-supplements-sold-on-amazon-ebay-a6199440119/.

Consistent with these findings, scientific studies have found that dietary supplements, including weight loss and muscle growth supplements, may contain ingredients prohibited by the FDA. In a review of FDA warnings issued to dietary supplement products from 2007 through 2016, researchers identified 776 dietary supplements containing adulterated ingredients. Jenna Tucker et al., *Unapproved Pharmaceutical Ingredients Included in Dietary Supplements Associated with US Food and Drug Administration Warnings*, 1 JAMA Network Open, Oct. 2018, at 1, 1. Most of these warnings were related to weight loss, muscle building, or sexual arousal supplements. *See id.*

Studies have also found that weight loss and muscle building supplement products may contain stimulants prohibited by the FDA and/or prohibited by the World Anti-Doping Agency, which can have a range of adverse effects including cardiac arrest and sudden death. Pieter A. Cohen et al., *Nine Prohibited Stimulants Found in Sports and Weight Loss Supplements: Deterenol, Phenpromethamine (Vonedrine), Oxilofrine, Octodrine, Beta-methylphenylethylamine (BMPEA), 1,3-Dimethylamylamine (1,3-DMAA), 1,4 Dimethylamylamine (1,4-DMAA), 1,3-Dimethylbutylamine (1,3 DMBA) and Higenamine*, 59 Clinical Toxicology 975 (2021).

Beyond the risk of these banned substances, a study of 138 dietary supplements, including for weight loss and muscle building, found toxigenic fungi, mold, or yeast in numerous products, including at levels higher than permitted by the U.S.

Pharmacopeia, which establishes standards for medicines, food ingredients, and dietary supplement ingredients. Valerie H. Tournas, *Microbial Contamination of Select Dietary Supplements*, 29 J. Food Safety 430, 439–40 (2009). Ingesting products with bacterial and fungal contamination can cause infections and poisonings. *See id.* at 439. Another study of 121 supplements, including weight loss and muscle building, found that many had metal levels that exceeded acceptable daily intakes. Stephen J. Genuis, et al., *Toxic Element Contamination of Natural Health Products and Pharmaceutical Preparations*, 7 PLOS One, no. 11, 2012 at 1, 6. Consumption of heavy metal contamination can cause depression, fatigue, cognitive function decline, and dementia. *See Heavy Metal Poisoning*, National Organization for Rare Disorders (Mar. 28, 2008), https://rarediseases.org/rare-diseases/heavy-metal-poisoning.

II. Weight Loss and Muscle Growth Supplements Are Especially Harmful to Children

Numerous research studies show increased health harms to children who consume dietary supplements, especially for the purported effect of losing weight or gaining muscle. Children are (1) at substantial risk from consuming such supplements due to their size and metabolism, which causes them to react differently to these supplements than adults; (2) more susceptible to consuming supplements in dangerous ways, due to their poor assessment of risks associated with taking supplements; (3) vulnerable to additional long-term health effects, like eating disorders and

steroid use, which are linked to consuming weight loss and muscle growth supplements from a young age; and (4) especially impressionable to targeted advertising for these products.

A. Weight Loss and Muscle Growth Supplements are Dangerous for Children to Consume at All

Children who consume weight loss and muscle growth supplements face serious physical health effects like kidney disease and cardiac arrhythmias or even death. Michele LaBotz & Bernard A. Griesemer, *Use of Performance Enhancing Substances*, 138 Pediatrics, no. 1, 2016 at e1, e5–e7; Vivienne M. Hazzard et al., *Diet Pill and Laxative Use for Weight Control Predicts First-Time Receipt of an Eating Disorder Diagnosis Within the Next 5 Years Among Female Adolescents and Young Adults*, 54 Int'l. J. Eating Disorders 1289, 1290 (2021). A 2019 study showed that the risk of severe medical outcomes including death, disability, and hospitalization for persons aged 0 to 25 years was three times higher from consuming weight loss and muscle building dietary supplements than from consuming vitamins. Or et al., *supra*, at 1.[4]

Accordingly, the FDA has issued a warning related to teen and young adult consumption of muscle building supplements, citing "serious or life-threatening

[4] This study drew from voluntary reports by consumers and healthcare professionals and mandatory reports from supplement manufacturers. Or et al. at 2.

health problems" from their consumption, such as: [i]ncreased risk of heart attack or stroke; [p]sychosis/hallucinations; [s]leep disturbances; [s]exual dysfunction; [l]iver injury and acute liver failure; [i]nfertility; [p]regnancy miscarriage; [and] [t]esticular shrinkage"). FDA, *FDA Warns of Use of Selective Androgen Receptor Modulators (SARMs) Among Teens, Young Adults*, U.S. Food & Drug Administration (Apr. 26, 2023), https://www.fda.gov/consumers/consumer-updates/fda-warns-use-selective-androgen-receptor-modulators-sarms-among-teens-young-adults.

Consistent with these concerns, the American Academy of Pediatrics recommends against children consuming weight loss and muscle gain supplements. Neville H. Golden et al., *Preventing Obesity and Eating Disorders in Adolescents*, 138 Pediatrics, no. 3, 2016 at e1, e6; LaBotz & Bernard A. Griesemer, at e5–e7. And the Cleveland Clinic similarly recommends that children not consume muscle building supplements. *See Diets and Supplements for Teens: What's Dangerous and What's Healthy*, Cleveland Clinic (Dec. 5, 2022), https://health.clevelandclinic.org/diets-and-supplements-can-be-dangerous-for-teens; *see also Dietary Supplements for Weight Loss*, Nat'l Inst. of Health (Mar. 22, 2021), https://ods.od.nih.gov/factsheets/WeightLoss-Consumer (noting "makers of weight-loss supplements rarely carry out studies in people to find out whether their product works and is safe").

B. Children Are Likely to Consume Weight Loss and Muscle Growth Supplements in Dangerous Ways

Children may suffer greater harms from ingesting weight loss and muscle growth supplements than adults because they are at heightened risk of consuming those products in unsafe ways due to their immature neurodevelopment and inferior ability to perceive and sufficiently account for risks.

A study of dietary supplement use among Australian young adults found unsafe consumption among that group due to misconceptions regarding the health risks associated with consuming such products. *See* Alexander Campbell et al., *Motivators of Indiscriminate and Unsafe Supplement Use among Young Australians*, 18 Int'l J. Env't. Rsch. Pub. Health, no. 19, 2021 at 1, 2. Few children verify or check information about supplements with a nutritionist or doctor before consuming them, compounding their risk from ingesting products like dietary supplements for weight loss or muscle growth. *See* Junaura Barretto et al., *Use of Dietary Supplements by Children and Adolescents*, 100 J. Pediatra 531 (2024).

Children are also at unique risk of adverse health events if they combine dietary supplements with medications in unsafe ways. Children metabolize food products and drugs differently than adults, and as a result, may experience different, unsafe interactions between supplements and FDA-approved drugs than will adults. FDA, *Mixing Medications and Dietary Supplements Can Endanger Your Health*

(June 2, 2022), https://www.fda.gov/consumers/consumer-updates/mixing-medications-and-dietary-supplements-can-endanger-your-health. The FDA warns: "Children's metabolisms are unique, and at different ages they metabolize substances at different rates." As a result, "[f]or kids, ingesting dietary supplements together with other medications make adverse events a real possibility." *Id.*

Children may also not appreciate or understand that supplements they take can cause other prescribed medications to be substantially less effective or even ineffective. *See, e.g.*, Hlengwa et al., *Herbal Supplements Interactions with Oral Oestrogen-Based Contraceptive Metabolism and Transport*, 34 Phytotherapy Rsch. 1519 (2019) (discussing evidence that weight-loss supplements may cause contraceptive failure or otherwise interact with oral contraceptives, an interaction that is not broadly publicized as related to consuming weight loss supplements).

C. Taking Weight Loss and Muscle Growth Supplements as a Child Can Lead to Other Harmful Health Effects

Studies have shown that consuming weight loss and muscle growth supplement as a child is linked to other long-term harmful health effects; in particular, childhood consumption of these supplements may lead to an increased risk of eating disorders or anabolic steroid abuse later in life.

Studies have shown that, especially for adolescent girls and young women, consuming weight loss supplements can "serve as a 'gateway' behavior to escalating weight-control practices, dysregulate normal digestive functioning leading to more

disordered eating, and exacerbate emotion dysregulation through dependence on unhealthy and ineffective coping." Jordan A. Levinson et al., *Diet Pill and Laxative Use for Weight Control and Subsequent Incident Eating Disorder in US Young Women: 2001–2016*, 110 Am. J. Pub. Health 109, 109 (2020); *see also* Hazzard et al., *supra*, at 1292–93. A 2020 study published in the *American Journal of Public Health* found that girls and young women who used over-the-counter diet pills had a more than five times greater risk than those who did not of receiving an eating disorder diagnosis within one to three years.[5] Levinson et al., *supra*, at 110. A 2021 study published in the *International Journal of Eating Disorders* similarly found that girls and young women who consumed diet pills had three-and-a-half times greater risk than those who did not of reporting a first-time eating disorder diagnosis five years later. Hazzard et al., *supra*, at 1291.

Studies have shown that childhood consumption of muscle growth supplements, too, can serve as a gateway to other serious, long-term health effects. One study found that consumption by young people of muscle growth supplements with ingredients like creatine was associated with a three-fold higher risk of steroid use

[5] Eating disorders, of course, risk severe consequences for adolescents, especially girls. *See, e.g.*, Hazzard et al., *supra*, at 1290 (noting consequences such as "substantial psychosocial impairment, psychiatric comorbidity, physical consequences such as gastrointestinal and cardiovascular complications," and "elevated mortality rate").

in early adulthood. Jason M. Nagata et al., *Association Between Legal Performance-Enhancing Substances and Use of Anabolic-Androgenic Steroids in Young Adults*, 174 JAMA Pediatrics 992, 992–93 (2020). Another study found that boys and young men who used muscle growth supplements were over eight times more likely to start taking anabolic-androgenic steroids within one to five years.[6] A.J. Bulens et al., *Use of Muscle-Building Dietary Supplements Prospectively Associated with Onset of Illicit Anabolic-Androgenic Steroid Use in Boys and Young Men*, 5–6 (publication forthcoming).

D. Children Are at Increased Risk of Taking Weight Loss and Muscle Building Supplements Because They Are Targeted by Marketing for these Products

Children are especially likely to consume weight loss and muscle building supplements because those products are aggressively marketed to them. As far back as 2002, the FTC observed targeted advertising of weight loss supplements to children. Fed. Trade Comm'n, *FTC Testifies on the Marketing of Dietary Supplements to Children* (June 16, 2004), https://www.ftc.gov/news-events/news/press-releases/2004/06/ftc-testifies-marketing-dietary-supplements-children. Weight loss and muscle building supplements are commonly marketed online, where children

[6] The severe adverse consequences of consuming such steroids are well established. *See, e.g.*, Campbell, *supra*, et al. at 2 (discussing "adverse effects on the cardiovascular system, atherosclerosis, hypertension, arrhythmia, thrombosis, and erythrocytosis").

are likely to encounter them, Jennifer L. Pomeranz et al., *Over-the-Counter and Out-of-Control: Legal Strategies to Protect Youth from Abusing Products for Weight Control*, 103 Am. J. Pub. Health. 220, 220 (2013), outside the supervision of adults. Jennifer E. Carroll, et al., *Children's Perception of Food Marketing Across Digital Media Platforms*, 3 AJPM Focus, June 2024, at 2; Jenny Radesky et. al., *Digital Advertising to Children*, 146 Pediatrics, July 2020, at 1. They are also commonly and increasingly marketed with celebrity endorsements and on influencer-based marketing on social platforms. Jennifer L. Pomeranz et al., *supra*, at 220; Joshua J. Klein & Scott J. Schweikart, *Does Regulating Dietary Supplements as Food in a World of Social Media Influencers Promote Public Safety?*, 24 AMA J. Ethics 396 (2022).

Children are especially susceptible to this type of advertising. There is evidence that children have more trouble than adults in distinguishing advertisements from entertainment, *see* Carroll et al., *supra*, at 2, and can be especially impressionable to advertising of weight loss and muscle growth dietary supplements—more so than adults—especially when their peers engage in similar behavior. Leah H. Somerville, *The Teenage Brain: Sensitivity to Social Evaluation*, Curr Directions. in Psychol. Sci. at 121, 121 (2013); Mara van der Meulen et al, *Brain Activation upon Ideal-Body Media Exposure and Peer Feedback in Late Adolescent Girls*, Cognitive Affect Behav. Neuroscience at 712, 712 (2017); *see also* Lauren E. Sherman et al,

The Power of the Like *in Adolescence: Effects of Peer Influence on Neural and Behavioral Responses to Social Media*, Psych. Sci. at 1027, 1030–31 (2016) (when adolescents are presented with images associated with "risky behavior" or banned substances and then shown that their peers had "liked" similar content, they are more likely to like it themselves).

III. Weight Loss or Muscle Building Supplements Are Easily Identified

While Plaintiff-Appellant claims that it "do[es] not understand what the Act actually requires or even what it means" for a product or an ingredient to "aid[] in weight loss or muscle building," ECF No. 25.1 at 14, manufacturers and sellers know and are readily able to identify which supplements are "labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building," N.Y. Gen. Bus. Law §391-oo(1)(a).

For thirty years, federal law has required manufacturers to disclose precisely that information to the FDA. Under the Dietary Supplement Health and Education Act of 1994, as well as Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 343(r)(6)), and 21 CFR § 101.93, manufacturers must disclose to the FDA "structure/function claims" 30 days in advance of the marketing or selling products with those claims—that is, any claim that a nutrient or dietary ingredient is intended to affect or maintain the normal structure or function of the human body. *See* 21 CFR § 101.93. Manufacturers must also disclose claims about a product's

effect on a consumer's well-being or on a nutrient deficiency disease. *See* 21 U.S.C. § 343(r)(6).

These disclosures, which are public and searchable on the FDA's website,[7] show that manufacturers routinely claim that their supplements are for weight loss or muscle growth. From 2013 to the present—the period in which supplement disclosures are searchable on the FDA's website—manufacturers submitted thousands of disclosures using terms like "weight loss," "weight management," or "metabolism." Manufacturers submitted thousands more disclosures related to "muscle" growth supplements.

[7] The FDA's website allows users to search claim disclosure letters, which are sorted by year. Limited key terms including "weight loss" or "muscle growth" can be searched directly on that website (*see* regulations.gov), or via public extensions built on top of that website that allow additional search functionalities. *See, e.g.*, STRIPED FDA Docket Explorer, available at https://www.hsph.harvard.edu/striped/fda-docket-explorer/.

Chart 1: Keyword searches of claim disclosures made to the FDA (2013–2023)

Year	"Weight Loss"	"Weight Management"	"Weight"	"Muscle"	"Metabolism"
2013	21	21	73	122	215
2014	16	20	51	98	191
2015	38	56	148	250	250
2016	36	43	117	250	250
2017	27	29	75	202	196
2018	19	23	71	168	180
2019	22	35	74	210	213
2020	14	26	70	176	250
2021	26	33	91	175	222
2022	17	14	66	162	205
2023	11	16	42	122	138
Total	**247**	**316**	**878**	**1935**	**2310**

Source: FDA Docket Explorer, STRIPED (https://www.hsph.harvard.edu/striped/fda-docket-explorer/).

Review of specific FDA disclosures by supplement manufacturers in the last year reveals that manufacturers commonly claim that their products "support loss of body fat" and "reduc[e] . . . waist & hip size" (CK Ingredients Inc. letter to FDA re "CardiaSlim" supplement, Sept. 14, 2023); support "weight management" and "reduce[] waist circumference" (Health & Her Ltd. letter to FDA re weight management probiotic, Nov. 24, 2023); "support[] . . . fat metabolism" and "weight management" (Jetson Health LLC letter to FDA re "Fit" probiotic, July 6, 2023); burn "extra . . . calories," "reduce[] belly fat," and "reduce body fat mass" (Waterpure, Inc., letter to FDA re "MyMetabolism" "Pro Clinical" supplement, May 31, 2022); and "support . . . weight management," "support[] a flatter stomach," and "ease[] bloating" (Hum Nutrition Inc. letter to FDA re "Flatter Me" supplement, August 8,

2023), among other similar claims. Manufacturers similarly claim that their supplements "increase[] muscle mass" and "strength" (True North Nutrition letter to FDA re "Mammoth" supplement, Nov. 27, 2023); "promote testosterone production, energy metabolism, and muscle function" (Church & Dwight, Co., Inc. letter to FDA re "Trojan Man Boost" supplement, June 27, 2023); and "support optimal muscle mass, strength and fat loss" (Performance Health Products, Ltd letter to FDA re "Apex Labs" "Muscle Defense" supplement, Oct. 10, 2023), among other similar claims.

Retailers and online sellers also have readily identified weight loss and muscle building supplements to comply with the Act. Amazon, for example, began requiring third-party sellers to certify whether their supplement products were intended for "weight management" or "sports nutrition and body building." *See Listings Lounge: New Requirements for Dietary Supplements*, Amazon (Apr. 2, 2024), https://seller-central.amazon.com/seller-forums/discussions/t/c23c51e6-159c-4d01-b297-9836d7d16419. The Vitamin Shoppe, a national chain for vitamin and supplement sales, similarly changed its computer systems to identify restricted supplements that could no longer be sold to minors. Maysoon Khan, *Selling Weight-Loss and Muscle-Building Supplements to Minors in NY Is Now Illegal*, Associated Press (Apr. 25, 2024), https://apnews.com/article/new-york-law-dietary-supplements-weight-loss-

77ca3e0fdc4b291636e3768ffb5c9b25. Vitamin Shoppe stores in New York now require consumers to present an ID when purchasing age-restricted weight loss and muscle building supplements. *Id.*

Industry trade publications for supplement manufacturers have published several "how-to" guides for complying with the Act—indicating that the industry has no trouble understanding what is required. *See, e.g.*, Danielle Masterson, *Is Your Age Verification Process in Place? Everything You Need to Know About Selling in NY*, NutraIngredients USA (May 23, 2024), https://www.nutraingredients-usa.com/Article/2024/05/23/Is-your-age-verification-process-in-place-Everything-you-need-to-know-about-selling-in-NY.

CONCLUSION

Weight loss and muscle building supplements pose demonstrated harms if consumed by children. Restricting sales of these hazardous products to children is highly likely to benefit public health by reducing children's consumption of those products—just as similar restrictions on tobacco have done. Michael W. Long et al., *Cost-Effectiveness of 5 Public Health Approaches to Prevent Eating Disorders*, 63 Am. J. of Preventive Medicine 935 (2022); April K. Wilhelm MD, MPH et al., *Local Tobacco 21 Policies are Associated With Lower Odds of Tobacco Use Among Adolescents*, 24 Nicotine & Tobacco Rsch. 478 (2022); James Macinko & Diana Silver,

Impact of New York City's 2014 Increased Minimum Legal Purchase Age on Youth Tobacco Use, 108 Am. J. Public Health 669 (2018).

Amici respectfully join Defendant-Appellee in urging the Court to affirm the District Court's judgment dismissing Plaintiff-Appellant's request for a preliminary injunction.

Dated: New York, NY
August 14, 2024

Respectfully submitted,

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