UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

AIMEE LOMEDICO on behalf of herself and all others similarly situated,

Plaintiff,

Case No.:

v.

AMERICAN BEHAVIORAL RESEARCH INSTITUTE LLC, d/b/a Relaxium,

Defendant.

COMPLAINT

Plaintiff Aimee Lomedico, on behalf of herself and all others similarly situated ("Plaintiff"), by and through her undersigned counsel, Denlea & Carton LLP, states for her Complaint against the American Behavioral Research Institute LLC, d/b/a Relaxium ("Relaxium" or "Defendant"), as follows:

PRELIMINARY STATEMENT

Sleep Wellness Revolutionized! RELAXIUM® Sleep Aid is an All-Natural Clinically Proven Formula. it's Unique Triple- Action Approach with Exclusive Valerest® Addresses the Root Cause of Sleeplessness & Stress

1. This action seeks to redress the false, misleading, and deceptive advertising and packaging claims that Relaxium has made in connection with the sale of its purportedly "all-natural, clinically proven" sleep aid supplement marketed under the not-so-subtle brand name "Relaxium Sleep."¹ Despite claims that it is a "scientifically" tested and proven dietary

¹. <u>https://www.relaxium.com/sleep.php?btl=3&</u>

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supplement, a designation intended to exploit the imprimatur of "scientific authority" to elicit trust from the average consumer, the science behind Relaxium Sleep is threadbare and illusory. Worse yet, it is being peddled by a self-anointed "sleep expert," who has no discernible experience or background in treating sleep disorders of any variety, and with paid testimonials from a lineup of minor Hollywood figures and former Arkansas Governor turned radio host, Mike Huckabee.

2. According to a recent report, the global market for sleeping aids generated nearly \$60 billion dollars in 2020.² That market is projected to reach a staggering \$111.9 billion dollars by 2030.³ By far the largest subset of sleeping disorders plaguing Americans is insomnia, an all-too-common disorder characterized by difficulty falling and staying asleep.⁴ Unfortunately, the COVID-19 Pandemic only exacerbated a deep rooted, pre-existing problem in American society. "In 2020 alone more than half of Americans say their sleep worsened due to the pandemic, and 76% of American's admitted to purchasing a sleep aid to help them fall asleep, stay asleep or improve the quality of sleep had at night."⁵

3. Further, given the expense and side effects associated with prescription sleep-aid medications, millions of Americans have found themselves increasingly turning to natural overthe-counter supplements.⁶ However, since these types of supplements (referred to as nutraceuticals) are not regulated by the Food and Drug Administration ("FDA"), American consumers are left to navigate the sleep-aid market with little to no guidance apart from the unscrupulously extravagant claims often put forward by the supplement manufacturers themselves.

². <u>https://www.globenewswire.com/news-release/2022/03/29/2411532/0/en/Sleep-Aids-Market-Is-Expected-to-Reach-111-9-Billion-by-2030-Claims-Allied-Market-Research.html</u>

³. Id. 4 Id.

 $^{^4}$ Id.

⁵. <u>https://www.forbes.com/sites/nicoleroberts/2022/03/20/despite-65-billion-a-year-sleep-aid-market-americans-remain-sleep-deprived/?sh=10367f5e7521</u>

⁶. <u>https://www.sleepfoundation.org/sleep-aids/natural-sleep-aids</u>

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4. Given the dearth of comprehensive regulation, American consumers have repeatedly found themselves targeted by opportunistic fraudsters hawking dubious and, sometimes, dangerous supplements. By way of example, in 2015, GNC, Target, Walgreens, and Walmart, four of the nation's largest retailers, were forced by the New York State Attorney General's office to pull a variety of fraudulent herbal supplements from their shelves, including several sleep aids, which contained no herbs at all but did contain other unlisted substances like rice, pine, or asparagus.⁷

5. In 2019, the FDA discovered that another "all-natural" sleep aid widely sold in retails stores under the brand "U-Dream" actually contained the controlled substance eszopiclone, the active ingredient in the prescription sleep aid Lunesta.⁸

6. Regrettably, the nutraceutical market is particularly susceptible to shameless and deceptive advertising. Over the years, American consumers have consistently been exposed to the prospect of either spending their hard-earned money on useless supplements or, alternatively, ingesting powerful pharmacological cocktails under the mistaken belief that they were consuming "natural" products.

7. Relaxium Sleep is billed as a unique sleep aid developed by "renowned neurologist" and "founder" of the American Behavioral Research Institute, Dr. Eric Ciliberti, MD. ("Ciliberti") for the specific purpose of helping "patients and millions of others who suffer from lack of sleep."⁹ In addition to being marketed as a "perfect synergistic blend of melatonin, magnesium, passionflower, GABA, ashwagandha, and chamomile," Relaxium Sleep is also

⁷. <u>https://well.blogs.nytimes.com/2015/02/03/sidebar-whats-in-those-supplements/; https://ag.ny.gov/press-release/2015/ag-schneiderman-asks-major-retailers-halt-sales-certain-herbal-supplements-dna</u>

^{8. &}lt;u>https://www.fda.gov/drugs/medication-health-fraud/public-notification-u-dream-full-night-contains-hidden-drug-ingredient</u>

^{9.} https://www.relaxium.com/sleep.php?btl=3&

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widely advertised as "the only sleep solution that contains a proprietary ingredient, Valerest, to help induce sleep safely."¹⁰

8. Of course, this is untrue. Valerest, the purported secret ingredient behind Relaxium

Sleep, is nothing more than an unremarkable blend of valerian root extract and hops:

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SALE	✓ CLINICALLY TE ✓ PROVEN EFFE	CTIVE			
	Supplement Serving Size 2 Capsules Servings Per	Fac Container 60			
	and the second	Amount per servin			
	Magnesium (as Magnesium Oxide, Magnesium Citrate and Magnesium Glycinate)	100 mg	25%		
	L-Tryptophan	500 mg	t		
	Valerest® Proprietary Blend of Valerian (Valeriana officinalis) (root) extract 5:1, Hops (Humulus lupulus) (aerial part) extract 10:1	228.9 mg	†		
(Ashwagandha (Whithania somnifera) (root and leaf) extract (standardized to 8 % withanolide glycoside conjugates)	125 mg	†		>
	GABA (Gamma Amino Butyric Acid)	100 mg	t	· ·	
	Chamomile (Matricaria recutitia) (flower)	75 mg	t		
	Passionflower (Passiflora incamata) (whole herb)	75 mg	†		
	Melatonin	5 mg	†		
	† Daily Value (DV) not established.				
	OTHER INGREDIENTS: Rice Flour, Cellulose (Capsule)	Vegetable			
	Valerest" is a registered trademark Behavioral Research Institute, USA	of the Am	erican		
	CONTAINS NO: GMO, gluten, nuts, dairy, eggs, tree nuts, fish, shellfish, wheat, barley, or artificial ingredien	soy, corn,			

9. Rather than being unique or proprietary, this an exceedingly common herbal cocktail found in countless other sleep aid nutraceuticals whose efficacy has long been deemed insignificant when compared to a placebo.¹¹ At best, the efficacy of valerian root and hops in

¹⁰. Id.

¹¹. <u>https://pubmed.ncbi.nlm.nih.gov/16335333/</u>

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treating insomnia and other sleep disorders is inconclusive, making the affirmative misrepresentations peddled by Defendants a deliberate falsehood.¹²

10. Nevertheless, Relaxium has for years marketed Relaxium Sleep and its "Valerest" component as being "clinically proven" to help people "fall asleep faster," "stay asleep longer," and "wake refreshed and alert," as seen below:

<complex-block> SUE C C C</complex-block>	RELAXIUM [®] shop our story our research revi	WS # CART ORDER NOW: 1-800-709-4538
Ibottle (30 Days supply) - Get \$20 OFF Ibottle (30 Days supply) - Get \$20 OFF	Image: State	Atural Sleep Support Clinically Proven to Help You: TALL ASLEEP FASTER* STAY ASLEEP LONGER* WAKE REFRESHED AND ALERT* 00% No-Risk Money Back Guarantee
		Subscribe & Save Save An Additional 10% + Free Shipping
Clinically Proven".		+ \$7.95 Shipping

11. Despite the misleading stamp of scientific authority, there has only ever been one "clinical study" conducted to test the efficacy of Relaxium Sleep and, unsurprisingly, this less than rigorous study was sponsored by none other than Relaxium itself.¹³

12. The practical limitations of the faux clinical study, moreover, were myriad and included:

- a. an unrepresentative sample size,
- b. the use of subjective questionnaires,

¹². <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7585905/</u>

¹³. <u>https://truthinadvertising.org/wp-content/uploads/2022/05/1103-A-Study-to-Evaluate-the-Effects-of-Relaxium.pdf</u>

- c. the exclusion of any participants with pre-existing neurological conditions (i.e., anxiety, depression, chronic pain, etc.) who are likely to be the very consumers who would benefit from a truly "clinically proven" supplement,
- d. and the obvious flaw of tracking and interpreting the quality of sleep participants experience with a Fitbit *Inspire* (which crudely tracks "sleep" by the participants bodily movements at night).¹⁴

13. Much like the study itself, the proclamation that Dr. Ciliberti is a "renowned" sleep expert who developed Relaxium only after "years of clinical research" appears to be belied by his actual education and training as a general ophthalmologist from Florida who has never once published, studied, or practiced in the field of somnology, or sleep medicine.

14. Contrary to the exaggerated claims made on the Relaxium websites, there is absolutely nothing listed in Dr. Ciliberti's curriculum vitae¹⁵ supporting his self-aggrandizing designation as a world renowned "sleep expert," or supporting his treatment of patients for sleep disorders.

15. Indeed, Dr. Ciliberti's "relevant" experience appears to be drawn from his work in the field of neuro-ophthalmology, a discipline involving the relationship between neurologic and ophthalmic diseases. The American Board of Neurology, however, maintains no record of him being board certified and the Florida State Department of Health has no record of Dr. Ciliberti holding <u>any</u> specialty certification.¹⁶ It is therefore clear that, in addition to disseminating a bevy of false affirmative claims designed to deceptively market Relaxium Sleep as a clinically proven

¹⁴. <u>https://truthinadvertising.org/blog/a-lullaby-of-deception/</u>

 ¹⁵. https://wp02-media.cdn.ihealthspot.com/wp-content/uploads/sites/460/2020/05/05201251/Eric-Cilliberti-MD.pdf
 ¹⁶. https://mga-

internet.doh.state.fl.us/MQASearchServices/HealthCareProviders/Details?LicInd=68911&ProCde=1501

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sleep-aid supplement, Dr. Ciliberti is actively misrepresenting his own credentials to bolster the unremarkable snake oil he peddles to unsuspecting consumers.

16. To be sure, outside of the Relaxium websites and related promotional materials, including an apparent advertising partnership with former Arkansas Governor Mike Huckabee,¹⁷ there is no independent reference anywhere to Dr. Ciliberti's alleged experience or stellar reputation as a sleep expert. Indeed, Mr. Huckabee must be a relative newcomer to the nutraceutical community, because when he was pushing a "diabetes solution kit" with no pills, he claimed "they're going to keep you a loyal, pill popping, finger pricking, insulin-shooting customer, so big pharma and the mainstream medical community can rake in over \$100 billion a year annually (sic)." Now, he is a card-carrying, pill popping, purveyor.

17. Compounding the bad science, the dubious medical pedigree of its front man, and obvious conflicts of interests, the marketing force behind the Relaxium confidence operation belongs to none other than Timea Ciliberti, Dr. Ciliberti's wife and, not coincidentally, the Chief Executive Officer ("CEO") of the American Behavioral Research Institute. There is no indication that Ms. Ciliberti, for her part, holds any medical degrees, licenses, or qualifications relevant to the development, testing, or distribution of unregulated nutraceuticals.

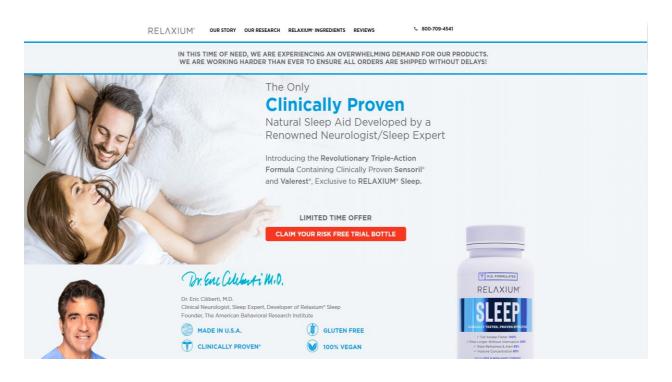
18. To the contrary, a review of Ms. Ciliberti's LinkedIn profile reveals not an ounce of detail regarding her professional history and background but, instead, contains an endless cavalcade of posted advertisements for Relaxium Sleep, among other Relaxium branded products.¹⁸

¹⁷. <u>https://www.prnewswire.com/news-releases/struggling-with-covid-somnia-desperate-for-a-good-nights-sleep-gov-mike-huckabee-announces-study-showing-relaxium-helps-you-sleep-and-wake-up-refreshed-301412711.html</u>

¹⁸. <u>https://www.linkedin.com/in/timea-ciliberti-56088919/recent-activity/</u>

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19. Each advertisement, in addition to providing a purported factoid relating to sleep disorders, also contains a link to <u>https://www.tryrelaxium.com/fb/</u>, which greets users with the below depicted landing page boldly (and, falsely) touting Relaxium Sleep, in prominent lettering, as "The Only Clinically Proven Natural Sleep Aid Developed by a Renowned Neurologist/Sleep Expert:



20. By deceptively misrepresenting the efficacy of Relaxium Sleep, as well as Dr. Ciliberti's credentials, Defendant has defrauded consumers into purchasing the supplement and has commanded and continues to command a price premium for each bottle sold.

21. Based upon the unfair and deceptive "Clinically Proven" claim, Plaintiff and consumers like her purchased Relaxium Sleep because they believed that it was clinically proven to help them fall asleep faster, stay asleep longer, and wake refreshed. Plaintiff and other consumers purchased Relaxium Sleep with a reasonable expectation as to its premium quality and, more importantly, clinical efficacy. Moreover, Plaintiff purchased Relaxium Sleep

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notwithstanding the fact that similar sleep aid supplements not marketed as "clinically proven" were available from other manufacturers for much less money.

22. Accordingly, Plaintiff and her fellow class members have been injured because they purchased Relaxium Sleep supplements that they would not have otherwise purchased and/or paid a premium for a sleep aid supplement that purported to be clinically proven to improve sleep quality but, in actuality, was not clinically proven to be effective. Plaintiff and members of the class were deceived by Defendant's fraudulent marketing and Defendant profited from that deception at Plaintiff's and the class members' expense.

23. By this action, Plaintiff seeks to redress Relaxium's unfair and deceptive marketing campaign built upon the misleading claims that it makes and to obtain the financial recompense to which Plaintiff and her fellow class members are entitled.

THE PARTIES

24. Plaintiff Aimee Lomedico is an individual who resides in Stormville, New York.

25. Defendant American Behavioral Research Institute LLC d/b/a Relaxium is a Florida limited liability company with its principal address at 1515 North Federal Highway, Suite 300, Boca Raton, Florida 33432.

26. Relaxium manufactures, markets, and sells Relaxium Sleep through online and brick-and-mortal retail stores such as GNC, Bed Bath & Beyond, and Amazon.

JURISDICTION AND VENUE

27. This Court has subject matter jurisdiction over this action pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d), because (1) the amount in controversy exceeds

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the sum or value of \$5,000,000.00, exclusive of interest and costs, and (2) the named Plaintiff and Defendant are citizens of different states. 28 U.S.C. § 1332(d)(2)(A).

28. The Court also has jurisdiction over this action pursuant to 28 U.S.C. § 1332(a), as the parties are diverse and the amount in controversy exceeds the requisite threshold.

29. This Court may exercise jurisdiction over Defendant because Defendant has sufficient minimum contacts in New York and purposely avails itself of the markets within New York through the promotion, sale, marketing, and distribution of its products, thus rendering jurisdiction by this Court proper and necessary.

30. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events giving rise to Plaintiff's claims occurred within this judicial district and because Defendant has marketed and sold the products at issue in this action within this judicial district and has done business within this judicial district.

CHOICE OF LAW

31. New York law governs the state law claims asserted herein by Plaintiff and the class members she seeks to represent.

32. New York has a substantial interest in protecting the rights and interests of New York consumers against wrongdoing by companies that market and distribute their products within the State of New York.

FACTUAL BACKGROUND

I. Due to the Premium Consumers are Willing to Pay for Products that are Backed by Science, Manufacturers Routinely Misrepresent That Their Products Have Been Scientifically Proven to be Effective

33. Consumers who are seeking relief from sleep related problems and disorders are particularly vulnerable targets for unscrupulous manufacturers and advertisers. In a bid to avoid

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the side effects and chemical dependencies that can arise when using prescription sleep medications, consumers plagued by sleep problems are willing to pay a premium for nutraceutical supplements that are scientifically proven to be effective. In an overcrowded marketplace where beneficial health claims are ubiquitous, being able to demonstrate the efficacy of a product is critical.

34. Unsurprisingly, in order to differentiate their products and gain a competitive edge, manufacturers and advertisers routinely mislead consumers by claiming that the efficacy of their products is backed by science (*i.e.*, "establishment claims"), when, in fact, it is not. Equally unsurprising is the fact that Courts are wary of claims by manufacturers that their product has been scientifically proven to be effective when, as here, those claims are false.

35. An advertiser's health-related claims about the efficacy of a product must "be supported with 'competent and reliable scientific evidence," which the Federal Trade Commission (the "FTC") defines as "'tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have 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."¹⁹ As the FTC has stated, "well-controlled human clinical studies are the most reliable form of evidence."²⁰

II. <u>Relaxium Markets Its Sleep Aid Supplement as "Clinically Tested, Proven Effective"</u>

36. The American Behavioral Health Institute LLC was founded in or around 2009 and, in November 2010, began marketing and selling its federally trademarked "Relaxium" brand of

¹⁹. FTC, Dietary Supplements: An Advertising Guide to Industry, Section II(B), at <u>https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry</u>

²⁰. FTC, Dietary Supplements: An Advertising Guide to Industry, Section II(B)(2), at <u>https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry</u>

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dietary supplements to meet the demands of a growing market consisting of consumers that were looking for alternatives to habit forming prescription sleep medications.²¹

37. Presently, Relaxium is a nationally recognized supplement brand whose commercials regularly appear on cable television, including FOX News and Newsmax. The supplement is also marketed through two websites, relaxium.com and tryrelaxium.com/fb, both of which falsely describe the flagship supplement "Relaxium Sleep" as a clinically tested and proven natural sleep aid. In addition, Relaxium markets its products though various social media sites such as Facebook, Instagram, and LinkedIn.

38. According to CEO Timea Ciliberti's LinkedIn page, Relaxium leverages a "\$100million-dollar national television advertising campaign" as a result of which Relaxium is now "a leading nutraceutical brand, and a clear leader in the Sleep and Mood categories."²² It goes on to state that "[w]ith a solid foundation and backed by multiple clinical studies, RELAXIUM® has achieved unparalleled consumer demand and loyalty."

39. Likewise, the packaging on the "Relaxium Sleep" bottle (as advertised on Relaxium's websites)²³ prominently displays the words "M.D. Formulated" and "Clinically Tested, Proven Effective," as seen below:

²¹. <u>https://tsdr.uspto.gov/#caseNumber=77862102&caseType=SERIAL_NO&searchType=statusSearch</u>

²². <u>https://www.linkedin.com/in/timea-ciliberti-56088919/</u>

²³. <u>https://www.relaxium.com/sleep.php?btl=1&</u>



40. As such, it is clear that Relaxium Sleep is deliberately and conspicuously marketed to unsuspecting consumers as a scientifically proven supplement that was not only developed by a medical doctor, but whose efficacy has been rigorously tested and confirmed.

III. <u>The "Clinically Tested, Proven Effective" Claim is False and Misleads Consumers</u>

41. Reasonable consumers understand that the "Clinically Tested, Proven Effective" claim conveys that the dietary supplement sold under the name "Relaxium Sleep" has been proven to increase sleep duration, help people fall asleep faster, leave people feeling refreshed, and to improve concentration. Indeed, these four metrics are distinctly identified on the label as the benefits to be obtained by taking the supplement.

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42. The "Clinically Tested, Proven Effective" claim, however, is patently false since the only clinical study conducted testing Relaxium Sleep clearly <u>did not</u> prove its effectiveness.

43. Indeed, the study clearly hedges its conclusions and stresses that "the contribution of each of the 6 sleep-inducing or anxiety/stress reducing components [in Relaxium] *cannot be determined with this study*." *See* <u>http://www.annexpublishers.com/articles/JISD/1103-A-Study-to-Evaluate-the-Effects-of-Relaxium.pdf</u> (emphasis added).

44. These are the same ingredients that Relaxium openly advertises as part of Dr. Ciliberti's "proprietary" blend and/or formula, which includes an herbal combination trademarked under the name Valerest.

45. The study concludes that Valerest "*may have* also contributed to Relaxium's effects," before going on to examine prior flawed studies that attempted unsuccessfully to determine the efficacy of valerian root as a sleep-inducing supplement. (emphasis added). Thus, contrary to Relaxium's deceptive advertising materials, there is no factual basis for the affirmative claim that the specialized blend of herbs in "Relaxium Sleep" has been "Clinically Tested, Proven Effective." Rather, based upon subjective participant reporting, the study amounts to nothing more than an exercise in inconclusive equivocation, and conjecture.

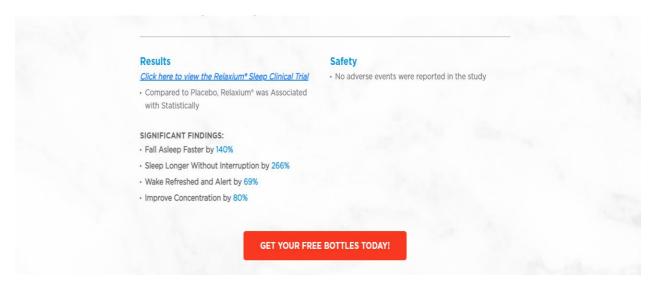
46. Simply stated, the clinical study touted by Relaxium did not actually <u>test</u> any of the ingredients in Relaxium Sleep and, as such, does not <u>prove</u> anything, let alone prove the effectiveness of these ingredients, as falsely claimed, in alleviating or treating sleep disorders.

47. None of these underlying qualifiers and explanations, however, are disclosed to the consumer, which is precisely what makes the advertising of Relaxium Sleep so deceptive and misleading. Relaxium's advertising is very clearly designed to manipulate consumers with an appeal to definitive scientific authority while, at the same time, withholding critical facts and

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conclusions that reveal Relaxium Sleep to be no different than any other non-clinically proven sleep-aid supplement on the market.

48. To be clear, although Relaxium's website purports to provide prospective customers exploring the option of purchasing Relaxium Sleep with a link to the results of the study under the heading "*Click here to view the Relaxium*® *Sleep Clinical Trial*," as seen below, this is yet another act of deception.



49. When one clicks on the link, rather than being directed to a .pdf containing the actual results of the study,²⁴ including clear disclaimers regarding the study's limits, one is directed to a distinct and evidently truncated "Study Summary" .pdf²⁵ that entirely omits any mention of the fact that none of the ingredients in Relaxium Sleep, including the "proprietary" blend Valerest, have been tested for efficacy and, as such, that the contribution of these ingredients to improving the quality of sleep (much less awakening refreshed) has not been determined.

50. However, the deceptions do not stop there. The actual published study, which must be separately located on the internet (therefore making it exceedingly easy to overlook), is titled

²⁴. See supra ¶ 38.

²⁵. <u>https://www.relaxium.com/assets/pdf/clinal_study_new.pdf</u>

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"A Study to Evaluate the Effects of Relaxium in Subjects with *Insomnia*," while the manipulated "Study Summary," which is embedded and promoted on the Relaxium website, is titled "A Study to Evaluate the Effects of Relaxium in Subjects with *Sleep Disorders*." This is a major difference and further underscores the misleading nature of Relaxium's advertising practices.

51. Insomnia is itself but one type of sleep disorder and, as used in most contexts, a generalized reference to symptoms associated with many different underlying conditions.²⁶ For example, insomnia may be caused by something as straightforward and relatively innocuous as stress at work. On the other hand, insomnia may also be the result of serious underlying mental health conditions like depression, alcoholism, chronic pain, post-traumatic stress disorder, and Parkinson's disease, as well other medical conditions like asthma, sleep apnea, an overactive thyroid, or heart disease.²⁷

52. In total, there are over 80 different types of sleep disorders, acute and chronic, varying in their degree of severity.²⁸ By falsely mislabeling the "Study Summary" as reporting the results of a test broadly conducted on subjects with "sleep disorders," Relaxium intended to create the false impression that Relaxium Sleep helps to alleviate a much wider range of conditions and symptoms than those it for which it was actually tested.

53. The deliberate mislabeling of the "Study Summary" to broadly include all "sleep disorders" is all the more egregious, considering that the clinical study identified a broad range of conditions as "Exclusion Criteria," meaning that people with a history of these particular listed conditions were ineligible to participate in the study in the first place.

Id.

²⁶. <u>https://www.mayoclinic.org/diseases-conditions/insomnia/symptoms-causes/syc-20355167</u>

^{27.}

²⁸. <u>https://medlineplus.gov/sleepdisorders.html</u>

54. Per the clinical study, the litany of conditions that fell within the umbrella of

disqualifying "Exclusion Criteria" were listed as follows [emphasis added]:

Subjects with clinically unstable medical abnormality, chronic disease or history or presence of significant neurological disorders (including cognitive disorders), <u>depression</u>, <u>schizophrenia</u>, <u>anxiety disorder</u>, <u>dementia</u>, <u>chronic pain</u>, <u>frequent nightly urination</u> (>2 times per night), <u>seizure disorder</u>, <u>restless leg syndrome</u>, <u>diagnosis of sleep</u> <u>apnea or risk factors for undiagnosed sleep apnea</u> (witnessed apneic episodes) and/or use of psychotropic medication or beta blockers were excluded. Other exclusion criteria included <u>all concomitant</u> <u>medications that are known to affect sleep</u> or those known to interfere with drug metabolizing enzymes activity within 14 and 28 days prior to Day 1, respectively, as well as during the study. A history of <u>alcoholism</u>, <u>drug addiction</u> or participation in a clinical trial within the past year, or 30 days of entering the study, was prohibited.

55. A consumer reviewing the manipulated "Study Summary" on Relaxium's website would have no idea that Relaxium Sleep was, in fact, never tested at all in conjunction with, or proven to alleviate, any sleep disruptions caused by the myriad conditions identified as "Exclusion Criteria."

56. Thus, for example, a consumer with depression or anxiety disorder would be falsely led to believe that any sleep related disruptions they are experiencing could be alleviated using Relaxium Sleep. A consumer with sleep apnea would be in a similar position, as would anyone suffering from "chronic pain," an incredibly broad category that encompasses any pain, anywhere in the body, that lasts more than three months.²⁹

57. For perspective, approximately 40 million Americans, or 19.1% of the population of the United States, suffer from some form of anxiety disorder.³⁰ Approximately 21 million Americans, or roughly 8.4% of the population, suffer from some form of depression.³¹ Another 22

²⁹. <u>https://my.clevelandclinic.org/health/diseases/4798-chronic-pain</u>

³⁰. <u>https://adaa.org/understanding-anxiety/facts-statistics</u>

³¹. <u>https://www.nimh.nih.gov/health/statistics/major-depression</u>

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million Americans are estimated to suffer from sleep apnea.³² Chronic pain affects nearly 50 million Americans.³³

58. Therefore, a consumer purchasing Relaxium Sleep in the hopes of alleviating a form of insomnia or sleep disruption beyond the garden variety type cherry picked for Relaxium's manipulated clinical study would, by virtue of the "Exclusion Criteria," fall into a very wide class of misled consumers across the country.

59. Unsurprisingly, negative reviews for Relaxium Sleep abound, with common complaints being lodged about its lack of effectiveness and, in some cases, adverse and unpleasant side effects, such as wakening with a "hangover" and gastrointestinal disturbances. Overall, the general impression among consumers is that Relaxium Sleep is nothing but a "scam."³⁴



Reviewed in the United States on July 9, 2022

This product does nothing to aid in my sleep. And it cost me \$119 to find that out.

Helpful

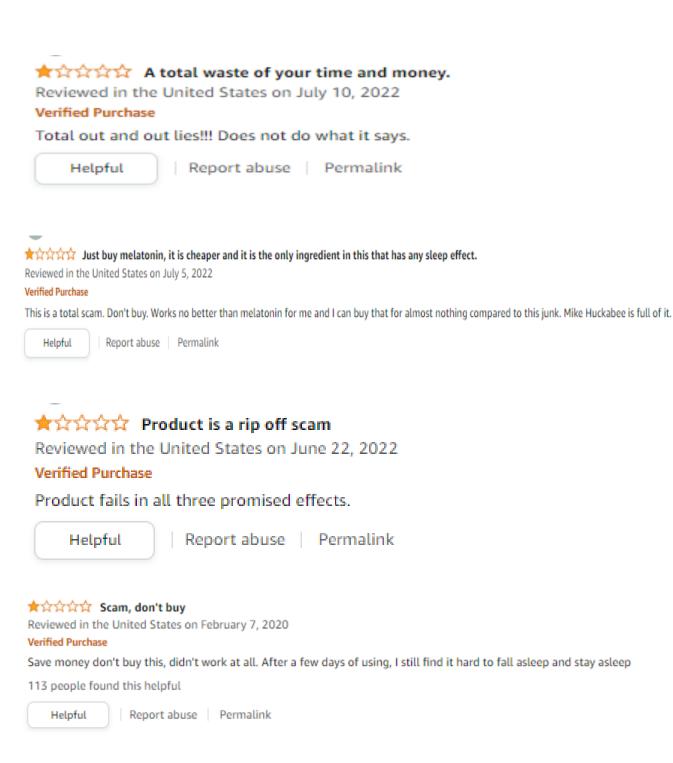
Report abuse Permalink

³². <u>https://www.sleepapnea.org/learn/sleep-apnea-information-</u> <u>clinicians/#:~:text=Sleep%20disorders%2C%20including%20sleep%20apnea,severe%20obstructive%20sle</u> ep%20apnea%20undiagnosed.

 ³³. <u>https://www.healthline.com/health-news/chronic-pain-the-impact-on-the-50-million-americans-who-have-it</u>
 <u>https://www.amazon.com/product-</u>

 $[\]underline{reviews/B00NJ1BQZA/ref=acr_dp_hist_1?ie=UTF8\&filterByStar=one_star&reviewerType=all_reviews\#reviews-filter-bar$

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★☆☆☆☆ JUNK...JUNK...JUNK

Reviewed in the United States on October 24, 2019 Verified Purchase

Total rip off. I don't know what's in this crap...but it isn't any kind of sleep aid. Buying this is like flushing your money down the toilet.

613 people found this helpful

Helpful

Report abuse

★☆☆☆☆ Waste of money

Reviewed in the United States on April 12, 2020

Verified Purchase

Waste of money. Over hyped like every other over the counter sleep aid. Don't waste your money. Does not work

20 people found this helpful

Helpful Report abuse Permalink

★ជំជំជំជំ Be Wary

Reviewed in the United States on September 11, 2021

Verified Purchase

Be wary of this and similar products which are promoted and advertised with "proven" results. This is misrepresented. The all-natural, vegan product did NOT perform as promoted. It kept us AWAKE and did nothing to assist with sleep.

3 people found this helpful

Helpful

Report abuse Permalink

★ជំជំជំជំ Worthless

Reviewed in the United States on September 29, 2021

Verified Purchase

Advertised heavily on TV...Fox and Huckabee. It made NO difference in a week of taking 2 a night, then three....back to two. Tylenol PM works better, much less expensive. This is a sham. Hype is BS.

2 people found this helpful

Helpful Repo

Report abuse Permalink

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60. Relaxium's advertising is very clearly designed to manipulate consumers with an appeal to scientific authority while, at the same time, withholding critical facts and conclusions that belie its false claims and reveal Relaxium Sleep to be no different and no more "effective" than any other sleep-aid supplement on the market that is not marketed as clinically tested and proven.

IV. <u>Plaintiff Purchased Relaxium Sleep</u>

61. Plaintiff purchased Relaxium Sleep in approximately October 2021 at a local GNC store in Hopewell Junction, New York. She took the sleep aid every night before bed over the course of approximately three weeks, with no apparent benefit.

62. Prior to purchasing Relaxium Sleep, Plaintiff was exposed to Relaxium's marketing by way of a television commercial featuring Dr. Ciliberti and touting its efficacy as a "clinically proven" sleep-aid. In addition, Plaintiff reviewed the product packaging, which stated that it was "clinically tested, proven effective."

63. Plaintiff purchased Relaxium Sleep believing that, as a clinically proven product, it would help her fall asleep and improve the quality of her sleep. However, Plaintiff soon discovered that Relaxium Sleep had no effect.

64. Had Plaintiff known that Relaxium Sleep was not clinically proven to improve quality of sleep, she would not have purchased it or, at the very least, would not have paid the premium charged.

65. By way of comparison, a run-of-the-mill sleep-aid such as Natrol "Melatonin Advanced," also available through GNC in a 60-tablet bottle, costs \$10.99. A bottle of GNC branded "Melatonin," 60-tablets, costs \$9.99. A 60-tablet bottle of Spring Valley's "Advanced

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Sleep Formula," with melatonin, can be purchased from Walmart for \$7.88. A 120-table bottle of melatonin can be purchased from Rite Aid for as little as \$4.84.

66. In sum, there is no shortage of alternatives in the realm of over-the-counter sleep aid supplements, many of which sell for a fraction of the hefty \$29.99 price that Plaintiff paid for her bottle of Relaxium Sleep. Plaintiff could have purchased any of the aforementioned supplements, among many others, but was instead induced by Relaxium's deceptive advertising to purchase a bottle of "clinically proven" Relaxium Sleep.

67. Alternatively, had Plaintiff not been misled by Relaxium's deceptive claims as to Relaxium Sleep's clinical effectiveness, and was aware that, in fact, Relaxium Sleep offered no benefits, she would not have purchased it at all.

CLASS DEFINITION AND ALLEGATIONS

68. Plaintiff brings this action on behalf of herself and all other similarly situated consumers in the State of New York pursuant to Rule 23 of the Federal Rules of Civil Procedure, and seeks certification of the following class (the "Class"):

All consumers who, within the applicable statute of limitations period, purchased in the State of New York (whether online or inperson) Relaxium Sleep supplements – manufactured, marketed, distributed, and/or sold by Defendant which Defendant warranted as being "Clinically Tested, Proven Effective" (the "Class Product"). Excluded from the class are Defendant, its parents, subsidiaries, affiliates, officers and directors, judicial officers and their immediate family members and associated court staff assigned to this case, and those who purchased the Class Product for resale.

69. Plaintiff expressly disclaims any intent to seek any recovery in this action for

personal injuries that she or any Class member may have suffered.

70. <u>Numerosity</u>. This action is appropriately suited for a class action. The members of the Class are so numerous that joinder of all members of the Class is impracticable. Plaintiff is

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informed, believes, and thereon alleges, that the proposed Class contains thousands of purchasers of the Class Product who have been damaged by Defendant's conduct as alleged herein. The precise number of Class members is unknown to Plaintiff.

71. Existence and Predominance of Common Questions of Law and Fact. This

action involves questions of law and fact common to the Class. The common legal and factual questions include, but are not limited to, the following:

- Whether Defendant's conduct, as alleged herein, constitutes violations of New York General Business Law Section 349.
- Whether Defendant's conduct, as alleged herein, constitutes violations of New York General Business Law Section 350.
- Whether Defendant labeled, advertised, marketed, and/or sold the Class Product as "Clinically Tested, Proven Effective."
- Whether Defendant's labeling, advertising, marketing, and/or selling of the Class Product as "Clinically Tested, Proven Effective" was and/or is false, fraudulent, deceptive, and/or misleading.

72. <u>Typicality</u>. Plaintiff's claims are typical of the claims of the members of the Class, because, *inter alia*, all Class members have been injured through the uniform misconduct described above and were subject to Defendant's blatant misrepresentation that the Class Product was "Clinically Tested, Proven Effective."

73. Moreover, Plaintiff's claims are typical of the Class members' claims. Plaintiff is advancing the same claims and legal theories on behalf of herself and all members of the Class.

74. <u>Adequacy of Representation</u>. Plaintiff will fairly and adequately protect the interests of the members of the Class. Plaintiff purchased the Class Product, and she was harmed by Defendant's deceptive misrepresentations. Plaintiff has therefore suffered an injury in fact as a result of Defendant's conduct, as did all Class members who purchased the Class Product.

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75. **Superiority**. A class action is superior to other methods for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class members is relatively small compared to the burden and expense that would be entailed by individual litigation of their claims against Defendant. It would be virtually impossible for a member of the Class, on an individual basis, to obtain effective redress for the wrongs done to him or her. Further, even if the Class members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no management difficulties under the circumstances here.

76. Plaintiff seeks monetary damages, including statutory damages on behalf of the entire Class, and other equitable relief on grounds generally applicable to the entire Class. Unless a Class is certified, Defendant will be allowed to profit from its deceptive practices, while Plaintiff and the members of the Class will have suffered damages.

COUNT I (Violation of New York General Business Law Section 349)

77. Plaintiff realleges and incorporates by reference the allegations in paragraphs 1 through 76 as if fully set forth herein.

78. New York General Business Law § 349 prohibits "deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in [New York]."

79. By labeling, advertising, marketing, distributing, and/or selling the Class Product to Plaintiff and the other Class members as "Clinically Tested, Proven Effective" Defendant

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engaged in, and continues to engage in, deceptive acts and practices because the Class Product has not been proven to be effective.

80. In taking these actions, Defendant failed to disclose material information about its product, which omissions were misleading in a material respect to consumers and resulted in the purchase of the Class Product.

81. Defendant has deceptively labeled, advertised, marketed, promoted, distributed, and sold the Class Product to consumers.

82. Defendant's conduct was consumer oriented.

83. Defendant engaged in the deceptive acts and/or practices while conducting business, trade, and/or commerce and/or furnishing a service in New York.

84. Defendant's false "Clinically Tested, Proven Effective" claim was and is misleading in a material respect as to whether the Class Product was, in fact, clinically tested and proven effective.

85. Based on, among other things, Defendant's knowledge that the Class Product was not proven effective in a clinical setting, Defendant knew that by making the misrepresentations addressed herein, Plaintiff and other consumers would be misled into purchasing the Class Product and/or paying a premium price for the Class Product.

86. Plaintiff and the Class members have been aggrieved by and have suffered losses as a result of Defendant's violations of Section 349 of the New York General Business Law. By virtue of the foregoing unfair, unconscionable, and deceptive acts in the conduct of trade or commerce, Plaintiff and the members of the Class have been substantially injured by purchasing and/or overpaying for the Class Product which is not what Defendant represents it to be.

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87. By reason of the foregoing, Defendant's conduct, as alleged herein, constitutes deceptive acts and practices in violation of Section 349 of the New York General Business Law, and Defendant is liable to Plaintiff and the Class for the actual damages that they have suffered as a result of Defendant's actions, the amount of such damages to be determined at trial, plus statutory damages, treble damages, and attorneys' fees and costs.

88. Defendant's conduct, as alleged herein, in violation of Section 349 of the New York General Business Law was engaged in by Defendant willfully and/or knowingly. Accordingly, Plaintiff and members of the Class are entitled to an award of damages above and beyond their actual damages in accordance with Section 349(h) of the New York General Business Law.

COUNT II (Violation of New York General Business Law Section 350)

90. Defendant's labeling, marketing, and advertising of the Class Product is "misleading in a material respect," as it fails to disclose to consumers material information in Defendant's sole possession and, thus, is "false advertising."

91. No rational individual would purchase the Class Product at the premium price at which it is sold if that individual knew that the Class Product was not clinically tested and proven effective, which is how Defendant markets the Class Product.

92. Defendant's advertisements and marketing of the Class Product as "Clinically Tested, Proven Effective" were consumer oriented.

93. Defendant's advertisements and marketing of the Class Product as "Clinically Tested, Proven Effective" were misleading in a material respect.

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94. By virtue of the foregoing unfair, unconscionable, and deceptive acts in the conduct of trade or commerce in New York, Plaintiff and the members of the Class have been substantially injured by overpaying for a product that has diminished value due on account of the false claim that it has been tested clinically and proven effective.

95. Defendant's conduct, as alleged herein, constitutes false advertising in violation of Section 350 of the New York General Business Law, and Defendant is liable to Plaintiff and the members of the Class for the actual damages that they have suffered as a result of Defendant's actions, the amount of such damages to be determined at trial, statutory damages, plus treble damages, and attorneys' fees and costs.

96. Defendant continues to violate Section 350 of the New York General Business Law and continues to aggrieve Plaintiff and the members of the Class.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court enter judgment against Defendant as follows:

A. Certifying this action as a class action as soon as practicable, with the Class as defined above, designating Plaintiff as the named Class representative, and designating the undersigned as Class Counsel.

B. On Plaintiff's Count I, awarding against Defendant the damages that Plaintiff and the other members of the Class have suffered as a result of Defendant's actions, the amount of such damages to be determined at trial, plus statutory damages and treble damages.

C. On Plaintiff's Count II, awarding against Defendant the damages that Plaintiff and the other members of the Class have suffered as a result of Defendant's actions, the amount of such damages to be determined at trial, plus statutory and treble damages.

D. On Plaintiff's Count I and II, awarding Plaintiff and the Class interest, costs, and attorneys' fees.

E. Awarding Plaintiff and the Class such other and further relief as this Court deems

just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: July 18, 2022 White Plains, New York

DENLEA & CARTON LLP

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By:

James R. Denlea Jeffrey I. Carton Stan Sharovskiy 2 Westchester Park Drive, Suite 410 White Plains, New York 10604 Tel.: (914) 331-0100 Fax: (914) 331-0105 jdenlea@denleacarton.com jcarton@denleacarton.com ssharovskiy@denleacarton.com

KRAVIT SMITH LLP

Philip M. Smith 75 South Broadway, Suite 400 White Plains, New York 10601 Tel.: (646) 433-8004 Fax: (917) 858-7101 psmith@kravitsmithllp.com

ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: <u>Relaxium Sleep Aid Falsely Advertised</u> with 'Illusory' Science, Class Action Alleges