1 2	NEWPORT TRIAL GROUP Scott J. Ferrell, Bar No. 202091 sferrell@trialnewport.com	ELECTRONICALLY FILED Superior Court of California, County of Orange
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8	SUPERIOR COURT OF TH	E STATE OF CALIFORNIA
9	FOR THE COUN	TY OF ORANGE
10		
11	JANE DOE, individually, and on behalf of all	Case No. 30-2011-00510631-CU-MT-CXC
12	others similarly situated;	For all purposes assigned to Hon. Nancy Wieben Stock
13	Plaintiffs,	Dept. CX-105
14	VS.	THIRD AMENDED CLASS ACTION
15	DSM NUTRITIONAL PRODUCTS, INC., a New Jersey corporation; I-HEALTH, INC., a	COMPLAINT
16	Connecticut corporation; and DOES 1-20, Inclusive,	Complaint filed: September 23, 2011 Trial date: None Set
17	Defendants.	
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I. INTRODUCTION

Defendants DSM NUTRITIONAL PRODUCTS, INC. and I-HEALTH, INC. ("Defendants") are defrauding Californians by making blatant and provably false claims to market a dietary supplement called "i-cool for Menopause," ("i-cool" or the "product"), which they claim is "clinically proven to safely reduce hot flashes by up to 85%." Defendants falsely advertise that "i-cool" has the ability to provide "relief from night sweats, mood swings, and sleeplessness" and that "one pill a day takes the heat away." Defendants go so far as to claim that i-cool is "effective for nine out of ten women" but there is no scientific or medical evidence for such claims, and in fact the claims are absolutely false.

Plaintiff JANE DOE ("Plaintiff") brings this lawsuit to enjoin ongoing deceptions and to recover the many millions of dollars of profits generated by this false and misleading claim.

II. THE PARTIES

A. Plaintiff

1. Plaintiff is a resident of California and purchased i-cool from a CVS Pharmacy located at 4040 East Chapman Avenue in Orange, California in May of 2011 for \$16.99 after experiencing several symptoms of menopause. Plaintiff's Venue Declaration is concurrently filed herewith.

B. <u>Defendant</u>

- 2. Defendants are the manufacturers and distributors of i-cool. Plaintiff is informed and believes that defendant DSM Nutritional Products, Inc. is a New Jersey corporation and defendant I-Health, Inc. is a Connecticut corporation that each do business in California.
- 3. Plaintiff does not know the true names or capacities of the persons or entities sued herein as DOES 1 to 20, inclusive, and therefore sues such defendants by such fictitious names. Plaintiff is informed and believes and thereon alleges that each of the DOE defendants is in some manner legally responsible for the injuries suffered by Plaintiff and the members of the class as alleged herein. Plaintiff will amend this Complaint to set forth the true names and capacities of these defendants when they have been ascertained, along with appropriate charging allegations, as may be necessary.

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4. This Court has jurisdiction over all causes of action asserted herein.

5. Venue is proper in this Court because Defendants have received substantial compensation from sales in this County. Specifically, Defendants knowingly engage in activities directed at consumers in this County, the transaction occurred in this County as Plaintiff purchased the product in this County, and Defendants obtain substantial benefits from the common scheme perpetrated in this County. Plaintiff has filed concurrently herewith the declaration of venue required by Civil Code Section 1780(d).

6. Defendant and other out-of-state participants can be brought before this Court pursuant to California's "long-arm" jurisdictional statute.

IV. **FACTS**

7. Defendants market, advertise, and distribute i-cool.

8. Defendants have placed i-cool for sale to the general public and labeled it in such a way that is misleading to the public. By labeling the product "i-cool for Menopause" along with such product names and descriptors as "hormone-free" and "dietary supplement," a reasonable consumer would be led to believe that this product has the actual ability to have any effect on menopausal symptoms. Further, other claims on the product packaging such as "clinically proven to safely reduce hot flashes by up to 85%," and has the ability to provide "relief from night sweats, mood swings, and sleeplessness," and "one pill a day takes the heat away," and "effective for nine out of ten women," only further misleads women into believing i-cool can bring any relief to a very often uncomfortable time in a woman's life. Defendant's product labeling for i-cool is attached hereto as Exhibit 1. After experiencing several symptoms of menopause including but not limited to sleeplessness, mood swings, and hot flashes, Plaintiff purchased i-cool in May of 2011 because of the product's labeling and efficacy assertions contained thereon, including based on its alleged ability to aid in relieving

¹ It is Plaintiff's understaning and belief that in the second quarter of 2011, there was a labeling change on the front of the icool box. The new packaging removed the phrase: "Clinically proven to safely reduce hot flashes by up to 85 percent," This class action seeks to represent those California consumers who purchased i-cool from a retailer while this claim was included on the i-cool packaging, and does not seek to represent those who purchased i-cool after that date who purchased i-cool without the "Clinically proven to safely reduce hot flashes by up to 85 percent" claim.

∠O NEWPORT TRIAL GROUP menopausal symptoms. She used the product as directed and it failed to make any of the promised changes and failed to relieve any of her menopausal symptoms. In fact, it was useless to her.

- 9. Defendants also falsely claim on the product's packaging that the ingredients within icool, and specifically geniVida, have an impact on the symptoms of menopause, and make unsubstantiated claims regarding scientific research performed on the product. Defendants falsely claim that i-cool and geniVida are "clinically proven to reduce hot flashes" and falsely allege that i-cool can "reduce[] hot flashes and night sweats" and "reduce[] sleeplessness, irritability, and mood swings." See Exhibit 1. Defendants additionally claim on the product labeling that i-cool can reduce "feeling tired or lack of energy", "difficulty in concentrating", "loss of interest in most things", and "vaginal dryness". Id.
- 10. In reality, too little research has been done to support Defendants' claims about the efficacy of their product. Further, genistein, which is an isoflavone that has been associated with its apparent ability to make symptoms of menopause more moderate, is not what is present in i-cool.² Rather, Defendants' product uses a synthetic form of genistein, geniVida, which has been associated with treating bone-density in *post*-menopausal women.³ The study upon which Defendants' base their over-dramatized, alleged results lacks credibility in several respects: first, the advertising fails to disclose one of the authors, Dr. Elliot's association with defendant DSM Nutritional Products, Inc., their sponsorship of the study, or the fact that Dr. Elliott is not a M.D. Second, the study contained only 42 non-placebo participants. Third, and most importantly, only 28% of the participants in the Elliott study actually reported the improvements identified in the labeling and advertising.⁴
- 11. Defendants falsely represent that i-cool has characteristics, uses and benefits which it does not have, specifically the ability to substantially reduce menopausal symptoms in most women.
 - 12. Defendants falsely represent that i-cool is of a particular standard, quality, or grade.

² Press Release, The North American Menopause Society, NAMS Isoflavones Report Findings (June 24, 2011) (on file with author) *available at* http://www.menopause.org/prisoflavones11.aspx.

³ Metzner, J.E., Study on the pharmacokinetics of synthetic genistein after multiple oral intake in post-menopausal women, Arzneimittelforschung, 2009 at 513-20.

⁴ Evans, M., The effect of synthetic genistein on menopause symptom management in healthy postmenopausal women: a multi-center, randomized, placebo-controlled study, Maturitas, Feb. 2011, at 189-96.

13.

believe that i-cool and the ingredients within it have therapeutic properties that it does not have.

V. CLASS ACTION ALLEGATIONS

14. Plaintiff brings this class action for restitution and other equitable relief on behalf of the following class:

Defendants fraudulently induce consumers to purchase i-cool by causing them to

All women who were located within California when they purchased icool from a retailer for personal use at any time during the four years preceding the filing of this Complaint and contained the "Clinically proven to safely reduce hot flashes by up to 85 percent" claim.

- 15. Excluded from the Class are governmental entities, Defendants, any entity in which Defendants have a controlling interest, and Defendants' officers, directors, affiliates, legal representatives, employees, co-conspirators, successors, subsidiaries, and assigns. Also excluded from the Class is any judge, justice, or judicial officer presiding over this matter and the members of their immediate families and judicial staff. Also excluded from the class are those who purchased i-cool after the "Clinically proven to safely reduce hot flashes by up to 85 percent" claim was removed from the product's label.
- 16. The proposed Class is so numerous that individual joinder of all its members is impracticable. Due to the nature of the trade and commerce involved, however, Plaintiff believes that the total number of Class members is at least in the tens of thousands and members of the Class as numerous and geographically dispersed across California. While the exact number and identities of the Class members are unknown at this time, such information can be ascertained through appropriate investigation and discovery. The disposition of the claims of the Class members in a single class action will provide substantial benefits to all parties and to the Court.
- 17. There is a well-defined community of interest in the questions of law and fact involved affecting the plaintiff class and these common questions predominate over any questions that may affect individual Class members. Common questions of fact and law include, but are not limited to, the following:

- Is Defendants' labeling indicating that i-cool can substantially relieve symptoms a. of menopause in most women false?
- b. Is Defendants' labeling indicating that i-cool can substantially relieve symptoms of menopause in most women misleading to a reasonable consumer?
- Do Defendants have adequate substantiation to support the labeling claims that c. i-cool can substantially reduce the symptoms of menopause in most women to the extent claimed?
- d. When and to what extent did Defendants know the labeling indicating that icool can substantially reduce the symptoms of menopause in most women was false or misleading?
- Did Defendants continue to sell i-cool after knowing the preceding facts? e.
- Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all 18. members of the Class have been similarly affected by Defendants' common course of conduct since they all relied on Defendants' labeling representations concerning i-cool and purchased the product based on those representations.
- 19. Plaintiff will fairly and adequately represent and protect the interests of the Class. Plaintiff has retained counsel with substantial experience in handling complex class action litigation. Plaintiff and her counsel are committed to vigorously prosecuting this action on behalf of the Class and have the financial resources to do so. Plaintiff has retained a firm who is widely recognized as one of the most successful and effective class action litigators in California, and whose victories have been publicized on CNN, Fox News, MSNBC, and nearly every major California newspaper. The firm has also been certified as lead class counsel in similar class actions.
- 20. Plaintiff and the members of the Class suffered, and will continue to suffer, harm as a result of Defendants' unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of the present controversy. Individual joinder of all members of the class is impracticable. Even if individual class members had the resources to pursue individual litigation, it would be unduly burdensome to the courts in which the individual litigation would proceed. Individual litigation magnifies the delay and expense to all parties in the court system

of resolving the controversies engendered by Defendants' common course of conduct. The class action device allows a single court to provide the benefits of unitary adjudication, judicial economy, and the fair and efficient handling of all class members' claims in a single forum. The conduct of this action as a class action conserves the resources of the parties and of the judicial system and protects the rights of the class members. Furthermore, for many, if not most, a class action is the only feasible mechanism that allows an opportunity for legal redress and justice.

21. Adjudication of individual class members' claims with respect to the Defendants would, as a practical matter, be dispositive of the interests of other members not parties to the adjudication, and could substantially impair or impede the ability of other class members to protect their interests.

VI. <u>CAUSES OF ACTION</u>

FIRST CAUSE OF ACTION

VIOLATION OF CALIFORNIA LEGAL REMEDIES ACT

(By Plaintiff and On Behalf of the Class as against Defendants)

- 22. Plaintiff incorporates by this reference the allegations set forth at paragraphs 1 through 21 as if fully set forth herein.
- 23. Plaintiff has standing to pursue this claim as Plaintiff has suffered injury in fact and has lost money or property as a result of Defendants' actions as set forth herein. Specifically, prior to the filing of this action, Plaintiff purchased i-cool for her own personal use. In so doing, she reviewed, believed, and relied upon each of the preceding false marketing claims. Plaintiff used the product as directed, but it did not work as advertised. Plaintiff did not experience the promised benefit of reduced menopausal symptoms as a result of i-cool. i-cool provided no additional value to Plaintiff beyond that of much less expensive placebo pill.
- 24. Prior to filing this action, Plaintiff's counsel mailed to Defendants, by certified mail, return receipt requested, the written notice required by Civil Code Section 1782(a). A copy of that letter is attached hereto as Exhibit 2.
 - 25. Plaintiff filed the declaration of venue required by Civil Code Section 1780(d).

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- 30. Defendants' actions as alleged in this Complaint constitute an unfair or deceptive business practice within the meaning of California Business and Professions Code section 17200 in that Defendants' actions are unfair, unlawful, and fraudulent, and because Defendants have made unfair, deceptive, untrue or misleading statements in advertising media, specifically on their label for i-cool, within the meaning of California Business and Professions Code sections 17500, et seq.
- 31. Defendants' business practices, as alleged herein, are unfair because they offend established public policy and/or are immoral, unethical, oppressive, unscrupulous and/or substantially injurious to consumers in that consumers are potentially misled by the claims made with respect to icool as set forth herein.
- 32. Defendants' business practices as alleged herein are unlawful because the conduct constitutes false marketing and advertising and other causes of action alleged herein.
- 33. Defendants' business practices as alleged herein are fraudulent because they are likely to deceive customers into believing that i-cool has properties that it in fact does not have.
- 34. Defendants' wrongful business practices constituted, and constitute, a continuing course of conduct of unfair competition since Defendants marketed and sold their products in a manner likely to deceive the public.
 - 35. Defendants' wrongful business practices have caused injury to Plaintiff and the Class.
- 36. Pursuant to section 17203 of the California Business and Professions Code, Plaintiff and the Class seek an order of this court enjoining Defendants from continuing to engage in unlawful, unfair, or deceptive business practices and any other act prohibited by law, including those set forth in the complaint. Plaintiff and the Class also seek an order requiring Defendants to make full restitution of all moneys they wrongfully obtained from Plaintiff and the Class.

THIRD CAUSE OF ACTION

VIOLATION OF CALIFORNIA BUSINESS AND PROFESSIONS CODE SECTIONS 17500 ET SEQ.

(By Plaintiff and On Behalf of the Class as against Defendants)

37. Plaintiff incorporates by this reference the allegations set forth at paragraphs 1 through 36 as if fully set forth herein.

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- 38. As alleged herein, Plaintiff has standing to pursue this claim as Plaintiff has suffered injury in fact and has lost money as a result of Defendants' false advertising and unfair business practices. Specifically, prior to the filing of this action, Plaintiff i-cool for her own personal use. In so doing, she reviewed and relied upon the preceding marketing claims regarding the product. She has used the product as directed, but it has not worked as advertised, nor did she experience any of the promised benefits.
- 39. For a period of time from four or more years prior to the filing date of this lawsuit, Defendants have been responsible for the manufacturing, marketing, and distribution of i-cool.
- 40. Defendants have marketed and advertised i-cool using misleading labels, descriptors, and terminology on their product packaging for i-cool, which have been previously described and presented herein as Exhibit 1.
- 41. Defendants' labeling for i-cool is false and misleading because reasonable consumers are left with the overall net impression that i-cool provides benefits that it does not provide. Defendants' campaign has been persuasive and uniform, as such representations were communicated on all Defendants' packaging of i-cool during the class period.
- 42. Defendants knew or recklessly disregarded the fact that i-cool does not provide the advertised benefits, but is instead simply a pill that does not provide an relief from the symptoms of menopause, and has no unique or special formula(s).
- 43. Based on the foregoing, Defendants deceived Plaintiff and the Class by falsely representing that i-cool has certain characteristics, benefits, uses and qualities which it does not have.
- 44. Defendants' use of advertising media to advertise, call attention to or give publicity to the sale of goods or merchandise which are not as represented in any manner constitutes unfair competition, unfair, deceptive, untrue or misleading advertising, and an unlawful business practice within the meaning of Business and Professions Code Sections 17531 and 17200, and advertising which has deceived and is likely to deceive the consuming public, in violation of Business and Professions Code § 17500 et seq.

1	I, Jane Doe, declare as follows:
2	1. I am a Plaintiff in this action, and am a citizen of the State of California. I have
3	personal knowledge of the facts herein and, if called as a witness, I could and would testify
4	competently thereto.
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6	2. The Complaint in this action, filed concurrently with this Declaration, is filed in the
7	proper place for trial under Civil Code Section 1780(d) in that Orange County is a county in which
8	Defendants are doing business.
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10	I declare under penalty of perjury under the laws of the State of California that the foregoing is
11	true and correct.
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13	Jane Doe
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EXHIBIT 1

Relief from:

- ✓ Night sweats†
 ✓ Mood swings†
 ✓ Sleeplessness†



Effective for 9 out of 10 women^{†1}

One pill a day takes the heat away™¹

Hormone-free

For Menopause

Clinically proven to safely reduce hot flashes by up to 85%^{†1}

Dietary Supplement 30 Tablets • 1 Month Supply

i-cool



i-cool™, containing geniVida® genistein, is the menopause relief supplement that is clinically proven to safely help relieve menopausal symptoms.¹¹

A randomized, double-blind, placebo-controlled, clinical study $^{\rm 1}$ of geniVida $^{\rm 0}$ genistein showed:

Rate (%)

Avg. Reduced Hot Flashes and Night Sweats

- Reduced hot flashes and night sweats
- · Reduced sleeplessness, irritability and mood swings

What does this mean? If you have menopausal

symptoms, you can improve your quality of life, and the quality of life of those around you, with i-cool™. i-cool™ brings back the better you.

Reduces:

- Feeling tired or lacking energyt
 Difficulty in concentratingt
 Loss of interest in most thingst
- Vaginal dryness[†]

Directions: Take one tablet per day. For best results, daily use is recommended.

Educating yourself about menopause is a must! Learning the facts can help you make objective and informed decisions about your health at menopause and beyond. Red Hot Mamas® provides education, support, understanding, hope and optimism.

Learn more about Red Hot Mamas® at www.RedHotMamas.org.

i-cool™ does not contain synthetic estrogen and may be taken with other supplements. i-cool™ is non-allergenic.

Important information: As with other supplements, seek professional advice before use if you are pregnant or breast-feeding. Consult a health care professional before use if you are taking any medication or have a medical condition. KEEP OUT OF REACH OF CHILDREN.

Storage: Store in a dry place at room temperature.



Other ingredients: microcrystalline cellulose, dicalcium phosphate, croscarmellose sodium, stearic acid, magnesium silicate, hypromellose, magnesium stearate, titanium dioxide, silica, triacetin, mineral oil and sodium lauryl sulfate.

i-cool™ is free of artificial dyes and colors, preservatives, flavors, soy, yeast, wheat, gluten, lactose, sugar, starch or animal products.

128% of patients taking genVida* for 12 weeks had an 85% or more reduction in hot flashes. Elliott, J., et al. Genistein reduces the number and duration of hot flashes in per-post menopousal women in a randomized, doubte-blind, placebo-controlled, multi-ameriral. Experimental Biology 2009, 1947, 409 Results may vary.

More on i-cool™ and menopausal symptom relief at www.i-cooltoday.com.

†These statements have not been evaluated by the U.S. Food and Drug Administration. This product is not intended to treat, mitigate, diagnose or cure any disease.



A Professional Corporation

July 6, 2011

By Certified Mail, Return Receipt Requested

DSM Nutritional Products, Inc. 45 Waterview Boulevard Parsippany, NJ 07054 Attention President and CEO

Re: Violations of California Consumer Legal Remedies Act

Dear Sir or Madam:

I am writing on behalf of an individual Californian, as well as a putative class of similarly situated persons, to advise you that we believe you are violating the California Consumer Legal Remedies Act.

Specifically, you label, advertise, and sell the product "i-Cool for Menopause." Your packaging and labeling describe i-Cool for Menopause as "clinically proven to safely reduce hot flashes by up to 85%." Your packaging also claims that i-Cool for Menopause will "safely reduce menopausal symptoms" such as "feeling tired or lacking energy", "difficulty in concentrating", and "loss of interest in most things." Based upon these representations, our client purchased i-Cool for Menopause, used it as directed, and achieved none of the promised benefits. It was, in fact, worthless to her.

We believe that the preceding claims are false, misleading, and lack credible scientific substantiation. The claims are apparently based upon the inclusion of 30 milligrams per serving of genistein, along with misplaced reliance upon the 2009 Elliott study published in the Journal of Experimental Biology. First, the advertising fails to disclose Dr. Elliot's association with DSM, DSM's sponsorship of his study, or the fact that Dr. Elliott is not an M.D. Second, the study contained only 42 non-placebo participants. Third, and most importantly, only 28% of the participants in the Elliott study actually reported the improvements identified in the labeling and advertising.

As such, we believe that you are advertising *i-cool for Menopause* as having characteristics, uses and benefits that it does not have. We respectfully request that you agree to irrevocably stop all false and misleading advertising and labeling of *i-cool for Menopause*, provide all consumers who have purchased the product with a full refund, and

conform your conduct to the requirements of California law, including the California Consumer Legal Remedies Act.

Very truly yours,

NEWPORT TRIAL GROUP

Scott J. Ferrell

SJF/lb

1 PROOF OF SERVICE 2 STATE OF CALIFORNIA. COUNTY OF ORANGE 3 I am employed in the County of Orange, State of California. I am over the age of 18 and not a party to the within action; my business address is 895 Dove Street, Suite 425, Newport Beach, CA 92660. 4 5 On May 24, 2013, I served the foregoing document described as THIRD AMENDED CLASS **ACTION COMPLAINT** on the following person(s) in the manner indicated: 6 SEE ATTACHED SERVICE LIST 7 (BY MAIL) I am familiar with the practice of Newport Trial Group for collection and 8 processing of correspondence for mailing with the United States Postal Service. Correspondence so collected and processed is deposited with the United States Postal Service that same day in the ordinary course of business. On this date, a copy of said document was placed in a sealed envelope, with postage fully prepaid, addressed as set forth herein, and such envelope was placed for collection 10 and mailing at Newport Trial Group, Newport Beach, California, following ordinary business practices. 11 (BY FEDERAL EXPRESS) I am familiar with the practice of Newport Trial Group for 12 collection and processing of correspondence for delivery by overnight courier. Correspondence so collected and processed is deposited in a box or other facility regularly maintained by Federal Express 13 that same day in the ordinary course of business. On this date, a copy of said document was placed in a sealed envelope designated by Federal Express with delivery fees paid or provided for, addressed as 14 set forth herein, and such envelope was placed for delivery by Federal Express at Newport Trial Group, Newport Beach, California, following ordinary business practices. 15 (BY FACSIMILE TRANSMISSION) On this date, at the time indicated on the transmittal 16 sheet, attached hereto, I transmitted from a facsimile transmission machine, which telephone number is (949) 706-6469, the document described above and a copy of this declaration to the person, and at the 17 facsimile transmission telephone numbers, set forth herein. The above-described transmission was reported as complete and without error by a properly issued transmission report issued by the facsimile 18 transmission machine upon which the said transmission was made immediately following the transmission. 19 (BY ELECTRONIC SERVICE) I am causing the document(s) to be served by email or 20 electronic transmission via One Legal sent on the date shown below to the email addresses of the persons listed in the attached service list. 21 I declare under penalty of perjury under the laws of the State of California that the foregoing is 22 true and correct, and that this declaration was executed on May 24, 2013, at Newport Beach, California. 23 24 eanette D. Francis 25

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SERVICE LIST David Jacobs, Esq. Deanna L. Ballesteros, Esq. EPSTEIN BECKER & GREEN, P.C. 1925 Century Park East, Suite 500 Los Angeles, CA 90067-2506 Attorneys for Defendants, DSM Nutritional Products, Inc. and I-Health, Inc. Tel: (310) 556-8861 Fax: (310) 553-2165 djacobs@ebglaw.com dballesteros@ebglaw.com