



431.047 of the TFDCA authorizes the Attorney General to seek injunctive relief under certain circumstances and recover any costs and attorney fees incurred in obtaining that relief. This action is also brought pursuant to §431.0585 of the TFDCA that authorizes the Commissioner of Health to refer to the Attorney General to seek civil penalties in favor of the State per day per violation of §431.021 of the TFDCA and regulations pursuant to this Act.

2. This action is brought by Attorney General Greg Abbott, through his Consumer Protection Division, in the name of the STATE OF TEXAS and in the public interest under the authority granted him by §17.47 of the Texas Deceptive Trade Practices - Consumer Protection Act, TEX. BUS. & COM. CODE ANN. §17.21 *et seq.* (“DTPA”), upon the grounds that Defendants have engaged in false, misleading or deceptive acts or practices in the course of trade and commerce as defined in, and declared unlawful by §§17.46(a) and (b) of the DTPA.

#### **PARTY DEFENDANTS**

3. Defendant Airborne Health, Inc., also doing business as Airborne and Airborne, Inc., and formerly doing business as Knight-McDowell Labs, is a Delaware corporation with its principal place of business at 26811 South Bay Drive, Suite 300, Bonita Springs, FL 34134. Airborne Health also has another office located at 100 Clock Tower, Suite 120, Carmel, CA 93923. Since 2005, Airborne Health has, alone or acting in concert with others, manufactured, marketed, distributed Airborne Products to consumers throughout the United States, including Texas.

4. Defendant Airborne Holdings, Inc., is a Delaware corporation with its principal place of business at 26811 South Bay Drive, Suite 300, Bonita Springs, FL 34134. Airborne Holdings is the sole owner of Airborne Health. In May 2005, Summit Partners, a venture capital firm based in Boston, acquired Airborne from Victoria Knight-McDowell and John Thomas McDowell, Airborne’s original founders. During this acquisition, Airborne Acquisition

Company, a California corporation and wholly owned subsidiary of Airborne Holdings, Inc., merged with and into Airborne, Inc. which also did business under the name Knight-McDowell Labs, a California corporation with its principal place of business in Carmel, California. Through the merger, Airborne Holdings became the parent company of Airborne, Inc. In December 2005, Airborne Holdings merged Airborne, Inc. with and into Airborne Health, Inc., which has continued to use the name "Airborne, Inc." as a business name. In the summer of 2008, Individual Defendants Victoria Knight-McDowell and Thomas John McDowell reacquired Airborne Holdings and are currently majority shareholders of the company. Since May 2005, acting alone or in concert with others, Airborne Holdings has marketed, distributed, and sold Airborne Products to consumers throughout Texas or has caused the Airborne Products to be marketed, distributed, and sold to consumers throughout Texas.

5. Defendant Victoria Knight-McDowell, sued individually, is purportedly the creator of Airborne Health Formula and is the former co-owner, President, and Secretary of Airborne, Inc. She currently resides in Pacific Grove, CA, and is currently a majority owner and board member of Airborne Holdings along with Mr. McDowell and others. At all times relevant to this Complaint, Defendant Knight-McDowell acting alone or in concert with others has directed, formulated, controlled, or participated in the policies, acts, or practices as set forth herein.

6. Defendant Thomas John McDowell, also known as "Rider" McDowell, sued individually, is Defendant Knight-McDowell's husband. Defendant McDowell also currently resides in Pacific Grove, CA, and together with Mrs. Knight-McDowell is a majority owner of Airborne Holdings. At all times relevant to this Complaint, Defendant McDowell acting alone or in concert with others, has directed, formulated, controlled, or participated in the policies, acts, or practices as set forth herein.

7. While the Individual Defendants did not have control over a majority of shares of Airborne Holdings, Inc. during the time of Summit Partners' acquisition, the Individual Defendants actively participated in key decisions of the company including Airborne's marketing and advertising.

#### **VENUE**

8. Venue of this action lies in Dallas County on the basis of §431.047( c) and §431.0585(d) of the TFDCA by virtue of the fact that Defendants were engaged in the business of offering to sell and selling dietary supplements throughout Texas, including Dallas, Texas.

9. Venue of this action lies in Dallas County on the basis of §17.47(b) of the DTPA because Defendants' acts and practices that violate these statutes occurred throughout Texas, including Dallas County, Texas.

#### **PUBLIC INTEREST**

10. Because Plaintiff STATE OF TEXAS has reason to believe that Defendants have engaged in, and will continue to engage in, the unlawful practices set forth below, Plaintiff STATE OF TEXAS has reason to believe that Defendants have caused and will cause immediate and irreparable injury, loss and damage to the STATE OF TEXAS, and its citizens, and will also cause adverse effects to legitimate business enterprises which conduct their trade and commerce in a lawful manner in this State. Therefore, the Attorney General of the STATE OF TEXAS believes and is of the opinion that these proceedings are in the public interest.

#### **ACTS OF AGENTS**

11. Whenever in this petition it is alleged Defendants did any act or thing, it is meant that Defendants performed or participated in such act or thing or that such act was performed by agents or employees of Defendants and in each instance, the agents or employees of Defendants

were then authorized to and did in fact act on behalf of Defendants or otherwise acted under the guidance and direction of Defendants.

### **TRADE AND COMMERCE**

12. Defendants have, at all times described below, engaged in conduct which constitutes “trade” and “commerce” as those terms are defined by §17.45(6) of the DTPA.

### **NOTICE BEFORE SUIT**

13. Plaintiff informed Defendants herein at least seven (7) days before instituting this action of the alleged unlawful conduct of which complaint is now made.

### **NATURE OF DEFENDANTS’ CONDUCT**

14. Defendants have made health-related claims in the marketing, packaging, advertising, offering, and selling of their line of dietary supplements that cannot legally be made for dietary supplements. Specifically, Defendants have explicitly or implicitly claimed to sell a cold prevention remedy, a sore throat remedy, a germ fighter, and an allergy remedy without the required approval by the Federal Food and Drug Administration (“FDA”) of these products as drugs. The State also alleges that the Defendants failed to adequately warn consumers about potential health risks to select populations, including pregnant women, at the time that Airborne contained 5,000 International Unit of Vitamin A per dose under prior formulations. Currently, the level of Vitamin A in Airborne is 2,000 International Units. Under the current directions for use, consumers are directed not to take beyond three doses a day.

15. Airborne Effervescent Health Formula (“Airborne Original”) is a dietary supplement containing seventeen herbs and nutrients. Airborne Original is the Defendants most successful product and has been the number one selling item in the cough and cold section of major retailers within the last two years. Aside from a modest proprietary blend, Airborne consists of Vitamin A, Vitamin C, Vitamin E, Riboflavin, Magnesium, Selenium, Manganese,

Potassium, and Amino Acids. Airborne Original is a citrus-flavored effervescent tablet sold in plastic tubes of ten tablets.

16. Under the control of Airborne Holdings, Airborne Health has expanded the Airborne brand to include several additional lines of products sold as dietary supplements. Additional Airborne products include Airborne, Jr., a grape flavored effervescent tablet for use by children ages four to ten containing half the dosage of the herbs and nutrients found in Airborne Original, Airborne Nighttime, an apple cider flavored effervescent tablet based on the same formula as Airborne Original, Airborne On-the-Go, a lemon-lime flavored powder that is supposed to be poured directly into a water bottle, Airborne Power Pixies, a cherry flavored powder similar in form to the candy Pixie Stix that is supposed to be poured directly onto the tongue by children between ages four and twelve, Airborne Gummi Lozenges (formerly Airborne Sore Throat Gummi Lozenges), a gelatin-based lozenge that is designed to be dissolved in the mouth, and Airborne Seasonal Relief, a citrus flavored tablet that contains Vitamin C, Vitamin B6, Pantothenic Acid, Sodium and a proprietary blend of herbal extracts that purports to “promote normal histamine levels.”

17. Airborne products can be found in the cough/cold aisle of most retail stores including Walgreens, CVS, Kroger, Albertson’s, Target, Wal-Mart, Sam’s Club, Trader Joe’s, and Costco, as well as online at [www.airbornehealth.com](http://www.airbornehealth.com) and through third party Internet retailers

18. Since 1997 and continuing thereafter, the Defendants have individually or in concert with others, manufactured, marketed, advertised, promoted, offered for sale, sold, and distributed Airborne Original to the public. National distribution of Airborne Original began on or around 2000.

19. The Defendants have used both traditional (radio, television, print, Internet) and non-traditional (promotions with Airlines and celebrities) media to induce consumers to buy Airborne Original, and other Airborne Products.

20. The Defendants have generally run their marketing campaigns from October to February with the greatest spending taking place during November through January, the peak of cold, flu, and cough season.

21. The Defendants, alone or in concert with others, have intentionally positioned and marketed Airborne Original and all other Airborne products with the exception of Airborne Seasonal Relief as a preventative cold remedy. Until recently, the Defendants also marketed most of their product line as being able to fight germs in crowded areas such as airplanes, restaurants, offices, hospitals, schools, health clubs, carpools, theaters, and sports arenas.

22. The Defendants specifically referred to Airborne Original as a cold remedy by making the following claims, primarily on their website;

- (a) "Airborne Effervescent Cold Formula;"
- (b) "A Miracle Cold Buster;"
- (c) "Airborne Cold Remedy;"
- (d) "Sick of Catching Colds? Try Airborne;"
- (e) "Airborne Natural Cold Remedy;"
- (f) "Developed by a school teacher who was sick of catching colds in class an on airplanes!;"
- (g) "Developed by a school teacher who was sick of catching colds in class!;"
- (h) "I created Airborne because, as a teacher dealing with young children, I was sick of catching colds in the classroom;"
- (i) "Take at the first sign of a cold symptom or before entering crowded, potentially germ-infested places!;"

(j) “Take at the first sign of a cold symptom or before entering crowded environments;”

(k) “Airborne has become one of the fastest selling health products in retail history—largely by word of mouth—and the #1 selling natural product in the busy cough/cold aisle of all major drug stores;” and

(l) “Look in the cough-cold aisle of your favorite drug store.”

23. Defendants have also made health claims through vignettes of cartoon figures sneezing, coughing, or with other cold and cough indicators on their product packaging and on their marketing materials. Defendants have also made health claims about their products purported germ fighting abilities throughout.

24. In 2006, the Defendants launched an advertising campaign chiefly for their Airborne Original product that featured a man dressed as a giant germ sneezing on people, coughing on people, and engaging in other unsanitary acts. During this campaign, the Defendants used the tagline “Germs are everywhere? Have you taken your Airborne?” While the written claims in the 2006 advertising campaign were confined largely to Airborne’s purported ability to “fight germs,” the visual representations contained in the advertisements still stressed cold and cough symptom indicators.

25. After the first acquisition of the company, the Defendants expanded their product line. As part of this expansion, the Defendants launched a series of new products, including “Airborne Sore Throat Gummi Lozenge.” As part of the expanded product line, the Defendants launched a “Seasonal Relief” product that made implicit unsubstantiated “allergy relief” claims. The marketing campaign for the “Seasonal Relief” product ran during the peak of allergy season and featured individuals in the outdoors sneezing.

26. Defendants failed to comply with FDA’s monographs for over-the-counter drugs or seek clearance for marketing from FDA as a prescription drug although they made disease claims for their products, labeled as dietary supplements. In addition, Defendants did not

possess adequate substantiation for their cold prevention, cold treatment, fights germs, sore throat, or allergy relief claims.

27. Prior formulations of Airborne contained 5,000 International Units of Vitamin A. Currently, the highest dosage of Vitamin A for any Airborne product is 2,000 International Units with directions advising consumers not to exceed three tablets per day. Vitamin A, unlike Vitamin C, is retained longer in the body. Excessive Vitamin A can be toxic to the body at certain levels. While the scientific literature is not completely uniform, with some studies placing the toxicity levels of Vitamin A at 100,000 International Units of Vitamin A, other studies place the toxicity levels of Vitamin A at much lower amounts, particularly for pregnant women and children.

28. Early versions of Airborne's product packaging did not contain any limitations on the maximum number of doses of Airborne per day, which combined with Airborne's marketing strategy encouraging preventative use, likely caused consumers to ingest high levels of Vitamin A – especially when one accounts for the Vitamin A consumers receive from other sources. Subsequent versions of Airborne's product packaging advised consumers not to take more than three tablets per day.

#### **VIOLATIONS OF THE TEXAS FOOD, DRUG, AND COSMETIC ACT**

29. Based on the findings in paragraphs 1 through 28, Defendants have manufactured and introduced into commerce unapproved new drugs; misbranded drugs and foods; and falsely represented that these unapproved new drugs could treat or cure diseases.

30. Defendants manufacture and sell products that are drugs within the meaning of §431.002(14) of the TFDCA because these products are intended to cure, mitigate, treat, or prevent disease.

31. Defendants' products are additionally classified as "new drugs" within the meaning of § 431.002(25) of the TFDCA because the TDSHS is unaware of any evidence that establishes that these drugs are generally recognized as safe and effective for their intended uses.

32. Defendants' drugs are also misbranded under the terms of the TFDCA because their labeling fails to bear adequate directions for the uses for which these drugs are intended and being promoted in Texas. Section 431.112 (f) (1) of the TFDCA states that a drug is deemed to be misbranded unless its labeling bears adequate directions for use, unless the drug has been exempted from those requirements by regulations adopted by the Secretary of the United States Department of Health and Human Services.

33. By federal regulation, 21 CFR § 201.5 "adequate directions for use means directions under which the layman can use a drug safely and for the purposes for which it is intended." The drugs promoted and sold by Defendants fail to bear adequate directions for their intended use as a drug since adequate directions for use cannot be written providing for the use of an unapproved drug by a layperson under the terms of §431.112 (f) (1) of the TFDCA.

34. Accordingly, the sale, delivery, offer for sale, hold for sale or give away of any new drugs without an FDA approved new drug application submitted by Defendants violates §431.114 (a) (1) of the TFDCA. The introduction or delivery for introduction into commerce of any article in violation of §431.114 of the TFDCA is prohibited, under §431.021 (e) of the TFDCA.

35. Defendants' products which are intended to cure, mitigate, treat, or prevent disease and/or whose label and/or labeling is not in conformance with state and federal standards are misbranded pursuant to §431.112(a) of the TFDCA. Since Defendants' drugs are misbranded under Texas law, Defendants are in violation of §431.021 (a) of the TFDCA.

36. In the alternative, Defendants labeled their products as dietary supplements, which are foods under Texas law, and made claims to cure, treat, prevent or mitigate diseases which misbrands these foods pursuant to §431.082(a), (g), (j), (t), and (u) of the TFDCA.

37. Since Defendants' foods, including dietary supplements, are misbranded under Texas law, Defendants are in violation of §431.021 (a) of the TFDCA.

38. Defendants' promotion of misbranded foods or unapproved new drugs is false within the meaning of §431.182 of the TFDCA because it is misleading in numerous particulars as set out above.

39. Such representations for misbranded foods or unapproved new drugs by Defendants constitute advertising within the definition set out in §431.002(1) of the TFDCA since they are intended to induce consumers to purchase Defendants' drugs or foods. Section 431.005 of the TFDCA provides that the selling of drugs or foods includes "...the sale, dispensing, and giving of any such article..."

40. Any such advertisement by Defendants for unapproved new drugs or misbranded foods is false by the terms of § 431.183(a) of the TFDCA because it is directed toward the public is not consistent with labeling claims permitted by the FDA.

#### **PROHIBITED ACTS UNDER THE TEXAS FOOD, DRUG AND COSMETIC ACT**

41. Based on the conduct alleged above in paragraphs 1 through 40, Defendants have committed or caused to be committed the following acts prohibited and declared to be unlawful by §431.001 *et seq.* of the TFDCA:

- A. Selling, delivering, offering for sale, holding for sale, or giving away any drug in Texas unless the drug has been approved by FDA in violation of §431.021(e) of the TFDCA;

- B. Introducing into commerce a misbranded drug by manufacturing, advertising, offering to sell, and selling a drug that has not been approved by the FDA, in violation of §431.021(a) of the TFDCA;
- C. Introducing into commerce a misbranded food, including a dietary supplement, by manufacturing, advertising, offering to sell, and selling such food that makes claims to cure, treat, prevent, or mitigate disease, in violation of §431.021(a) of the TFDCA;
- D. Introducing into commerce a misbranded food, including a dietary supplement, by manufacturing, advertising, offering to sell, and selling such food that fails to comply with federal and state labeling requirements, in violation of §431.021(a) of the TFDCA; and
- E. Falsely advertising or falsely representing that a drug or food, including a dietary supplement, is effective for treating diseases of the body, such as, cancer, when FDA has not approved these drugs, in violation of §431.021(f) of the TFDCA.

#### **VIOLATIONS OF THE TEXAS DECEPTIVE TRADE PRACTICES ACT**

42. Defendants, as alleged above in paragraphs 1 through 41, have in the course of trade and commerce engaged in false, misleading and deceptive acts and practices declared unlawful in §17.46(a) of the DTPA. Additionally, Defendants have violated §17.46(b) of the DTPA as follows:

- A. Causing confusion or misunderstanding as to the approval of the drugs or foods, including dietary supplements, manufactured by Defendants, in violation of §17.46(b)(2) of the DTPA;
- B. Representing that Defendants' drugs or foods, including dietary supplements, have benefits which they do not have, in violation of §17.46(b)(5) of the DTPA;

- C. Representing that Defendants' drugs or foods, including dietary supplements, are of a particular standard, quality, or grade, if they are of another, in violation of §17.46(b)(7) of the DTPA; and
- D. Failing to disclose that Defendants' drugs or foods, including dietary supplements, have not been approved by the FDA as drugs, when such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed, in violation of §17.46(b)(24) of the DTPA.

### **INJURY TO CONSUMERS**

43. By means of the foregoing unlawful acts and practices, Defendants have acquired money or other property from identifiable persons to whom such money or property should be restored, or who in the alternative are entitled to an award of damages.

### **PERMANENT INJUNCTION**

44. The State alleges that by reason of the foregoing, Defendants should not continue to manufacture, advertise, or sell their products in Texas in violation of the laws of Texas. The interests of the State of Texas require a permanent injunction to prohibit Defendants from advertising and selling their products, unless Defendants are in compliance with the DTPA and the TFDCA.

45. Unless injunctive relief is granted, Defendants will continue to violate the laws of the State of Texas to irreparable injury of the State of Texas and to the general public.

### **PRAYER**

46. WHEREFORE, Plaintiff prays that Defendants be cited according to law to appear and answer herein; that after due notice and upon final hearing a PERMANENT INJUNCTION be issued, restraining and enjoining Defendants, their successors, assigns,

officers, agents, servants, employees, and any other person in active concert or participation with Defendants, from engaging in the following acts or practices:

- A. Selling, delivering, offering for sale, holding for sale, or giving away any drug in Texas unless the drug has been approved by FDA;
- B. Introducing into commerce a misbranded drug by manufacturing, advertising, offering to sell, and selling a drug that has not been approved by the FDA;
- C. Introducing into commerce a misbranded food, including a dietary supplement, by manufacturing, advertising, offering to sell, and selling such food that makes claims to cure, treat, prevent, or mitigate disease;
- D. Introducing into commerce a misbranded food, including a dietary supplement, by manufacturing, advertising, offering to sell, and selling such food that fails to comply with federal and state labeling requirements;
- E. Falsely advertising or falsely representing that a drug or food, including a dietary supplement, is effective for treating diseases of the body, such as, cancer, when FDA has not approved these drugs;
- F. Causing confusion or misunderstanding as to the approval of the drugs or foods, including dietary supplements, manufactured by Defendants;
- G. Representing that Defendants' drugs or foods, including dietary supplements, have benefits which they do not have;
- H. Representing that Defendants' drugs or foods, including dietary supplements, are of a particular standard, quality, or grade, if they are of another; and
- I. Failing to disclose that Defendants' drugs or foods, including dietary supplements, have not been approved by the FDA as drugs, when such failure to disclose such information was intended to induce the consumer into a transaction

into which the consumer would not have entered had the information been disclosed.

47. Plaintiff further prays that this court upon final hearing order Defendants to pay civil penalties in favor of the STATE OF TEXAS in the amount of \$25,000.00 per day per violation of §431.021 of the TFDCA pursuant to §431.0585 of the TFDCA.

48. Plaintiff further prays that, upon final hearing, this Court will order Defendants to pay civil penalties in favor of the STATE OF TEXAS in the amount of \$20,000.00 per violation of the DTPA pursuant to of § 17.47(c)(1) of the DTPA.

49. Plaintiff further prays that upon final hearing that his Court order Defendants to restore all money or other property taken from persons by means of unlawful acts or practices, or, in the alternative, award judgment for damages to compensate for such losses pursuant to §17.47(d) of the DTPA.

50. Plaintiff further prays that upon final hearing that this Court order Defendants to pay to the STATE OF TEXAS attorney fees and costs of court pursuant to the TEX. GOVT. CODE §402.006 (c) (Vernon 2005, Supp. 2007).

51. Plaintiff further prays that upon final hearing that this court order Defendants to pay to the Office of the Attorney General and to the Texas Commissioner of Health their reasonable expenses incurred in obtaining injunctive relief under §431.047 of the TFDCA, including investigative costs, court costs, reasonable attorneys' fees, witness fees, and deposition expenses pursuant to §431.047(d) of the TFDCA.

52. Plaintiff further prays that upon final hearing that this Court grant all other relief to which the STATE OF TEXAS may show itself entitled.

Respectfully submitted,

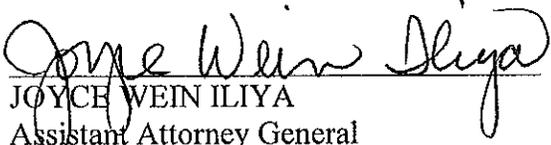
GREG ABBOTT  
Attorney General of Texas

C. ANDREW WEBER  
First Assistant Attorney General

JEFF L. ROSE  
Deputy First Assistant Attorney General

PAUL D. CARMONA  
Chief, Consumer Protection and Public Health Division

D. ESTHER CHAVEZ  
Deputy Chief, Consumer Protection and Public Health Division

  
JOYCE WEIN ILIYA  
Assistant Attorney General  
State Bar No. 00784319  
Consumer Protection and Public Health Division  
1412 Main Street, Suite 810  
Dallas, Texas 75202  
(214) 969-7639, ext. 8811  
Facsimile: (214) 969-7615  
Attorneys for the State

**Attorneys for Plaintiff State of Texas**