UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ALAN GULKIS, individually and on behalf of all others similarly situated, Plaintiff, v. ZICAM LLC and MATRIXX INITIATIVES, INC. Defendants.	**CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Alan Gulkis ("Plaintiff"), by his attorneys, makes the following allegations pursuant to the investigation of his counsel and based upon information and belief, except as to allegations specifically pertaining to himself and his counsel, which are based on personal knowledge.

NATURE OF ACTION

1. Defendants Zicam LLC and Matrixx Initiatives, Inc. (collectively "Defendants") sell fake medicine to consumers seeking treatment for cold symptoms. Double-blind placebo-controlled trials show that Defendants' "Zicam Pre-Cold Medicine" is nothing more than a placebo. Even though Defendants know that studies show that the "Pre-Cold Medicine" is no different than a placebo, Defendants represent that the "Pre-Cold Medicine" shortens and reduces the severity of cold symptoms, and that the "Pre-Cold Medicine" prevents full cold symptoms from occurring. Defendants have made millions of dollars selling dummy pills to New York residents.

2. Because Defendants' Pre-Cold Medicine Products are mere placebos, Defendants' representations that their Products shorten and reduce the severity of the common cold, as well as their representations that the Products stop full cold symptoms are false and misleading. The

Pre-Cold Medicine includes Zicam Pre-Cold RapidMelts Original, Zicam Pre-Cold RapidMelts Ultra, Zicam Pre-Cold Oral Mist, Zicam Pre-Cold Ultra Crystals, Zicam Pre-Cold Lozenges, Zicam Pre-Cold Lozenges Ultra, and Zicam Pre-Cold Chewables ("Pre-Cold Medicine," "Pre-Cold Products," or "Products").

3. Defendants falsely represent on the Pre-Cold Medicine product labels and in their nationwide advertising campaign that Zicam is "clinically proven to shorten cold," "reduces duration and severity of the common cold," and "reduces severity of cold symptoms ▪ sore throat ▪ stuffy nose ▪ sneezing ▪ coughing ▪ nasal congestion." According to the sales pitch: "That first sniffle, sneeze or throat tickle…you have a Pre-Cold™, the first sign a full blown cold is coming. Take Zicam® now – clinically proven to shorten a cold. GO FROM PRE-COLD™ TO NO COLD FASTER™." In fact, Zicam Pre-Cold Products do not produce a therapeutic effect and are nothing more than placebos.

4. Since the Pre-Cold Products are no more effective than a placebo, the Products do not prevent full blown colds from occurring, are not "clinically shown to shorten cold," do not "reduce[] duration of the common cold," and do not "reduce[] severity of cold symptoms ▪ sore throat ▪ stuffy nose ▪ sneezing ▪ coughing ▪ nasal congestion."

5. As a direct and proximate result of Defendants' false and misleading advertising claims and marketing practices, Plaintiff and the members of the Class, as defined herein, purchased Defendants' ineffective Products. Plaintiff and the members of the Class purchased the Pre-Cold Products because they were deceived into believing that the Products prevent full blown colds, and that they shorten and reduce the severity of the common cold. As a result, Plaintiff and members of the Class purchased Zicam Pre-Cold Products that were not effective and have been injured in fact. Plaintiff and the Class members have suffered an ascertainable and out-of-pocket loss because they paid for a worthless Product. Plaintiff and members of the Class seek a refund and/or rescission of the transaction and all further equitable relief as provided by applicable law.

6. Plaintiff seeks relief in this action individually and on behalf of all New York purchasers of Zicam Pre-Cold Products for breach of express warranties, as well as for violation of New York General Business Law § 349, and New York General Business Law § 350.

THE PARTIES

7. Plaintiff Alan Gulkis is a New York citizen residing in Stormville, New York.

8. Zicam LLC is an Arizona Limited Liability Corporation with its principal place of business at 8515 E. Anderson Drive, Scottsdale, AZ 85255. Zicam LLC is engaged in the business of manufacturing, mass marketing, and distributing homeopathic formulas, including the Pre-Cold Medicine, under the Zicam brand name. Zicam LLC is a wholly owned subsidiary of Defendant Matrixx Initiatives, Inc.

9. Matrixx Initiatives, Inc. is a privately held corporation organized under the laws of Delaware with its principal place of business located at 440 Rte. 22 East, 1 Grande Commons, Suite 130, Bridgewater, New Jersey, 08807. Matrixx Initiatives, Inc. is engaged in the business of manufacturing, mass marketing, and distributing homeopathic formulas, including the Pre-Cold Medicine, under the Zicam brand name. Every Pre-Cold Product package states "©2012 Distributed by Matrixx Initiatives, Inc." Also, Matrixx Initiatives, Inc.'s website maintains that Matrixx Initiatives, Inc. has "continuously developed and introduced Zicam cold shortening and symptom-relieving products to the $6 billion cough/cold/allergy/sinus category."

10. Defendants produce, market, and sell products that are labeled homeopathic throughout the United States. Defendants have long maintained substantial distribution and marketing operations in New York, and in this District.

11. Both of the Defendants acted jointly to perpetrate the acts described herein. At all times relevant to the allegations in this matter, each Defendant acted in concert with, with the knowledge and approval of, and/or as the agent of the other Defendant within the course and scope of the agency, regarding the acts and omissions alleged.

JURISDICTION AND VENUE

12. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because there are more than 100 Class members, the aggregate amount in controversy exceeds $5,000,000.00, exclusive of interest, fees, and costs, and at least one Class member is a citizen of a state different from at least one Defendant.

13. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Defendants do business throughout this District, Plaintiff purchased Zicam in this District, and the Products that are the subject of the present Complaint are sold extensively in this District.

FACTUAL ALLEGATIONS COMMON TO ALL CLAIMS

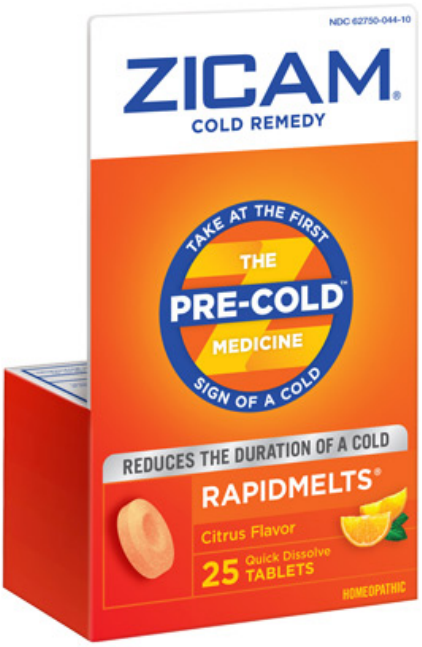
A. Zicam "The Pre-Cold Medicine" Is Labeled Homeopathic

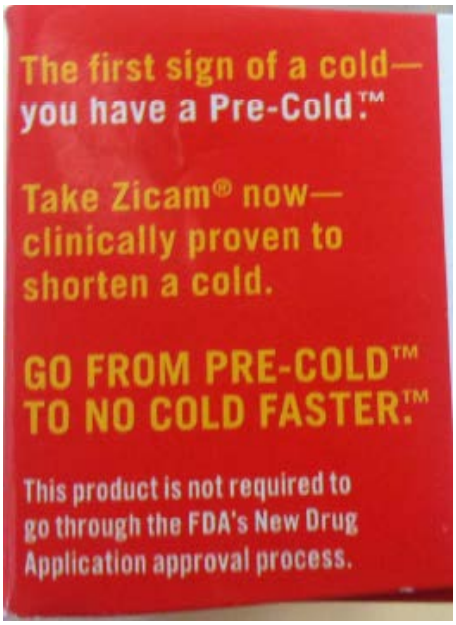
14. All of the Pre-Cold Products are labeled "Homeopathic" and contain zincum aceticum ("zinc acetate") and zincum gluconicum ("zinc gluconate").

15. Zicam Pre-Cold RapidMelts, Zicam Pre-Cold Rapid Melts Ultra, Zicam Pre-Cold Oral Mist, and Zicam Pre-Cold Crystals list zinc gluconate at a 1X dilution. Zinc acetate is listed at a 2X dilution. Zicam Pre-Cold "Liqui-Loz," Zicam Pre-Cold "Liqui-Loz," and Zicam Pre-Cold Chewables list both zinc acetate and zinc gluconate at a 2X dilution.

B. Zicam's False And Misleading Labels

16. On its Pre-Cold Product labels, depicted below, Defendants make numerous false and misleading marketing claims about the Products. Every Pre-Cold Product label bears the misleading trademarked tagline: "GO FROM PRE-COLD™ TO NO COLD FASTER™." The message to consumers is clear: Zicam shortens colds and prevents full colds from developing by treating a "Pre-Cold."



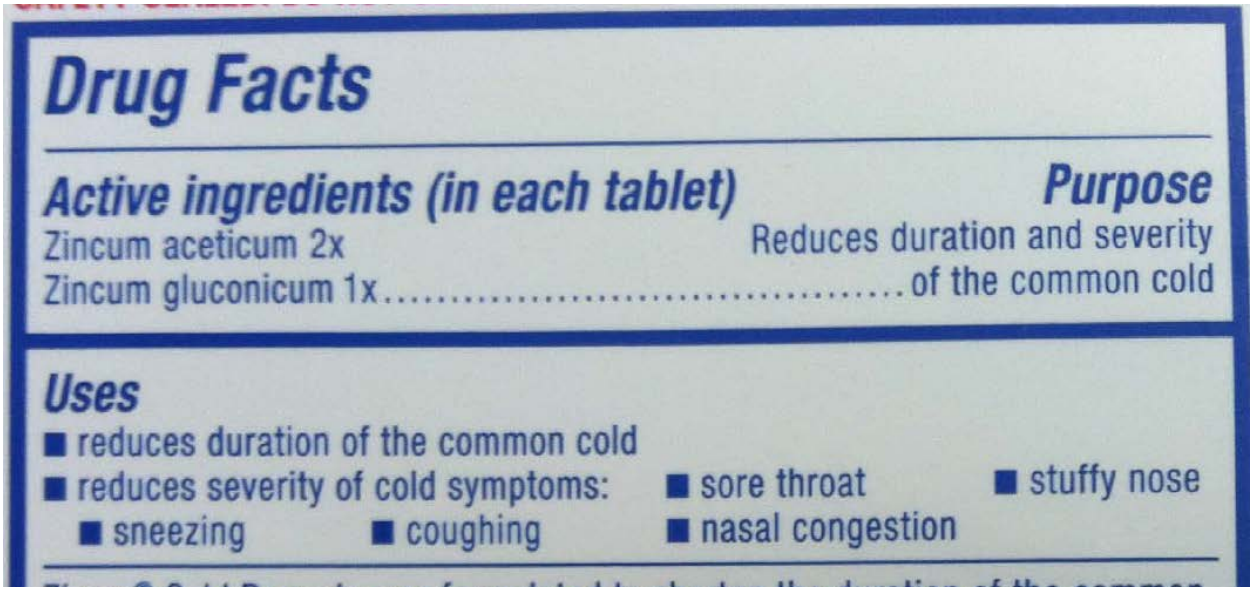


17. The prefix "Pre" means "before." Accordingly, the trademarked phrase "Pre-Cold" denotes *before*-Cold. Indeed, the Products' labels define "Pre-Cold™" as "That first sniffle, sneeze or throat tickle…you have a Pre-Cold,™ the first sign a full blown cold is

coming." Thus, consumers are told that Zicam Pre-Cold treats a "Pre-Cold" and will stop full blown cold symptoms. In effect, Defendants lead consumers to believe that they will only get a "Pre-Cold" because the Products can stop full blown cold symptoms before they start. However, Defendants' message is false and misleading.

18. On the Product labels, Defendants also tell consumers to "Take Zicam® now – clinically proven to shorten a cold." The Product labels further represent that the Pre-Cold Products "reduce[] the duration of a cold" or "shorten a cold."[1] In fact, as discussed more fully below, Defendants' so-called "clinical proof" actually demonstrates that the Zicam Pre-Cold Products *will not* shorten a cold because the Products are no different than a placebo pill.

19. All of the Pre-Cold Product labels also represent that the Pre-Cold Medicine "reduces severity of cold symptoms: ▪ sore throat ▪ stuffy nose ▪ sneezing ▪ coughing ▪ nasal congestion." This claim is likewise provably false because the Products are no different than a dummy pill.



[1] *See* Find Your Zicam: Cold Remedy Products, http://www.zicam.com/our_products/ (including photos of the front packaging of each of the Pre-Cold Products and the Drug Facts contained on the back of the products).

20. Indeed, *all* of Defendants' efficacy claims on the label are false and misleading because the Pre-Cold Products are nothing more than placebos.

21. Defendants deliberately and intentionally made uniform false labeling claims about the Products. Defendants spent a significant amount of time, thought, and money developing and implementing its marketing strategy to create a unified, homogenous look for its Pre-Cold Products. Matrixx Initiatives partnered with design firm Beardwood&Co to design the packaging for Zicam products. Julia Beardwood, a principal at Beardwood&Co, explained, "[Zicam] helped define [the pre-cold] segment… But to be successful, we had to help consumers quickly sort through this myriad of products in the cold aisle and understand what Zicam is and when to take it." For example, "[t]o help educate consumers," the Zicam packaging was re-designed to feature a "Pre-Cold seal in the shape of a bulls-eye." This serves as a "unifying element that communicates preparedness and reassurance." Directly below this is the prominent "benefit statement: 'Reduces the Duration of a Cold.'"[2]

22. Senior Vice President of Marketing at Zicam LLC, Leslie Malloy, also expressed that Pre-Cold seal is a "big advantage" for Defendants. She said: "It positions us as leaders in this category with a strong central unifying element that has badge value for consumers and empowers them to do something when they feel the first signs of a cold." Defendants extended the Pre-Cold seal into all its marketing platforms, including online and in-store displays. This indicates Zicam is well-aware that consumers rely on the representations asserted on product packaging when considering a cold product.[3]

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[2] *See* Michael Johnsen, "Matrixx Initiatives gives Zicam a makeover with design firm Beardwood&co," DRUG STORE NEWS (Feb. 22, 2013), http://www.drugstorenews.com/article/matrixx-initiatives-gives-zicam-makeover-design-firm-beardwoodco (last visited Jan. 6, 2014).

[3] *Id.*

C. Zicam's False And Misleading Television Commercials Featuring The "Cold Monster"

23. Beginning in 2012, Defendants started running a series of commercials introducing the "Cold Monster," a "monster version of a cold personified."[4] Defendants' Cold Monster commercials have aired on network and cable television nationwide. In fact, Zicam maintains a YouTube channel consisting of Zicam Pre-Cold Product and "Cold Monster" Commercials. Stills from the "Cold Monster" commercial are incorporated below.

24. As shown below, the "Cold Monster" commercial depicts a consumer *escaping the personification of a full cold* by taking a Zicam Pre-Cold product "at the first sign of cold." Instead, the Zicam user treats her "Pre-Cold," just one sneeze, by taking Zicam.

25. The commercial begins with a woman walking out of a building on an overcast day onto a crowded sidewalk.

26. As she walks, she is interrupted by a sneeze, and a voiceover says, "That first sneeze, you have a pre-cold."

[4] *Id.* *See also* Allison Schiff, "Common Cold, Uncommon Marketing," DIRECT MARKETING NEWS (Jan.9, 2013), http://www.dmnews.com/common-cold-uncommon-marketing/article/275311/ (last visited Jan. 3, 2014).

27. The "Cold Monster," dripping in phlegm with blood-shot eyes, comes into the frame. The "Cold Monster" exhibits signs of the common cold and wipes his nose with his hand as he sneezes, spewing phlegm and snot.

28. The consumer looks back in terror as the "Cold Monster" begins to chase after her, and the voiceover says, "The first sign of full-blown cold is coming."

29. As the consumer starts to run, the “Cold Monster” grabs for her arm.

30. She narrowly escapes his grasp and runs into a dark, wet alley.

31. The "Cold Monster" is close behind, and the music starts to crescendo as the "Cold Monster" corners her.

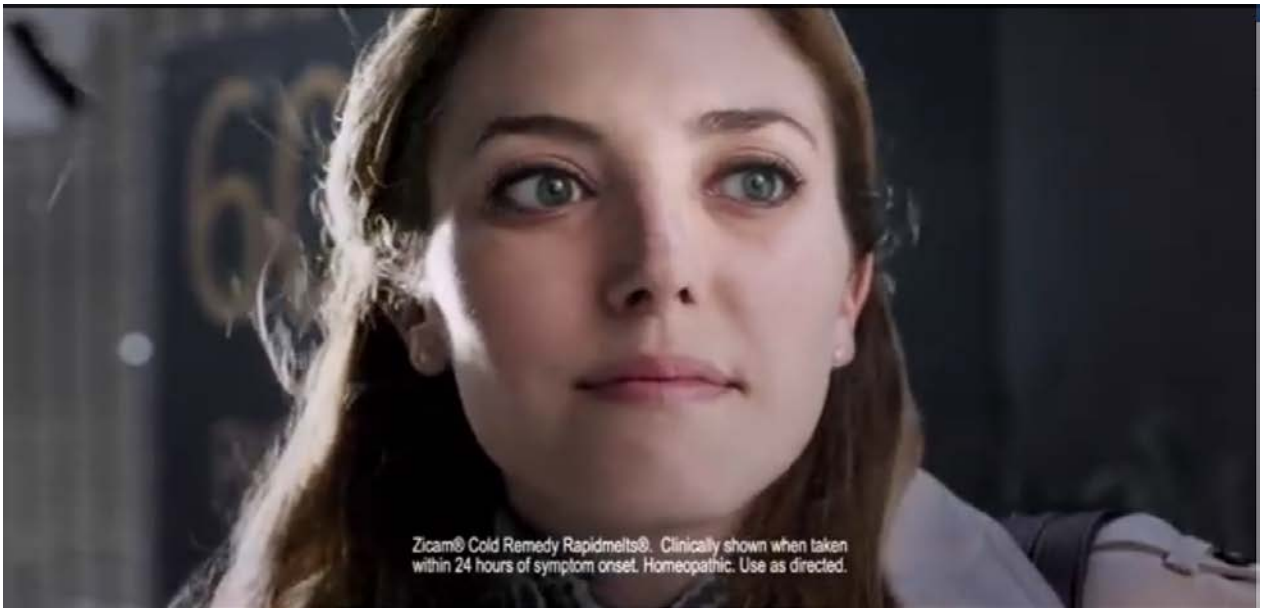
32. There is a close-up shot of the "Cold Monster," again exhibiting the external signs of the common cold: red eyes and dripping red nose. The camera zooms in as he reaches for her.

33. She pulls out her Zicam Pre-Cold Product, and the voiceover says, "Take Zicam now - the completely different kind of medicine that's clinically shown to shorten a cold."

34. Its red eyes clearly visible, the "Cold Monster" fearfully backtracks into the street at the mere presence of the product.

35. As she prepares to take the Pre-Cold Product, the "Cold Monster" is hit by a Zicam truck.

36. Looking healthy with a bright complexion and a smile, she watches as the "Cold Monster" is taken away. Notably, she is never "caught" by the "Cold Monster" and does not become ill beyond one sneeze. Instead, she goes from "pre-cold" to "no cold" without ever experiencing full blown cold symptoms.



37. The ad concludes, "Zicam: GO FROM **PRE-COLD**® TO **NO COLD** FASTER™."

38. The commercial portrays a consumer preventing the development of a full cold by taking a Zicam Pre-Cold Product. Although she exhibits signs of a "pre-cold," *one* sneeze at the start of the commercial, the Product treats her "Pre-Cold" and full blown cold symptoms never develop.

39. The representations in the Zicam commercial are false and misleading. Zicam Pre-Cold products do not stop the development of a cold at the "Pre-Cold" stage as depicted in the commercial, do not shorten colds, and do not reduce the severity of symptoms. In fact, studies demonstrate that the Products are no better than a placebo.

40. Again, Defendants recognize the importance of marketing in capturing customer attention and creating customer reliance in the highly competitive OTC market. Zicam was featured in a Direct Marketing News article entitled "Common Cold, Uncommon Marketing."[5]

[5] Allison Schiff, "Common Cold, Uncommon Marketing," DIRECT MARKETING NEWS (Jan. 9, 2013), http://www.dmnews.com/common-cold-uncommon-marketing/article/275311/ (last visited Jan. 3, 2014).

The article discusses Defendants' use of the "Cold Monster," a "monster version of a cold personified." Using the "Cold Monster," Zicam engages in an aggressive marketing campaign integrated in mobile, social, print, and TV advertisements. The CEO of Matrixx Initiatives, Inc. stated the goal of the marketing campaign is to "more engagingly" bring the brand's "promise" to life: the false and misleading claim that Zicam is clinically proven to reduce the duration of a cold when taken within the first 24 hours of feeling signs of a cold.[6]

As part of its savvy marketing campaign to "own the 'pre-cold' category" of products, Defendants also redesigned and re-launched their website in August 2012 to include the "Cold Monster."[7] This garnered significant traffic increases, resulting in page view increases of up to 66%. This also marked the introduction of Zicam's current tagline: "GO FROM PRE-COLD® TO NO COLD FASTER™."

D. Studies Show That Zinc Lozenges Are No More Effective Than A Placebo

41. In 2007, Thomas J. Caruso, Charles G. Prober, and Jack M. Gwaltney, Jr. conducted a structured review of studies that examined the efficacy of zinc lozenges, nasal sprays, and nasal gels as treatment for the common cold.[8] Dr. Caruso and Dr. Prober are both Professors at the Stanford School of Medicine. Dr. Gwaltney is a renowned professor from the University of Virginia School of Medicine. The review's analysis of studies on zinc lozenges is especially pertinent to Zicam's Pre-Cold Products because the lozenge is the delivery form of Defendants' flagship Products - RapidMelts, and RapidMelts Ultra.

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[6] *See id. See also* Andrew McCains, "Zicam Breaks Out the Achy Cold Monster," ADWEEK.COM (Oct. 8, 2012), http://www.adweek.com/news/advertising-branding/zicam-breaks-out-achy-cold-monster-144295 (last visited Dec. 30, 2013).

[7] Tanya Irwin, "Zicam Relaunches Website," MEDIAPOSTNEWS.com, http://www.mediapost.com/publications/article/185391/zicam-relaunches-web-site.html (last visited Dec. 30, 2013).

[8] *See* Thomas J. Caruso, *et al., Treatment of Naturally Acquired Common Colds With Zinc: A Structured Review,* Clin. Infect. Dis. 2007;45:569-74 ("Caruso Review").

42. The Caruso review evaluated the zinc studies against eleven predetermined criteria necessary for a valid experimental design. *See* Caruso Review at 570. The absence of any one of these criteria could potentially invalidate a study. *Id*.

43. Caruso et al. found that only two of the examined zinc lozenge studies met all eleven criteria for a valid experimental design. *Id*. at 571. Both of these studies, Macknin, Piedmonte, et al., 1998 (the "Macknin Study") and Turner, Cetnarowski, 2000 (the "Turner Study") reported that ***zinc lozenges have no effect on the symptom severity and duration of common cold***. *Id*.

44. The Macknin Study concluded zinc lozenges were "***not effective*** in treating cold symptoms."[9] The Macknin Study was a randomized, double blinded, and placebo-controlled 249-person study that satisfied all of the 11 criteria identified by Caruso et al. as "necessary for valid experimental design." *See* Caruso R note 13, at 571 ("Among the 7 studies reporting no effect, 3 fulfilled all criteria," including the Macknin study). The authors found that: (1) the time to resolve all cold symptoms was identical in the placebo and zinc lozenge groups; (2) zinc Lozenges had "no significant effect on the time for resolution on any of the individual symptoms"; (3) differences in school absences between the groups were not statistically significant; and (4) slightly more students in the zinc lozenge group experienced at least one adverse effect than in the placebo group.

45. The Turner Study likewise found that zinc lozenges "had no effect on the duration or severity of symptoms in either the experimental or natural study model" and "zinc compounds appear to have little utility for common-cold treatment."[10] The Turner Study was a double-blind, randomized, placebo-controlled study on the effect of zinc treatment on the duration of severity of common-cold symptoms using zinc lozenges, and placebo lozenges. Like the Macknin Study,

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[9] *See* Macknin, Piedmonte, et al., *Zinc Gluconate Lozenges for Treating the Common Cold in Children: A Randomized Controlled Trial*, JAMA. 1998; 279(24): 1962-1967 ("Macknin Study") (emphasis added).

[10] Turner and Cenarowski, *Effect of Treatment with Zinc Gluconate or Zinc Acetate on Experimental and Natural Colds*, Clinical Infectious Diseases. 2000; 31:1202-8 ("Turner Study").

the Turner Study met all 11 criteria set forth in the Caruso Review. *See* Caruso Review note 13, at 571.

46. The prestigious Mayo Clinic agrees with the findings of the Caruso Review. In a consumer guide to effective cold treatments, the Mayo Clinic includes zinc in a long list of ineffective cold remedies.[11] The Clinic Staff further noted, "… the highest quality randomized trials generally show no benefit [from zinc treatment]." *Id.*

47. Additionally, the Caruso Review also noted many of the reviewed studies failed to prove effective blinding of participants. *See* Caruso Review at 572-73. If there is no effective blinding, the placebo effect could explain any positive test results because participants in the experimental group will expect relief and participants in the control group will expect no relief. This is especially true in the context of zinc lozenges used to treat the common cold. The common cold is particularly susceptible to the influence of the placebo effect because the presence of a cold is largely determined by subjective self-evaluation of symptom severity.[12] Furthermore, unless great care is taken in the placebo formulation, study participants can identify the presence of zinc on the basis of aftertaste, nausea, and mouth soreness.[13]

E. Even Studies With Methodological Flaws Show That The Amount Of Zinc In The Pre-Cold Products Is Too Low To Have Any Effect Beyond That Of A Placebo

48. Defendants claim that the Zicam Pre-Cold Products are "clinically proven to shorten a cold" misleads consumers because the study cited for this proposition shows just the opposite. Zicam has asserted on its website: "While the exact mechanism has not been determined, the efficacy of zinc in reducing the duration of a cold, when taken at the first sign of a cold, is supported by multiple clinical trials (Zinc for the Common Cold [Review], The Cochrane Collaboration, Singh, 2013)." http://www.zicam.com/faqs/stopping-cold-monster.php.

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[11] *See* Mayo Clinic Staff, *Cold Remedies: What Works, What Doesn't, What Can't hurt You*, MAYO CLINIC WEBSITE, (Oct. 11, 2015, 1:26 PM), http://www.mayoclinic.org/diseases-conditions/common-cold/in-depth/cold-remedies/art-20046403

[12] *Id.*; *see also* Diehl HS. *Medicinal treatment of the common cold*, JAMA 1933, 101:2042–9;

[13] *Id.*; *see also* Farr BM, Gwaltney JM Jr., *The problems of taste in placebo matching: an evaluation of zinc gluconate for the common cold*, J. Chronic. Dis.1987, 40:875–9.

49. In fact, the systematic review Defendants cited observes that zinc treatment is no more effective than a placebo at dosages below 75 mg of zinc per day. [14] The Cochrane Systematic Review identified 18 randomized controlled trials that enrolled 1781 participants and compared zinc lozenges or syrup with placebo. Based on its review of studies that tested doses of zinc greater than 75 milligrams as compared to studies that tested zinc doses that were less than 75 milligrams, the Review concluded that there may be a reduction in the duration of cold symptoms "***at a dose of ≥ 75 mg/day***…."[15] (emphasis added).

50. Furthermore, the Cochrane Report concluded that zinc ***was not associated with a reduction of the severity of common cold symptoms*** at any tested dosage. Thus, the Cochrane Report cited by Defendants demonstrates that Defendants' representation that the Products "reduce[] severity of cold symptoms ▪ sore throat ▪ stuffy nose ▪ sneezing ▪ coughing ▪ nasal congestion" is affirmatively false.

51. The Cochrane Review's finding with respect to zinc treatments below 75 mg/day is consistent with other reviews. For example, in a similar review, Harri Hemila concluded that: "None of the five comparisons [to placebo] that used less than 75 mg/day of zinc found an effect."[16]

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[14] *See* Singh M, Das RR., *Zinc for the Common Cold*, 12 Cochrane Database of Systematic Reviews 2013 CD001364, *abstract available at* http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001364.pub4/abstract (last visited Jan. 9, 2015).

[15] The Cochrane editorial group withdrew this Review to explore the source and calculation of data used in the analysis in more detail. The ongoing Review does not affect the underlying studies evaluated in the Review. Cochrane Editorial Group, "Statement of Withdrawal" (Apr. 30, 2015), http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001364.pub5/abstract;jsessionid=CBAA1860892B694DBF75B0170AF0C865.f03t02 (last visited October 21, 2015)

[16] Hemila, Harri, *Zinc Lozenges May Shorten the Duration of Colds: A Systematic Review***,** The Open Respiratory Medicine Journal**,** 2011, *5*, 51-58; *see also id.* at 54 (table showing that the studies that used doses less than 75 milligrams, and that all were done before the class period in 1987, 1998, 1990, and 2000, showed no significant difference as compared to placebo)

52. Since a daily dose of Zicam Pre-Cold Products contains *much less* than 75 milligrams of zinc, the Cochrane and Hemila Reviews likewise show that Defendants' Products are no different than a placebo. [17]

53. Therefore, even if there is some possibility that the duration of a cold may be reduced with a daily dose of ***at least* 75 *milligrams*** of zinc, the daily dose of Defendants' Pre-Cold Products is still no more effective than a placebo.

F. The National Advertising Division Previously Determined That Defendants' Marketing Efforts Improperly Suggested Zicam Prevents The Common Cold

54. In April 2013, the National Advertising Division of the Council of Better Business Bureaus ("NAD") found that Zicam's product packaging and advertising in print, television, and on the website "could reasonably be understood by consumers" to mean that Zicam Pre-Cold Products protect consumers from catching a cold.[18]

55. The misrepresentation issues arose from the advertising campaign featuring the "Cold Monster" that encouraged consumers to treat their pre-cold using Zicam Pre-Cold Products. Among other things, the NAD looked at Zicam's title "The Pre-Cold Medicine," the claim "Take Zicam Now And Go From Pre-Cold To No Cold, Faster," and the claim that Zicam is "clinically proven [to reduce the duration of a cold]." The NAD focused extensively on the context in which Zicam made the representations to determine if they were misleading to consumers.[19]

56. The NAD concluded that taken in context, claims like "Don't let a monster of a cold catch you" could make consumers believe Zicam would prevent a cold or reduce the

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[17] Sekula, Stephen, "Fake Medicine: Zicam" (Dec. 6, 2013), http://steve.cooleysekula.net/blog/2013/01/06/fake-medicine-zicam/ (last visited Oct. 8, 2015).

[18] *See* ASRC Press Releases, "NAD Recommends Matrixx Discontinue Claims that Suggest 'Zicam' Products Protect Users from Catching Cold; Found Advertiser Could Support Certain Claims," ASRCREVIEWS.ORG (April 5, 2013), *available at* http://www.asrcreviews.org/2013/04/nad-recommends-matrixx-discontinue-claims-that-suggest-zicam-products-protect-users-from-catching-cold-found-advertiser-could-support-certain-claims/ (last visited Jan. 6, 2014).

[19] *See id.*

severity of the cold symptoms. Despite this warning, Zicam continues to market its Pre-Cold Products to mislead consumers into thinking Zicam Pre-Cold Products prevent the common cold. In the "Cold Monster" commercial, the Zicam consumer goes from pre-cold to no cold after escaping the clutches of the "Cold Monster."

57. The NAD also recommended that Defendants discontinue the "clinically proven" claim in advertising featuring "non-tested products and non-cold remedy products." Defendants have not done so.

G. The FDA Does Not Regulate Homeopathic Remedies

58. To determine whether *non*-homeopathic OTC drugs are safe, effective, and not misbranded, the FDA subjects non-homeopathic OTC drugs to stringent evaluations and testing using a drug monograph system created by the FDA. *See* 21 C.F.R. §§ 330.1, 330.10. In drafting the monographs, the FDA divided the non-homeopathic OTC drugs into drug categories, which were then assigned an advisory review panel of qualified experts who evaluate the safety and effectiveness of the non-homeopathic OTC drugs. The panel also reviews the drugs' labeling and advises the FDA Commissioner on the promulgation of monographs establishing conditions under which non-homeopathic OTC drugs listed within each monograph are generally recognized as safe, effective, and not misbranded. *Id.* § 330.10(a).

59. Under this system, a manufacturer seeking approval of a new, non-homeopathic OTC drug must submit a detailed new drug application, which must include:

> [E]vidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

21 U.S.C. § 355. Moreover, after the FDA approves a new drug application, any change in the drug's labeling requires a supplement to the application and further approval by the FDA either before or after the change. 21 C.F.R. §§ 314.70(b), (c), 314.71.

60. In stark contrast, OTC drugs that are labeled "homeopathic," including the Zicam Pre-Cold Products, are neither approved nor authorized by the FDA. As stated on the Zicam Pre-Cold Products' packaging: "This product is not required to go through the FDA's New Drug Application approval process."

61. Furthermore, on the U.S. National Library of Medicine ("the NLM") website responsible for providing information about FDA drug listing information, the NLM specifically states the following about Zicam: "THIS HOMEOPATHIC PRODUCT HAS NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION FOR SAFETY OR EFFICACY. [THE] FDA IS NOT AWARE OF SCIENTIFIC EVIDENCE TO SUPPORT HOMEOPATHY AS EFFECTIVE."[20]

PLAINTIFF'S PURCHASE OF ZICAM PRE-COLD MEDICINE

62. Plaintiff Alan Gulkis purchased Zicam Pre-Cold RapidMelts and Zicam Pre-Cold OralMist at a RiteAid near his home in Stormville, New York. Plaintiff purchased Pre-Cold RapidMelts in 2013. Plaintiff also purchased Zicam Pre-Cold Oral Mist in 2014. Each time he purchased Zicam, he carefully read the label before making his purchase.

63. In purchasing Zicam Pre-Cold RapidMelts and Zicam Pre-Cold Oral Mist, Plaintiff relied upon the various representations Defendants made on the product's label, including that Zicam is "clinically proven to shorten a cold," "reduces the duration of a cold," and "reduces severity of cold symptoms ▪ sore throat ▪ stuffy nose ▪ sneezing ▪ coughing ▪ nasal congestion." He also read that with Zicam he could "go from pre-cold to no cold faster."

64. Plaintiff used the Pre-Cold Products as directed but did not obtain the advertised relief from these symptoms, nor any benefits, from using Zicam Pre-Cold RapidMelts. The Zicam Products he purchased did not shorten the length of his colds, and they did not alleviate

[20] *See* "ZICAM (zinc acetate and zinc gluconate) tablet, orally disintegrating [Matrixx Initiatives, Inc.]," National Library of Medicine, http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=ba3cfc70-cead-489c-bf79-59774cf22fee (last visited Jan. 6, 2014).

his symptoms. Instead, Plaintiff's colds got better on their own. The Zicam Products Plaintiff purchased cost him approximately $10.00 to $12.00.

65. Plaintiff would not have purchased Zicam Pre-Cold RapidMelts or Oral Mist if he had known that they were no more effective than a placebo pill.

66. Zicam Pre-Cold RapidMelts and Oral Mist are worthless because they are no more effective than a placebo pill. Accordingly, Plaintiff was damaged in the amount of the full purchase price, *i.e.*, the difference in value between the Zicam Pre-Cold RapidMelts and Oral Mist products as advertised, and the Zicam Pre-Cold RapidMelts and Oral Mist products as sold.

CLASS ACTION ALLEGATIONS

67. Plaintiff brings this action as a class action under Federal Rule of Civil Procedure 23 on behalf of a Class consisting of all persons in New York who, within the relevant statute of limitations period, purchased Zicam Pre-Cold Products.

68. Excluded from the Class are Defendants, the officers and directors of the Defendants at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which either Defendant has or had a controlling interest.

69. Also excluded from the Class are persons or entities that purchased Zicam Pre-Cold Products for purposes of resale.

70. Plaintiff is a member of the Class he seeks to represent.

71. The Class is so numerous that joinder of all members is impractical. Although Plaintiff does not yet know the exact size of the Class, Zicam Pre-Cold Products are sold by most major New York retailers, including stores such as Walmart, CVS Pharmacy, Walgreens, Costco, Duane Reade and Target.[21] Major online retailers include Amazon.com and Drugstore.com. Consequently, Zicam hails itself as the "#1 cold shortening product in the USA."[22] According to Zicam, it enjoys the position as "the Pre-Cold medicine leader." Upon

[21] *See* Zicam: Where to Buy, http://www.zicam.com/where_to_buy/.

[22] *See* Zicam: About Us, http://www.zicam.com/ about_zicam/.

information and belief and based upon Defendants' statements, the Class includes more than one million members. Accordingly, joinder is impracticable.

72. The Class is ascertainable because the Class members can be identified by objective criteria. Individual notice can be provided to Class members "who can be identified through reasonable effort." Fed. R. Civ. P. 23(c)(2)(B).

73. There are numerous questions of law and fact common to the Class which predominate over any individual actions or issues, including but not limited to:

A. Whether Defendants breached an express warranty made to Plaintiff and the Class;

B. Whether Defendants' marketing of Pre-Cold Products is false, misleading, and/or deceptive;

C. Whether Defendants' marketing of Pre-Cold Products is unfair;

D. Whether Zicam Pre-Cold Products are efficacious, effective, and useful for treating a Pre-Cold and stopping a full cold;

E. Whether Zicam Pre-Cold Products are efficacious, effective, and useful for reducing the duration of the common cold;

F. Whether Zicam Pre-Cold Products are efficacious, effective, and useful for reducing the severity of the common cold;

G. Whether Defendants were unjustly enriched by their conduct;

H. Whether Defendants violated the GBL;

I. Whether Class members suffered an ascertainable loss as a result of Defendants' misrepresentations; and

J. Whether, as a result of Defendants' misconduct as alleged herein, Plaintiff and the Class members are entitled to restitution, and/or monetary relief and, if so, the amount and nature of such relief.

74. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct. Plaintiff has no

interests antagonistic to the interests of the other members of the Class. Plaintiff and all members of the Class have sustained economic injury arising out of Defendants' violations of common and statutory law as alleged herein.

75. Plaintiff is an adequate representative of the Class because his interests do not conflict with the interests of the Class members he seeks to represent, he has retained counsel competent and experienced in prosecuting class actions, and he intends to prosecute this action vigorously. The interests of the Class members will be fairly and adequately protected by Plaintiff and his counsel.

76. The class mechanism is superior to other available means for the fair and efficient adjudication of the claims of Plaintiff and the Class members. Each individual Class member may lack the resources to undergo the burden and expense of individual prosecution of the complex and extensive litigation necessary to establish Defendants' liability. Individualized litigation increases the delay and expense to all parties and multiplies the burden on the judicial system presented by the complex legal and factual issues of this case. Individualized litigation also presents a potential for inconsistent or contradictory judgments. In contrast, the class action device presents far fewer management difficulties and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court on the issue of Defendants' liability. Class treatment of the liability issues will ensure that all claims and claimants are before this Court for consistent adjudication of the liability issues.

COUNT I
(Deceptive Acts Or Practices, New York Gen. Bus. Law § 349)

77. Plaintiff repeats the allegations in the foregoing paragraphs as if fully set forth herein.

78. Plaintiff Gulkis brings this Count I individually and on behalf of the members of the Class against Defendants.

79. By the acts and conduct alleged herein, Defendants committed unfair or deceptive acts and practices. These acts and conduct include, but are not limited to, Defendants' misrepresentations that the Products "reduce[] the duration of a cold," "get rid of your cold

faster," "reduce[] the severity of the symptoms of the common cold," and are "clinically proven to shorten a cold."

80. The foregoing deceptive acts and practices were directed at consumers.

81. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the characteristics and benefits of the Pre-Cold Products to induce consumers to purchase the Products.

82. Plaintiff Gulkis and members of the Class were injured because: (a) they would not have purchased the Pre-Cold Products had they known that the Products were not clinically proven to reduce the duration of the common cold, were not effective for reducing the duration of the common cold, and were not effective for reducing the severity of cold symptoms per Defendants' misrepresentations described herein; (b) they purchased the Pre-Cold Products based on Defendants' misrepresentations; and (c) the Pre-Cold Products did not have the characteristics and benefits promised. As a result, Plaintiff Gulkis and the Class were damaged by the difference in value between the Pre-Cold Products as advertised and the Pre-Cold Products as actually sold. Because the Pre-Cold Products are worthless placebos, Plaintiff Gulkis and the Class were damaged in the full amount of the purchase price of the Pre-Cold Products.

83. As a result of Defendants' false, misleading and deceptive statements and representations of fact, including but not limited to the misrepresentations described herein, Plaintiff Gulkis and members of the Class have suffered and continue to suffer economic injury.

84. Plaintiff Gulkis and members of the Class suffered an ascertainable loss caused by Defendants' misrepresentations equal to the purchase price of the Pre-Cold Products.

85. On behalf of himself and other members of Class, Plaintiff Gulkis seeks to enjoin the unlawful acts and practices described herein, to recover actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT II
(False Advertising, New York Gen. Bus. Law § 350)

86. Plaintiff repeats the allegations in the foregoing paragraphs as if fully set forth herein.

87. Plaintiff Gulkis brings this Count II individually and on behalf of the members of the Class.

88. By the acts and conduct alleged herein, Defendants committed unfair or deceptive acts and practices. These acts and conduct include, but are not limited to, Defendants' misrepresentations that the Products "reduce[] the duration of a cold," "get rid of your cold faster," "reduce[] the severity of the symptoms of the common cold," and are "clinically proven to shorten a cold."

89. Based on the foregoing, Defendants have engaged in consumer-oriented conduct that is deceptive or misleading in a material way which constitutes false advertising in violation of Section 350 of the New York General Business Law.

90. Defendants' false, misleading and deceptive statements and representations of fact, including but not limited to the misrepresentations described herein, were and are directed to consumers.

91. Defendants' false, misleading and deceptive statements and representations of fact, including but not limited to the misrepresentations described herein, were and are likely to mislead a reasonable consumer acting reasonably under the circumstances.

92. Defendants' false, misleading and deceptive statements and representations of fact, including but not limited to the misrepresentations described herein, have resulted in consumer injury or harm to the public interest.

93. Plaintiff Gulkis and members of the Class were injured because: (a) they would not have purchased the Pre-Cold Products had they known that the products were not clinically proven to reduce the duration of the common cold, were not effective for reducing the duration of the common cold, and were not effective for reducing the severity of cold symptoms per Defendants' misrepresentations described herein; (b) they purchased the Pre-Cold Products

based on Defendants' misrepresentations; and (c) the Pre-Cold Products did not have the characteristics and benefits promised. As a result, Plaintiff Gulkis and the Class were damaged by the difference in value between the Pre-Cold Products as advertised and the Pre-Cold Products as actually sold. Because the Pre-Cold Products are worthless placebos, Plaintiff Gulkis and the Class were damaged in the full amount of the purchase price of the Pre-Cold Products.

94. As a result of Defendants' false, misleading and deceptive statements and representations of fact, including but not limited to the misrepresentations described herein, Plaintiff Gulkis and members of the Class have suffered and continue to suffer economic injury.

95. Plaintiff Gulkis and members of the Class suffered an ascertainable loss caused by Defendants' misrepresentations equal to the purchase price of the Pre-Cold Products.

96. On behalf of himself and other members of the Class, Plaintiff Gulkis seeks to enjoin the unlawful acts and practices described herein, to recover their actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT III
(Breach Of Express Warranty)

97. The Plaintiff repeats the allegations contained in the paragraphs above as if fully set forth herein.

98. Plaintiff brings this Count III individually and on behalf of the members of the Class.

99. In connection with the sale of the Products, Defendants issued Express Warranties including that the Pre-Cold Products are "clinically proven to shorten cold," "reduce[] severity of cold symptoms ▪ sore throat ▪ stuffy nose ▪ sneezing ▪ coughing ▪ nasal congestion," and "GO FROM PRE-COLD™ TO NO COLD FASTER.™" Defendants expressly warranted that the Zicam Pre-Cold Products were effective and would prevent full colds, reduce the duration of colds, and reduce the severity of symptoms of the common cold.

100. Defendants' affirmations of fact and promises made to Plaintiff and the Class on the Product labels and in their television and print advertisements became part of the basis of the

bargain between Defendants and Plaintiff and the Class members, thereby creating express warranties that the Products would conform to Defendants' affirmations of fact, representations, promises, and descriptions.

101. Defendants breached their express warranties because Zicam Pre-Cold Products do not in fact prevent full blown cold symptoms, and do not shorten, or reduce the severity of the common cold or cold symptoms. In short, the Products do not perform as expressly warranted.

102. Plaintiff and the Class members were injured as a direct and proximate result of Defendants' breach because: (a) they would not have purchased Zicam Pre-Cold Products if they had known the true facts; (b) they paid for the Products due to the mislabeling of Zicam Pre-Cold Products; and (c) Zicam Pre-Cold Products did not have the quality, effectiveness, or value as promised. As a result, Plaintiff Gulkis and the Class were damaged by the difference in value between the Pre-Cold Products as advertised and the Pre-Cold Products as actually sold. Because the Pre-Cold Products are worthless placebos, Plaintiff Gulkis and the Class were damaged in the amount of the purchase price of the Pre-Cold Products.

COUNT IV
(Unjust Enrichment)

103. Plaintiff repeats the allegations of the foregoing paragraphs as if fully set forth herein.

104. Plaintiff brings this Count IV individually and on behalf of members of the Class against Defendant.

105. Plaintiff and members of the Class conferred benefits on Defendants by purchasing the Pre-Cold Products.

106. Defendants have knowledge of such benefits.

107. Defendants have been unjustly enriched in retaining the revenues derived from Plaintiff's and Class members' purchases of the Pre-Cold Products. Retention of those moneys under these circumstances is unjust and inequitable because Defendants falsely and misleadingly represented that their Pre-Cold Products were clinically proven to reduce the duration of the common cold, were effective for reducing the duration of the common cold, and were effective

for reducing the severity of cold symptoms, which caused injuries to Plaintiff and members of the Class because they would not have purchased the Pre-Cold Products had the true facts been known.

108. Because Defendants' retention of the non-gratuitous benefits conferred on it by Plaintiff and members of the Class is unjust and inequitable, Defendants must pay restitution to Plaintiff and members of the Class for their unjust enrichment, as ordered by the Court.

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. For an order certifying a class of consumers who purchased the Products in New York;

B. For an order declaring that the Defendants' conduct violates the statutes referenced herein;

C. Awarding compensatory, statutory, and punitive damages in favor of Plaintiff, members of the Class, against Defendants for all damages sustained as a result of the Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

D. For an order of restitution and/or disgorgement and all other forms of equitable monetary relief;

E. Awarding Plaintiff and members the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

F. Awarding such other and further relief as the Court may deem just and proper.

JURY DEMAND

109. The Plaintiff hereby demands a trial by jury on all claims so triable in this action.

Dated: December 17, 2015

Respectfully submitted,

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