GOMEZ TRIAL ATTORNEYS
JOHN H. GOMEZ (171485)
jgomez@gomeztrialattorneys.com
DEBORAH S. DIXON (248965)
ddixon@gomeztrialattorneys.com
655 W. Broadway Suite 1700
San Diego, California 92101
Telephone: (619) 237-3490
Facsimile: (619) 237-3496

LAW OFFICES OF RONALD A. MARRON
RONALD A. MARRON (175650)
ron@consumersadvocates.com
SKYE RESENDES (278511)
skye@consumersadvocates.com
651 Arroyo Drive
San Diego, California 92103
Telephone: (619) 696-9006
Facsimile: (619) 564-6665

KREINDLER & KREINDLER, LLP
GRETCHEN M. NELSON (112566)
gnelson@kreindler.com
707 Wilshire Boulevard, Suite 3600
Los Angeles, California 90017
Telephone: (213) 622-6469
Facsimile: (213) 622-6019

Class Counsel

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

KIM ALLEN, et al., on behalf of themselves, all others similarly situated and the general public,

Plaintiffs,

v.

HYLAND'S, INC., et al.,

Defendants.

Case No: 12-cv-1150-DMG-MAN

CLASS ACTION

PLAINTIFFS' NOTICE OF MOTION AND MOTION FOR NEW TRIAL

Judge: Honorable Dolly M. Gee
Date: October 21, 2016
Time: 9:30 a.m.
Location: Courtroom 7, 2nd Floor

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE THAT on October 21, 2016 at 9:30 a.m. in Courtroom 7, or as soon thereafter as the matter may be heard, Plaintiffs Kim Allen, Melissa Nigh, Nancy Rodriguez, Diana Sisti, Sherrell Smith, Daniel Xenos and Yuanke Xu ("Plaintiffs") on behalf of themselves and the class will, and hereby do, respectfully move the Court to order a new trial in this matter pursuant to Federal Rule of Civil Procedure 59 and on the grounds that:

1. The jury instructions contained an erroneous statement of the law and heightened burden for Plaintiffs and Plaintiffs' legally sound jury instruction was rejected such that there was prejudicial error and the jury instructions were misleading.
2. The verdict is contrary to the weight of the evidence.

This motion is based on this Notice, the accompanying Memorandum of Points and Authorities, the accompanying Declarations of Deborah S. Dixon and all other pleadings and papers on file in this action, and such oral and documentary evidence and argument as may be presented at the time of hearing.

This motion is made following the conference of counsel pursuant to L.R. 7-3 which took place on September 2, 2013.

Dated: September 13, 2016

GOMEZ TRIAL ATTORNEYS

/s/ Deborah S. Dixon

JOHN H. GOMEZ (171485)
jgomez@gomeztrialattorneys.com
DEBORAH S. DIXON (248965)
ddixon@gomeztrialattorneys.com
655 W. Broadway Suite 1700
San Diego, California 92101
Telephone: (619) 237-3490
Facsimile: (619) 237-3496

Class Trial Counsel

Dated: September 13, 2016

LAW OFFICES OF RONALD A. MARRON

/s/ Skye Resendes

RONALD A. MARRON
ron@consumeradvocates.com
SKYE RESENDES
skye@consumeradvocates.com
651 Arroyo Drive
San Diego, California 92101
Telephone: (213) 892-9200
Facsimile: (213) 892-9494

Dated: September 13, 2016

KREINDLER & KREINDLER, LLP

/s/ Gretchen M. Nelson

GRETCHEN M. NELSON
gnelson@kreindler.com
GABRIEL S. BARENFELD
gbarenfeld@kreindler.com
707 Wilshire Boulevard, Suite 3600
Los Angeles, California 90017
Telephone: (213) 622-6469
Facsimile: (213) 622-6019

GOMEZ TRIAL ATTORNEYS
JOHN H. GOMEZ (171485)
jgomez@gomeztrialattorneys.com
DEBORAH S. DIXON (248965)
ddixon@gomeztrialattorneys.com
655 W. Broadway Suite 1700
San Diego, California 92101
Telephone: (619) 237-3490
Facsimile: (619) 237-3496

KREINDLER & KREINDLER, LLP
GRETCHEN M. NELSON (112566)
gnelson@kreindler.com
707 Wilshire Boulevard, Suite 3600
Los Angeles, California 90017
Telephone: (213) 622-6469
Facsimile: (213) 622-6019

LAW OFFICES OF RONALD A. MARRON
RONALD A. MARRON (175650)
ron@consumersadvocates.com
SKYE RESENDES (278511)
skye@consumersadvocates.com
651 Arroyo Drive
San Diego, California 92103
Telephone: (619) 696-9006
Facsimile: (619) 564-6665

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v.

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Case No: 12-cv-1150-DMG-MAN

CLASS ACTION

PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION FOR NEW TRIAL

Judge: Honorable Dolly M. Gee
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Plaintiffs Kim Allen, Melissa Nigh, Nancy Rodriguez, Diana Sisti, Sherrell Smith, Daniele Xenos and Yuanke Xu ("Plaintiffs") respectfully submit this Memorandum in support of their Motion for New Trial pursuant to Federal Rule of Civil Procedure ("FRCP") 59.

I. INTRODUCTION

Plaintiffs move for a new trial based on the following grounds:

First, it was error for the Court to create a heightened burden of proof for Plaintiffs to prove their claims for violation of Consumer Legal Remedies Act ("CLRA"), Magnusson Moss Warranty Act ("MMWA") and breach of express warranty. The increased burden was not required nor supported by the law. Plaintiffs were required to prove a negative in that they were required to prove Defendant's products "cannot" work, instead of that the products "do not" provide relief from the symptoms as advertised. This change in the burden materially affected Plaintiffs' ability to prove the asserted causes of action and resulted in prejudicial error.

Second, the verdict is contrary to the weight of the evidence *at least* as to the clinical trials that unequivocally demonstrated the Defendant's cough and cold products and teething tablets were less effective than the placebo. As to all the products, Plaintiffs demonstrated the products did not perform as promised and did not alleviate the symptoms. The jury findings resulted in a miscarriage of justice and, notwithstanding the erroneous jury instruction, the evidence supported a finding in favor of Plaintiffs.

II. STATEMENT OF FACTS

A. Overview

The trial in this case involved eight products ("the "Product or Products") manufactured, marketed and sold by Defendants Hyland's Inc. and Standard Homeopathic Company throughout the United States. (Doc. No. 291, at p. 2.) The Products are Calms Forte, Teething Tablets, Migraine Headache Relief, Colic

Tablets, Leg Cramps (and Leg Cramps with Quinine), Defend Cold & Cough, Defend Cold & Cough Night, Hyland's Cough, and Seasonal Allergy Relief. (Doc. No. 382, ¶ 5.)[1]

The Named Plaintiffs purchased one or more of Defendants' Products. (Doc. No. 457 [09/04/2015 Rep. Tr. Morning Session (Allen) 44:18-19 and 59:7-8], attached to the Declaration of Deborah S. Dixon ("Dixon Decl.") submitted herewith as Ex. 19; (Doc. No. 457 [09/04/2015 Rep. Tr. Morning Session (Smith) 12:5-9], Dixon Decl. Ex. 20); (Doc. No. 459 [09/09/2015 Rep. Tr. Morning Session (Xu) 13:24-14:1], Dixon Decl. Ex. 21; (Doc. No. 457 [09/04/2015 Rep. Tr. Morning Session (Sisti) 96:5-6, 97:7-20, 101:23-102:5], Dixon Decl. Ex. 22; (Doc. No. 445 [09/03/2015 Rep. Tr. Afternoon Session (Nigh) 81:21-82:7, 82:19-22], Dixon Decl. Ex. 23).

As to each of the Products, Defendants make various representations that lead the consumer to believe that the Product will alleviate various symptoms and that the Products contain specific active ingredients in specific quantities. For example, Defendants represent that (i) Calms Forte will relieve stress to help the consumer sleep and the consumer will wake up rested and refreshed (Trial Exs. 42-33, 203, 1010-1 and 1010-2); (ii) Leg Cramps will stop the pain caused by leg cramps (Trial Exs. 6, 42-30 and 1010-2); (iii) Migraine Relief will relieve pressure, throbbing, light and noise sensitivity and the product is "effective" (Trial Ex. 1012-1-2); (iv) Defend Cold & Cough Day is "effective" for relief of nasal congestion, cough, sore throat and sneezing (Trial Ex. 1016-1-2); (v) Defend Cold & Cough Night is "effective" for relief of sleeplessness, congestion, cough, sore throat and sneezing (Trial Ex. 1017-1-2); (vi) Cough will provide relief for coughs (Trial Ex. 42-15 and 42-16);

[1] References to the trial transcripts include the Docket numbers for the filed transcripts. The afternoon session transcripts have been released but the morning session transcripts will not be released publicly until September 19, 2016. As a result, Plaintiffs refer to the Docket numbers but not the internal docketed pages.

(vii) Seasonal Allergy Relief is "effective" and will relieve itchy, watery eyes, sneezing, runny nose, itchy nose and throat (Trial Ex. 1019-1-2); (viii) Teething Tablets will provide relief for teething children (Trial Exs. 15, 42-37 and 42-38, Dixon Decl. Ex. 39).

Defendants were not selling a placebo as the intended benefit to consumers. (09/02/2015 Rep. Tr. Morning Session (Borneman) 75:19-22, Dixon Decl. Ex. 24.) Rather, Defendants through their Product labels, make promises that if consumers buy their products, they will be provided medical relief. (09/02/2015 Rep. Tr. Morning Session (Borneman) 75:19-22, Dixon Decl. Ex. 24; 09/02/2015 Rep. Tr. Afternoon Session (Borneman) 27:19-22; 49:25-50:5; 58:16-19; 83:13-19; 84:1-5; 92:22-25; 102:16-21, Dixon Decl. Ex. 25.)

Plaintiffs were not intending on purchasing placebos when they purchased the Products. (09/03/2015 Rep. Tr. Afternoon Session (Nigh) 97:20-22, Dixon Decl. Ex. 26; 09/04/2015 Rep. Tr. Morning Session (Smith) 20:20-22, Dixon Decl. Ex. 27; 09/04/2015 Rep. Tr. Morning Session (Allen) 66:12-23, Dixon Decl. Ex. 28; 09/04/2015 Rep. Tr. Morning Session (Sisti) 105:7-17, Dixon Decl. Ex. 29.) And they would not have purchased the Products if they knew they were not effective. (09/03/2015 Rep. Tr. Afternoon Session (Nigh) 97:20-22, Dixon Decl. Ex. 26; 09/04/2015 Rep. Tr. Morning Session (Smith) 20:20-22, Dixon Decl. Ex. 27; 09/04/2015 Rep. Tr. Morning Session (Allen) 66:12-23, Dixon Decl. Ex. 28; 09/04/2015 Rep. Tr. Morning Session (Sisti) 105:7-17, Dixon Decl. Ex. 29.)

B. Defendants Did Not Conduct Any Testing to Determine the Efficacy of the Products Prior to Selling them to Consumers

Defendants did not conduct any randomized controlled trials to test the Products to determine if they were effective before Defendants made the foregoing representations to consumers regarding the Products' alleged effectiveness. (Calms Forte: Doc. No. 444 [09/02/2015 Rep. Tr. Afternoon Session (Borneman) 34:22-35:5], Dixon Decl. Ex. 30; Doc. No. 447 [09/08/2015 Rep. Tr. Afternoon Session

(Phillips) 11:5-10], Dixon Decl. Ex. 31; (Leg Cramps (with/without quinine)); Doc. No. 455 [09/02/2015 Rep. Tr. Morning Session (Borneman) 128:7-129:11], Dixon Decl. Ex. 32; Doc. No. 444 [09/02/2015 Rep. Tr. Afternoon Session (Borneman) 34:22-35:5], Dixon Decl. Ex. 30; Doc. No. 447 [09/08/2015 Rep. Tr. Afternoon Session (Phillips) 11:5-10], Dixon Decl. Ex. 31); (Migraine Relief Doc. No. 444 [09/02/2015 Rep. Tr. Afternoon Session (Borneman) 34:22-35:5, Dixon Decl. Ex. 30; Doc. No. 447 [09/08/2015 Rep. Tr. Afternoon Session (Phillips) 11:5-10], Dixon Decl. Ex. 31); Hyland's Cough (Doc. No. 444 [09/02/2015 Rep. Tr. Afternoon Session (Borneman) 34:22-35:5], Dixon Decl. Ex. 30; Doc. No.447 [09/08/2015 Rep. Tr. Afternoon Session (Phillips) 11:5-10], Dixon Decl. Ex. 31); Seasonal Allergy Relief (Doc. No. 444 [09/02/2015 Rep. Tr. Afternoon Session (Borneman) 34:22-35:5, Dixon Decl. Ex. 30; Doc. No. 447 [09/08/2015 Rep. Tr. Afternoon Session (Phillips) 11:5-10], Dixon Decl. Ex. 31); Teething Tablets (Doc. No. 444 [09/02/2015 Rep. Tr. Afternoon Session (Borneman) 75:7-13], Dixon Decl. Ex. 33; Doc. No. 447 [09/08/2015 Afternoon Session (Le) Rep. Tr. 81:9-21)], Dixon Decl. Ex. 34); Defend Cold & Cough (night and day) (Doc. No. 447 [09/08/2015 Afternoon Session (Phillips) Rep. Tr. 10:18-11:5-10], Dixon Decl. Ex. 35; (Doc. No. 444 [09/02/2015 Rep. Tr. Afternoon Session (Borneman) 34:22-35:5], Dixon Decl. Ex. 30; Doc. No. 447 [09/08/2015 Rep. Tr. Afternoon Session (Phillips) 11:5-10], Dixon Decl. Ex. 31).

Prior to marketing and selling their Products, Defendants did not have medical testing to prove the Products could biologically help Plaintiffs' medical conditions or ailments. (Doc. No. 444 [09/02/2015 Rep. Tr. Afternoon Session (Borneman) 34:22-35:5], Dixon Decl. Ex. 30; Doc. No. 447 [09/08/2015 Rep. Tr. Afternoon Session (Phillips) 11:5-10], Dixon Decl. Ex. 31.) Prior to marketing and selling their Products, Defendants did not have medical testing to prove their Products could be effective to relieve Plaintiffs' symptoms or ailments. (Doc. No. 444 [09/02/2015 Rep. Tr. Afternoon Session (Borneman) 34:22-35:5], Dixon Decl. Ex. 30; Doc. No.

447 [09/08/2015 Rep. Tr. Afternoon Session (Phillips) 11:5-10], Dixon Decl. Ex. 31.) And, prior to marketing and selling the Products, Defendants did not know how their Products biologically could help Plaintiffs' medical conditions or ailments. (Doc. No. 448 [09/10/2015 Rep. Tr. Afternoon Session (Bell) 91:21-92:4: 105:1-8], Dixon Decl. Ex. 14; Doc. No. 450 [09/14/2015 Rep. Tr. Afternoon Session (Fisher) 9:11-24], Dixon Decl. Ex. 15.)

In sum, there was no valid pharmacological analysis conducted to design these Products. Rather Defendants' marketing department decided the alleged "active ingredients." (Doc. No. 447 [09/08/2015 Rep. Tr. Morning Session (Phillips) 112:2-6; 114:23-115:1], Dixon Decl. Ex. 36.)

C. Defendants' Post-Sale Testing of Two of the Products Confirmed the Products Performed No Better than a Placebo

Moreover, Defendants conducted a randomized controlled trial on their Teething Products in 2006 and learned the placebo performed better than the actual Product, meaning the Teething Tablets were not effective in providing relief any more than a placebo. (Doc. No. 455 [09/02/2015 Morning Session (Borneman) Rep. Tr. 113:24-25], Dixon Decl. Ex. 9; Trial Ex. 74-1, Dixon Decl. Ex. 38; Doc. No. 456 [9/3/2015 Morning Session (Borneman) Rep. Tr. 41:18-42:6, Dixon Decl. Ex. 10 (the placebo worked better than Teething Tablets].)

And, Defendants hired Dr. James Taylor from University of Washington to conduct a randomized controlled trial to determine if the Cold & Cough for Kids product was effective at relieving the symptoms stated on the package. The study demonstrated the placebo did better than the product (Defendants' product) and that the product did not relieve symptoms as stated, within the time period tested. (Taylor Dep., 06/19/2014 at p. 22:19-23-:3, 108:22-109:1, 113:14-24; 09/09/2015 Trial video, Dixon Decl. Ex. 11; Trial Ex. 191.) Dr. Taylor testified with respect to all four primary outcomes he set out to measure, Defendants' product did not show any effect that was different from placebo. (Taylor Dep., 06/19/2014 at p. 104:8-12,

Dixon Decl. Ex. 12; 09/10/2015 Trial video.) The products tested by Dr. Taylor are pharmacologically the same Products as the Defend Cold & Cough (night and day) Products. (Doc. No. 443 [09/01/2015 Rep/ Tr. Afternoon Session (Borneman) 69:23-25; 72:4-5], Dixon Decl. Ex. 13.)

Defendant's Cough & Cold Products and Teething Tablets Products, which unequivocally was clinically proven to not be as effective as advertised and did not alleviate the symptoms as Defendant's claimed. Defendants' Teething Tablets Product represent to provide relief for teething children. (Trial Exs. 15, 42-37 and 42-38, Dixon Decl. Ex. 37.) However, as was admitted at trial, Defendants conducted a randomized controlled trial on their Teething Products in 2006 and learned the placebo performed better than the actual Product, meaning the Teething Tablets were not effective in providing relief any more than a placebo. (Doc. No. 455 [09/02/2015 Morning Session (Borneman) Rep. Tr. 113:24-25], Dixon Decl. Ex. 9; Trial Ex. 74-1, Dixon Decl. Ex. 38; Doc. No. 456 [09/03/2015 Morning Session (Borneman) Rep. Tr. 41:18-42:6, Dixon Decl. Ex. 10 (the placebo worked better than Teething Tablets].)

D. Governmental Agencies in the United States, Australia and the United Kingdom All Concluded there is Little to No Scientific Evidence to Support the Underpinnings of Homeopathy

The U.S. Food & Drug Administration and the National Health Institute report that there is little to no scientific evidence to support the underpinnings of homeopathy. (Doc. No. 447 [09/08/2015 Rep. Tr. Afternoon Session (Le) 70:5-13], Dixon Decl. Ex. 39; Trial Ex. 296-2, Dixon Decl. Ex. 40.)

The United Kingdom's House of Commons Science and Technology Committee found there is no scientific evidence to support a claim that homeopathy works and that the systematic reviews and other meta-analyses conclusively demonstrated that homeopathic products perform no better than placebos, information not disclosed to consumers. (Trial Ex. 84-23, Dixon Decl. Ex. 41.)

The Australian Government's National Health & Medical Research Council (the "NHMRC") found that homeopathy is not an effective treatment. (Trial Ex. 409-6, Dixon Decl. Ex. 42.)

The National Center for Complementary and Integrative Health which is a division of the U.S. Department of Health and Human Services, has reported publicly "there is little evidence to support homeopathy as an effective treatment for any specific condition." (Trial Ex. 139-1, Dixon Decl. Ex. 43.)

The Staff at the Federal Trade Commission, after a vote by the Commission to adopt the Staff's Comments, determined consumers mistakenly believed manufacturers of homeopathic products tested their products on people to show their effectiveness. (Trial Ex. 406-15, Dixon Decl. Ex. 44.)

The foregoing was confirmed by Plaintiffs' expert Dr. Noel Rose. (Doc. No. 446 [09/04/2015 Afternoon Session (Dr. Rose) Rep. Tr. 55:24-56:1; 58:12-22; 63:14-64:12; 65:12-20, 98:9-16], Dixon Decl. Ex. 16.)

E. Plaintiffs' Experts Explained the Products Do Not Work Because of the Extraordinary Dilution Levels.

Dr. Noel Rose, a medical doctor, Ph. D. and the Director for the Center for Autoimmune Disease Research at Johns Hopkins Bloomberg School of Public Health, testified homeopathy does not work because when it has been put to trial, the overwhelming preponderance of evidence is that it does not work. (Doc. No. 446 [9/4/2015 Rep. Tr. Afternoon Session, (Rose) 79:21-24 and 80:3-18], Dixon Decl. Ex. 17.)

Defendants' Products do not contain ingredients that are ever sufficient to provide medical relief because of the extraordinary dilution levels. (Doc. No. 446 [09/04/2015 Afternoon Session (Dr. Rose) Rep. Tr. 27:1-23; 98:15-16, Dixon Decl. Ex. 16, "Well, with respect to the products that are under consideration and of concern in this – in this event, it is my opinion that there is no sound scientific or

medical evidence that they provide any benefit to patients with medical conditions such as those described and indicated on the labels, beyond the placebo effect"].)

F. The Jury Instruction

The Court instructed the jury that a decision as to whether Defendants breached their warranty was dependent on a finding that "Defendants' homeopathic products . . . cannot perform as promised." (Doc. No. 464 [09/15/2015 Rep. Tr. Morning Session 157:2-162:16, Dixon Decl. Ex. 1]; Doc. No. 465 [09/16/2015 Rep. Tr. Morning Session, 18:1-12], Dixon Decl. Ex. 4.)

Plaintiffs objected to the instruction because the term "cannot" improperly invites speculation by the jury and Plaintiffs argued the appropriate term should be "do not." (Doc. No. 464 [09/15/2015 Rep. Tr. 158:15-23, 160-161], Dixon Decl. Ex. 5.)

The Court instructed the jury that Plaintiffs were required to prove Defendant's products "cannot perform as promised." (Doc. No. 425, p. 35; Doc. No. 466 [09/17/2015 Rep. Tr. 19:6-24], Dixon Decl. Ex. 3.) In the CLRA instruction, the Court also tied the violation of that statute on a finding that "the products at issue cannot relieve symptoms as represented." (Doc. No. 425, p. 31; Doc. No. 466 [09/17/2015 Rep. Tr. Morning Session 18:1-12], Dixon Decl. Ex. 4.)

III. STANDARD OF REVIEW

Rule 59(a) states: "A new trial may be granted . . . in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States." Fed. R. Civ. P. 59(a)(1)(A). Similarly, Rules 59(a)(1)(B) and (a)(2) allow the district court to order a new trial after a nonjury trial and to "open the judgment if one has been entered, take additional testimony amend findings of fact and conclusions of law or make new ones, and direct the entry of a new judgment."

Rule 59(a) grants a district court with sound discretion to order a new trial, endowing the trial judge with the power to prevent a miscarriage of justice. *Moist*

Cold Refrigerator Co. v. Lou Johnson Co., 249 F.2d 246 (9th Cir. 1957). A new trial may be ordered to correct manifest errors of law or fact. *Malhiot v. S. Cal. Retail Clerks Union*, 735 F.2d 1133 (9th Cir. 1984). "Historically recognized grounds include but are not limited to 'claims that the verdict is against the weight of the evidence,…or that, for other reasons, the trial was not fair to the party moving.'" *Molski v. M.J. Cable, Inc.*, 481 F.3d 724, 729 (9th Cir. 2007) (quoting *Montgomery Ward & Co. v. Duncan*, 311 U.S. 243, 251 (1940)); *see also id.* (appellate court may "reverse the denial of [a motion for a new trial] where the District Court has 'made a mistake of law'") (quoting 12 James Wm. Moore et al., *Moore's Federal Practice* § 59.54 (3d ed. 2006)).

The standard of review for jury instructions in the Ninth Circuit is prejudicial error. *Smiddy v. Varney*, 665 F.2d 261, 265 (9th Cir. 1981), *cert. denied*, 459 U.S. 829 (1982). In the Ninth Circuit, prejudicial error exists if the instruction challenged, as a whole, did not fairly and adequately cover the issues presented, or when an instruction did not "correctly state[] the law," or was "misleading." *Thorsted v. Kelly*, 858 F.2d 571, 573 (9th Cir. 1988). "Whether a jury instruction is legally erroneous is a question of law." *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000). Where a jury instruction misleads the jury on an applicable legal standard or the necessary facts to establish a claim, it establishes grounds to grant a new trial. *See generally Ross v. M/V STUTTGART EXP.*, No. CV-08-03989 JCS, 2012 WL 3070739, at *6 (N.D. Cal. July 27, 2012) ("A new trial is warranted on the basis of erroneous jury instructions where the error 'clearly misled the jury.'"). The court should grant a motion for new trial based on a jury instruction that fails the test set forth in *Thorsted* whenever the moving party demonstrates it properly made a request for an alternative instruction (before the jury retires to deliberate) that could have corrected the "fatal flaws" in the instruction that was given. *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1258 (Fed. Cir. 2004); *Advanced Display Sys., Inc.*, 212 F.3d at 1281-82.

Additionally, a new trial can be granted "'if the verdict is contrary to the clear weight of the evidence, is based upon false or perjurious evidence, or to prevent a miscarriage of justice.'" *Id.* (quoting *Passantino v. Johnson & Johnson Consumer Prods.*, 212 F.3d 493, 510 n. 15 (9th Cir.2000)). In contrast to judgment as a matter of law motions, in determining whether a verdict is contrary to the clear weight of the evidence, the court "has 'the duty . . . to weigh the evidence as [the court] saw it'" and may set aside the verdict even if it is supported by substantial evidence. *Id.* at 729 (quoting *Murphy v. City of Long Beach*, 914 F.2d 183, 187 (9th Cir. 1990)). Where a movant claims that a verdict is against the clear weight of the evidence, a new trial should be granted where the judge "is left with the definite and firm conviction that a mistake has been committed" by the jury. *Landes Const. Co. v. Royal Bank of Canada*, 833 F.2d 1365, 1371–72 (9th Cir. 1987).

IV. THE JURY INSTRUCTION WAS ERRONEOUS AND PREJUDICED PLAINTIFFS

"A trial court should grant a motion for [Judgment as a Matter of Law] if substantial evidence does not support the jury's factual findings, presumed or express, or if those factual findings cannot support the legal conclusions implied from the jury's verdict. *Kearns v. *1253 Chrysler Corp.*, 32 F.3d 1541, 1547-48 (Fed. Cir. 1994). This court reviews a district court's denial of a judgment as a matter of law motion without deference. *Sextant Avionique, S.A. v. Analog Devices, Inc.*, 172 F.3d 817, 824 (Fed. Cir. 1999)." *Chiron Corp. v. Genentech, Inc.*, 363 F.3d at 1252-53. The *Chiron* court further held:

> A trial court should grant a motion for a new trial if (1) the jury instructions were erroneous or inadequate, (2) the court made incorrect and prejudicial admissibility rulings, or (3) the verdict is contrary to the great weight of the evidence. *Murphy v. Long Beach*, 914 F.2d 183, 186 (9th Cir.1990); *Chalmers v. City of Los Angeles*, 762 F.2d 753, 761 (9th Cir.1985). Chiron asserts that it is entitled to a new trial based on the first and second avenues. This court reviews the denial of a new trial motion after a jury verdict for an abuse of

> discretion. *Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, 265 F.3d 1294, 1308 (Fed. Cir. 2001); *De Saracho v. Custom Food Mach., Inc.*, 206 F.3d 874, 880 (9th Cir. 2000). With respect to the jury instructions, Chiron assigns error to four separate rulings. This court reviews jury instructions in their entirety and "only orders a new trial when errors in the instructions as a whole clearly misled the jury." *Delta–X Corp. v. Baker Hughes Prod. Tools, Inc.*, 984 F.2d 410, 415 (Fed. Cir. 1993). Furthermore, Chiron "must show both fatal flaws in the jury instructions and a request for alternative instructions which could have corrected the flaws."

Chiron Corp. v. Genentech, Inc., 363 F.3d at 1258.

In *Chiron*, numerous jury instructions were challenged. Notably, the appellate court found precise wording was not necessary: "Chiron argues that this instruction invited the jury to apply a test that does not correspond to this court's written description law. This court again rejects Chiron's argument. Once again, though using different words, the district court's instruction *captures the essence of the* written description *doctrine* that a patent cannot claim priority to earlier applications if it includes new matter not present in those earlier disclosures." *Id.* at 1259 (emphasis added). Here, the essence of the difference between does not and cannot, and the *Pantron* case is huge.

In *Ross v. M/V STUTTGART EXP.*, 2012 WL 3070739 (N.D. Cal. July 27, 2012). Plaintiffs moved for a new trial and the Court held:

> Plaintiffs argue that the Court improperly instructed the jury with respect to the turnover duty. Plaintiffs assert that the Court should have instructed the jury that "when a defect exists in the gear of the ship when it is turned over to the longshoremen, it is presumed known to the defendant." Motion at 14. Specifically, Plaintiffs contend that the Court should have instructed the jury based upon one sentence from Scindia Steam Navigation Co. v. De Los Santos that "[a]ny defect in the ship at the time of turnover to the stevedore is deemed known by the ship's owner and officers." 451 U.S. 156, 167, 101 S.Ct. 1614, 68 L.Ed.2d 1 (1981). This "quote" appears nowhere in the opinion. In any event, Jury Instruction No. 23 is consistent with the standard of care articulated in Scindia. Plaintiffs argue that a ship owner is liable for any defect at the time of turnover.

> Motion at 14. To the contrary, a vessel's turnover duty to warn of defects is quite narrow. Howlett v. Birkdale Shipping Co., S.A., 512 U.S. 92, 114 S.Ct. 2057, 129 L.Ed.2d 78 (1994). Generally, a ship owner only has the duty to warn of hazards that are not known to the stevedore and that would be neither obvious to, nor anticipated by, an experienced stevedore. Scindia, 451 U.S. at 167. Therefore, a jury instruction holding a ship owner liable for all defects at the point of turnover would be inconsistent with Scindia and Howlett. The Court correctly instructed the jury that the turnover duty requires a ship owner to turn over a vessel and its equipment in such condition that an experienced stevedoring contractor would be able, by the exercise of ordinary care, to carry on cargo operations with reasonable safety to persons and property. Id. The vessel must only warn the stevedore of hazards on the ship that are known to the vessel or should be known to it in the exercise of reasonable care.

Ross v. M/V STUTTGART EXP., 2012 WL 3070739, at *2 (N.D. Cal. July 27, 2012).

"A new trial is warranted on the basis of erroneous jury instructions where the error 'clearly misled the jury.' *Chiron Corp. v. Genentech,* Inc., 363 F.3d at 1258; *see also KeyStone Retaining Wall Sys., Inc. v. Westrock, Inc.*, 997 F.2d 1444, 1448 (Fed. Cir. 1993) ("In the Ninth Circuit, no prejudicial error exists if, considering the charge as a whole, the court's instructions fairly and adequately covered the issues presented, correctly stated the law, and were not misleading.") (quotation omitted). The Court finds that Plaintiffs are not entitled to a new trial on the basis of the alleged errors in the Court's instructions."

Here, a new trial is appropriate because of the prejudicial error in the jury instructions. Not only were Plaintiffs required to prove Defendant's products "cannot" work as represented, but they were also denied their request to instruct the jury that the placebo effect or benefit could not be considered in rendering the verdict. The latter requested instruction was directly in line with *F.T.C. v. Pantron I Corp.*, 33 F.3d 1088, 1100 (9th Cir. 1994) which affirmed that if a product's "effectiveness arises solely as a result of the placebo effect, a representation that the product is effective constitutes a 'false advertisement' even though some consumers may experience positive results." Plaintiffs did not get the benefit of this instruction

to the jury, which was prejudicial. A failure to give an appropriate jury instruction is a basis for ordering a new trial. *Murphy v. City of Long Beach*, 914 F.2d at 187 . "A defendant is entitled to an instruction concerning his theory of the case if it is supported by law and has some foundation in the evidence." *Home Indem. Co. v. Lane Powell Moss & Miller*, 43 F.3d 1322, 1329 (9th Cir.1995).

Both errors, the change from "does not" to "cannot" and the failure to instruct on the placebo effect, are significant. Not only did this change heighten Plaintiffs' burden of proof, but this grammatical issue undoubtedly adversely affected the jury's verdict. Over Plaintiffs' objection, the Court instructed the jury that a decision as to whether Defendants breached their warranty was dependent on a finding that "Defendants' homeopathic products . . . cannot perform as promised." (09/15/2015 Rep. Tr. Morning Session 157:2-162:16, Dixon Decl. Ex. 1; 09/16/2015 Rep. Tr. Morning Session, 18:1-12, Dixon Decl. Ex. 2.) Nonetheless, the instruction was provided requiring Plaintiffs prove Defendant's products "cannot perform as promised." (Doc. No. 425, p. 35; 09/17/2015 Rep. Tr. 19:6-24, Dixon Decl. Ex. 3.) And in the CLRA instruction, the Court similarly tied the violation of that statute on a finding that "the products at issue cannot relieve symptoms as represented." (Doc. No. 425, p. 31; 09/17/2015 Rep. Tr. Morning Session 18:1-12, Dixon Decl. Ex. 4.)[2]

The Court determined that it would instruct the jury using the term "cannot" based on its belief that it was constrained as a result of its class certification decision. (09/15/2015 Rep. Tr. pp. 157:2-162:16, Dixon Decl. Ex. 1.) However, a class certification ruling is not a ruling on substantive claims, but is procedural in nature.

[2] Plaintiffs are unaware of any other class action case in a state or district court within the Ninth Circuit where Plaintiffs were required to demonstrate a product "cannot" work to meet their burden of proof on either a cause of action under CLRA or breach of warranty. In fact, in another class action against a different homeopathic manufacturer, the jury was not instructed on the "cannot" standard for a similar CLRA claim. *Lewert v. Boiron, Inc., et al.*, Case No. CV 11-10803-AB(JPRx), (C.D. Cal. June 16, 2016) (Doc. No. 441, p. 7), Dixon Decl. Ex. 18.

In re Genentech, Inc. Sec. Litig., 1990 WL 120641, at *2 (N.D. Cal. June 8, 1990); *Harriss v. Pan American World Airways, Inc.*, 74 F.R.D. 24, 37 (N.D. Cal. 1977) (a class certification under Rule 23 "is essentially a procedural order").

Moreover, in certifying the class the Court actually utilized the phrase "do not work" along with "cannot work:"

> If Plaintiffs' theory of the case is correct—i.e., Defendants made material misrepresentations about products **which do not work** and cannot possibly work as a matter of scientific principle, given the level of dilution of their active ingredients—then consideration of individual users' symptoms and the distinct active ingredients in each product is unnecessary. Moreover, if Plaintiffs' theory is correct, the belief of some users that the products are effective would necessarily be attributable to the placebo effect.

(Docket No. 291, p. 20 [emphasis added]; see also Court's Order on Defendant's Motion for Summary Judgment Doc. No. 197, p. 5 and 7 [Defendants argue that Plaintiffs' allegations simply amount to conclusory statements that Defendants 'knew or should have known' that their products did not work,…"Plaintiffs claim both that the products **do not work** and that there simply *is* no active ingredient in Defendant's product"); Court's Order Denying Motion to Dismiss Doc. No. 80, p. 2 ["Plaintiffs allege exactly what Defendants argue they must: that the products at issue 'have no effect on ailments and symptoms they are advertised for, and in fact **did not** alleviate the ailments or symptoms for which Plaintiffs purchased them'"].)

In arguing against the instruction, Plaintiffs' counsel pointed out that the term "cannot" improperly invites speculation by the jury:

> [B]ecause we've had all kinds of experts by the defense talking about what we don't know how it really works, but may be it can work this way or maybe it can work this away. And so, I think it invites speculation.
>
> The question is, whether the representations are false or not. And so, if they do not provide relief as represented . . . I think we've met our burden. To say they cannot provide relief, I think just grammatically is a more difficult burden that invites speculation.

(09/15/2015 Rep. Tr. 158:15-23, Dixon Decl. Ex. 5.) Plaintiffs' counsel argued that the appropriate instructional term should have been "do not." (*Id.*, p. 160-161.) The distinction between "cannot" and "do not" is critical.

The verb "do" can be a *transitive* verb (i.e. one that has an object as in "I do homework") as well as an *intransitive* verb (one without an object). However, in the context of the phrase "do not relieve" the word "do" acts as an *auxiliary* or *helping* verb. To imply a negative you need to add an auxiliary verb. For example, if you want to imply the negative of "ghosts exist" you have to say "ghosts do not exist." Grammatically there is no other way to convey the meaning.

The word "can" in the context of the Court's instruction also acts as an auxiliary verb, but "can" is a special type of auxiliary verb that is called a *modal auxiliary*. *Modal auxiliary* verbs are like regular auxiliary verbs in that they have to accompany another verb. But the modal auxiliary verb is used to indicate four things: 1. Theoretical possibility (*i.e.* "the American dream can come true if you work hard enough"); 2. Ability (*i.e.* "I can run ten miles"); 3. Permission (*i.e.* "can you help me with my homework?"); or 4. Obligation.[3]

The instruction "[t]he representations were false because the products at issue cannot relieve symptoms as represented," is inherently ambiguous because it is unclear whether it is intended to express possibility or ability. In the context of this litigation, "cannot" must be intended to equate to "ability" and not "theoretically possibility" because it is irrelevant whether it's theoretically possible that simple table salt prepared homeopathically can cure depression. (09/14/2015 Rep. Tr. Afternoon Session, 46:13-18, Dixon Decl. Ex. 6; 09/15/2015 Rep. Tr. Morning Session 157:23-160:20, Dixon Decl. Ex. 7.) Ability on the other hand is proven empirically. For example, if one were to say "I can run ten miles" the term "can" is

[3] In the present case, the phrase "cannot relieve" is not about permission or obligation. Rather it can only be intended to convey ability or theoretical possibility.

expressing merely a theoretical possibility because the speaker maybe full of irrational optimism. But, once that same speaker has run 10 miles there is proof that supports the statement and the verb used in that context expresses ability.

This inherent ambiguity in "cannot" is eliminated by using the phrase "do not" instead of "cannot" because the issue is whether or not the products relieve symptoms, not whether or not they can *theoretically* relieve symptoms. And, employing "do not" instead of "cannot" would have thus eliminated the risk of a finding that symptomatic relief through the placebo effect was sufficient to defeat Plaintiffs' claims of false product packaging statements.[4]

Further, any ambiguity as to whether the instruction resulted in a finding of theoretical possibility or ability would have been eliminated had the instruction not shifted from the past to the present tense: "The representations **were** false [past tense] because the products at issue **cannot** relieve [present tense] symptoms as represented." To remain tense consistent, the sentence should have stated: "The representations were false because the products at issue **could not** relieve symptoms as represented."

[4] Plaintiffs sought an instruction that the Defendants cannot avoid liability by relying on the placebo effect, (Docket No. 408, p. 2), an instruction that was consistent with the Court's class certification decision that Defendants cannot rely on the placebo effect to support product efficacy. (Docket No. 291, p. 40, n. 26.) *See also F.T.C. v. Pantron I Corp.*, 33 F.3d 1088, 1100 (9th Cir. 1994) ("Where, as here, a product's effectiveness arises solely as a result of the placebo effect, a representation that the product is effective constitutes a 'false advertisement' even though some consumers may experience positive results.") The Court declined to issue the instruction. (09/16/2015 Rep. Tr. Afternoon Session, 18:10-19:9, Dixon Decl. Ex. 8.) An instruction that is in proper form and is supported by the evidence should be granted to avoid depriving the propounding party of an opportunity to have the jury consider a basic theory of his or her case. *Dang v. Cross*, 422 F.3d 800, 810-811 (9th Cir. 2005); *Ford Motor Co. v. Dallas Power & Light Co.*, 499 F.2d 400, 412 (5th Cir. 1974).

The error in shifting tenses further prejudiced Plaintiffs and rendered the jury instructions confusing and misleading.[5] Thus, had the instruction not shifted from past tense to present tense, the jury would have been left with only one option -- "ability" and theoretical possibility would have been eliminated.

V. THE VERDICT WAS CONTRARY TO THE CLEAR WEIGHT OF THE EVIDENCE

The Ninth Circuit has reversed a District Court's failure to grant a motion for new trial because the weight of the evidence contradicts the verdict. *Molski v. M.J. Cable, Inc.*, 481 F.3d 724, 726 (9th Cir. 2007). In *Molski*, a disabled patron sued a Cable's restaurant under the ADA and California Unruh Act, for failure to have adequate architectural features to permit disabled access in its restroom. Molski was a well-known professional plaintiff who so frequently sued businesses for ADA violations that he was declared a vexatious litigant. At trial, Molski "provided uncontradicted [expert] evidence that [restaurant] did not identify and remove architectural barriers." *Molski v. M.J. Cable, Inc.*, 481 F.3d at 726. The defense focused on Molski's status as a vexatious litigant and alleged extortionist, stating he made a living from his ADA lawsuits and held no other employment. *Id.* at 728. "The jury returned a verdict for [defendant], responding 'No' to the threshold question: 'Do you find that the defendant failed to identify and remove architectural barriers at Cable's restaurant?'" *Id.*

The Ninth Circuit held there was no evidence to support the jury's verdict because Molski put on uncontradicted evidence that architectural barriers existed and defendant failed to identify and remove them. *Id.* at 731. Defendant's vice president even "acknowledged the continued existence of these violations" and

[5] Although the word "could" can express possibility, it can only do so in the present tense (*i.e.* "We could play baseball today"). Since the instruction ("the representations were false because the products at issue …") is in the past tense, the expression of possibility is simply not possible.

admitted defendant did nothing about it. *Id.* at 732. Accordingly, the trial court abused its discretion in denying Molski's motion for a new trial.

In this case, the verdict was contrary to the clear weight of the evidence directly relating to the Defendant's Cough & Cold Products and Teething Tablets Products, which unequivocally was clinically proven to not be as effective as advertised and did not alleviate the symptoms as Defendant's claimed. Defendants' Teething Tablets Product represent to provide relief for teething children. (Trial Exs. 15, 42-37 and 42-38, Dixon Decl. Ex. 39.) However, as was admitted at trial, Defendants conducted a randomized controlled trial on their Teething Products in 2006 and learned the placebo performed better than the actual Product, meaning the Teething Tablets were not effective in providing relief any more than a placebo. (09/02/2015 Morning Session (Borneman) Rep. Tr. 113:24-25, Dixon Decl. Ex. 9; Trial Ex. 74-1, Dixon Decl. Ex. 38; 09/03/2015 Morning Session (Borneman) Re. Tr. 41:18-42:6, Dixon Decl. Ex. 10 (the placebo worked better than Teething Tablets.)

Additionally, Defendants hired Dr. James Taylor from University of Washington to conduct a randomized controlled trial to determine if the Cold & Cough for Kids product was effective at relieving the symptoms stated on the package. The study demonstrated the placebo did better than the product (Defendants' product) and that the product did not relieve symptoms as stated, within the time period tested. (09/09/2015 Rep. Tr. 116, Trial video of Taylor Depo, 06/19/2014 at p. 22:19-23-:3, 108:22-109:1, 113:14-24, Dixon Decl. Ex. 11; Trial Ex. 191.) Dr. Taylor testified with respect to all four primary outcomes he set out to measure, Defendants' product did not show any effect that was different from a placebo. (Taylor Depo, 06/19/2014 at p. 104:8-12; 09/09/2015 Rep, Tr. 116, Trial video, Dixon Decl. Ex. 12.)

The products tested by Dr. Taylor are pharmacologically the same Products as the Defend Cold & Cough (night and day) Products at issue in this case.

(09/01/2015 Rep. Tr. Afternoon Session (Borneman) 69:23-25; 72:4-5, Dixon Decl. Ex. 13.) Prior to making representations to consumers and selling and advertising their Products, Defendants did not know how their Products biologically could help Plaintiffs' medical conditions or ailments. (09/10/2015 Rep. Tr. Afternoon Session (Bell) 91:21-92:4; 105:1-8, Dixon Decl. Ex. 14; 09/14/2015 Rep. Tr. Afternoon Session (Fisher) 9:11-24, Dixon Decl. Ex. 15.)

Defendants' Products do not have ingredients to provide medical relief as advertised because of the diluted levels of the ingredients. (09/04/2015 Afternoon Session (Dr. Rose) Rep. Tr. 27:1-23; 98:15-16, Dixon Decl. Ex. 16, "Well, with respect to the products that are under consideration and of concern in this – in this event, it is my opinion that there is no sound scientific or medical evidence that they provide any benefit to patients with medical conditions such as those described and indicated on the labels, beyond the placebo effect." 55:24-56:1; 58:12-22; 63:14-64:12; 65:12-20; 98:9-16, Dixon Decl. Ex. 16.) Dr. Noel Rose, a medical doctor, Ph.D. and the Director for the Center for Autoimmune Disease Research at Johns Hopkins Bloomberg School of Public Health, testified homeopathy does not work because when it has been put to trial and the overwhelming preponderance of evidence is that it does not work as advertised. (9/4/2015 Rep. Tr. Afternoon Session, (Rose) 79:21-24 and 80:3-18, Dixon Decl. Ex. 17.)

As such, the verdict was contrary to the clear weight of the evidence since the evidence established the Defendant's Cough & Cold, Cough & Cold Defend and Teething Tablets Products "could not" and "did not" alleviate the symptoms as advertised because the clinical trial establishes the placebo was more effective than Defendant's Products.

VI. CONCLUSION

For the foregoing reasons, Plaintiffs seek this Court order a new trial to cure the prejudicial error created by the erroneous jury instruction increasing Plaintiffs' burden of proof and the lack of jury instruction on the placebo effect which misled

the jury as to Plaintiffs' legal burden. In addition, Plaintiffs request a new trial because the verdict contradicted the clear weight of the evidence.

Dated: September 13, 2016

GOMEZ TRIAL ATTORNEYS

/s/ Deborah S. Dixon

JOHN H. GOMEZ (171485)
jgomez@gomeztrialattorneys.com
DEBORAH S. DIXON (248965)
ddixon@gomeztrialattorneys.com
655 W. Broadway Suite 1700
San Diego, California 92101
Telephone: (619) 237-3490
Facsimile: (619) 237-3496

Class Trial Counsel

Dated: September 13, 2016

LAW OFFICES OF RONALD A. MARRON

/s/ Skye Resendes

RONALD A. MARRON
ron@consumeradvocates.com
SKYE RESENDES
skye@consumeradvocates.com
651 Arroyo Drive
San Diego, California 92101
Telephone: (213) 892-9200
Facsimile: (213) 892-9494

Dated: September 13, 2016

KREINDLER & KREINDLER, LLP

/s/ Gretchen M. Nelson

GRETCHEN M. NELSON
gnelson@kreindler.com
GABRIEL S. BARENFELD
gbarenfeld@kreindler.com
707 Wilshire Boulevard, Suite 3600

Los Angeles, California 90017
Telephone: (213) 622-6469
Facsimile: (213) 622-6019

GOMEZ TRIAL ATTORNEYS
JOHN H. GOMEZ (171485)
jgomez@gomeztrialattorneys.com
DEBORAH S. DIXON (248965)
ddixon@gomeztrialattorneys.com
655 W. Broadway Suite 1700
San Diego, California 92101
Telephone: (619) 237-3490
Facsimile: (619) 237-3496

LAW OFFICES OF RONALD A. MARRON
RONALD A. MARRON (175650)
ron@consumersadvocates.com
SKYE RESENDES (278511)
skye@consumersadvocates.com
651 Arroyo Drive
San Diego, California 92103
Telephone: (619) 696-9006
Facsimile: (619) 564-6665

KREINDLER & KREINDLER, LLP
GRETCHEN M. NELSON (112566)
gnelson@kreindler.com
707 Wilshire Boulevard, Suite 3600
Los Angeles, California 90017
Telephone: (213) 622-6469
Facsimile: (213) 622-6019

Class Counsel

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

KIM ALLEN, et al., on behalf of themselves, all others similarly situated and the general public,

Plaintiffs,

v.

HYLAND'S, INC., et al.,

Defendants.

Case No: 12-cv-1150-DMG-MAN

CLASS ACTION

DECLARATION OF DEBORAH S. DIXON IN SUPPORT OF PLAINTIFFS' MOTION FOR NEW TRIAL

Judge: Honorable Dolly M. Gee
Date: October 21, 2016
Time: 9:30 a.m.
Location: Courtroom 7, 2nd Floor

I, Deborah S. Dixon, declare:

1. I am an attorney duly licensed to practice before all courts in the State of California and before the United States District Court, Central District, of California. I am a Senior Trial Attorney with Gomez Trial Attorneys, attorneys of record for Plaintiffs in the above-captioned matter. If called as a witness, I could and would competently testify to the facts set forth below as I know each to be true based on my personal knowledge.

2. I participated in the trial in this case, examining multiple witnesses and attending every day of trial and all trial-related hearings. I have personally reviewed the transcripts and trial exhibits attached hereto and referenced in the Motion for New Trial.

3. Attached hereto as Exhibit 1 is a true and correct copy of excerpts from trial testimony on September 15, 2015, pages 157:2-162:16.

4. Attached hereto as Exhibit 2 is a true and correct copy of excerpts from trial testimony on September 16, 2015, page 18:1-21.

5. Attached hereto as Exhibit 3 is a true and correct copy of excerpts from trial testimony on September 17, 2015, page 19:6-24.

6. Attached hereto as Exhibit 4 is a true and correct copy of excerpts from trial testimony on September 17, 2015, page 18:1-12.

7. Attached hereto as Exhibit 5 is a true and correct copy of excerpts from trial testimony on September 15, 2015, page 158:15-23.

8. Attached hereto as Exhibit 6 is a true and correct copy of excerpts from trial testimony on September 14, 2015, page 46:13-18.

9. Attached hereto as Exhibit 7 is a true and correct copy of excerpts from trial testimony on September 15, 2015, pages 157:23-160:20.

10. Attached hereto as Exhibit 8 is a true and correct copy of excerpts from trial testimony on September 16, 2015, pages 18:10-19:9.

/ / /

11. Attached hereto as Exhibit 9 is a true and correct copy of excerpts from trial testimony on September 2, 2015, page 113:24-25.

12. Attached hereto as Exhibit 10 is a true and correct copy of excerpts from trial testimony on September 3, 2015, pages 41:18-42:6.

13. Attached hereto as Exhibit 11 is a true and correct copy of excerpts from trial testimony on September 9. 2015, page 116 and the corresponding deposition pages of Dr. Taylor's 2014 deposition, volume II, which were played via videotape to the jury.

14. Attached hereto as Exhibit 12 is a true and correct copy of excerpts from trial testimony on September 9. 2015, page 116 and the corresponding deposition pages of Dr. Taylor's 2014 deposition, volume II, which were played via videotape to the jury.

15. Attached hereto as Exhibit 13 is a true and correct copy of excerpts from trial testimony on September 1, 2015, pages 69:23-25, 72:4-5.

16. Attached hereto as Exhibit 14 is a true and correct copy of excerpts from trial testimony on September 10, 2015, pages 91:21-92:4, 105:1-8.

17. Attached hereto as Exhibit 15 is a true and correct copy of excerpts from trial testimony on September 14, 2015, pages

18. Attached hereto as Exhibit 16 is a true and correct copy of excerpts from trial testimony on September 4, 2015, pages 27:1-23, 98:15-16, 55:24-56:1, 58:12-22, 63:14-64:12, 65:12-20, 98:9-16.

19. Attached hereto as Exhibit 17 is a true and correct copy of excerpts from trial testimony on September 4, 2015, pages 79:21-24, 80:3-18.

20. Attached hereto as Exhibit 18 is a true and correct copy of Doc. No. 441, p. 7, from *Lewert v. Boiron, Inc., et al.*, Case No. CV 11-10803-AB(JPRx) (C.D. Cal. June 16, 2016).

21. Attached hereto as Exhibit 19 is a true and correct copy of excerpts from trial testimony on September 4, 2015, pages 44:18-19 and 59:7-8.

22. Attached hereto as Exhibit 20 is a true and correct copy of excerpts from trial testimony on September 4, 2015, pages 12:5-9.

23. Attached hereto as Exhibit 21 is a true and correct copy of excerpts from trial testimony on September 9, 2015, pages 13:24-14:1.

24. Attached hereto as Exhibit 22 is a true and correct copy of excerpts from trial testimony on September 4, 2015, pages 96:5-6, 97:7-20, 101:23-102:5.

25. Attached hereto as Exhibit 23 is a true and correct copy of excerpts from trial testimony on September 3, 2015, pages 81:21-82:7, 82:19-22.

26. Attached hereto as Exhibit 24 is a true and correct copy of excerpts from trial testimony on September 2, 2015, pages 75:19-22.

27. Attached hereto as Exhibit 25 is a true and correct copy of excerpts from trial testimony on September 2, 2015, pages 27:19-22, 49:25-50:5, 58:16-19, 83:13-19, 84:1-5, 92:22-25, 102:16-21.

28. Attached hereto as Exhibit 26 is a true and correct copy of excerpts from trial testimony on September 3, 2015, pages 97:20-22.

29. Attached hereto as Exhibit 27 is a true and correct copy of excerpts from trial testimony on September 4, 2015, pages 20:20-22.

30. Attached hereto as Exhibit 28 is a true and correct copy of excerpts from trial testimony on September 4, 2015, pages 66:12-23.

31. Attached hereto as Exhibit 29 is a true and correct copy of excerpts from trial testimony on September 4, 2015, pages 105:7-17.

32. Attached hereto as Exhibit 30 is a true and correct copy of excerpts from trial testimony on September 2, 2015, pages 34:22-35:5.

33. Attached hereto as Exhibit 31 is a true and correct copy of excerpts from trial testimony on September 8, 2015, pages 11:5-10.

34. Attached hereto as Exhibit 32 is a true and correct copy of excerpts from trial testimony on September 2, 2015, pages 128:7-129:11.

/ / /

35. Attached hereto as Exhibit 33 is a true and correct copy of excerpts from trial testimony on September 2, 2015, pages 75:7-13.

36. Attached hereto as Exhibit 34 is a true and correct copy of excerpts from trial testimony on September 8, 2015, pages 81:9-21.

37. Attached hereto as Exhibit 35 is a true and correct copy of excerpts from trial testimony on September 8, 2015, pages 10:18-11:5-10.

38. Attached hereto as Exhibit 36 is a true and correct copy of excerpts from trial testimony on September 8, 2015, pages 112:2-6, 114:23-115:1.

39. Attached hereto as Exhibit 37 are true and correct copies of trial exhibits 15, 42-37 and 42-38.

40. Attached hereto as Exhibit 38 is a true and correct copy of trial exhibit 74-1.

41. Attached hereto as Exhibit 39 is a true and correct copy of excerpts from trial testimony on September 8, 2015, pages 70:5-13.

42. Attached hereto as Exhibit 40 is a true and correct copy of trial exhibit 296-2.

43. Attached hereto as Exhibit 41 is a true and correct copy of trial exhibit 84-23.

44. Attached hereto as Exhibit 42 is a true and correct copy of trial exhibit 409-6.

45. Attached hereto as Exhibit 43 is a true and correct copy of trial exhibit 139-1.

46. Attached hereto as Exhibit 44 is a true and correct copy of trial exhibit 406-15.

47. On September 2, 2016, I spoke with Defendant's counsel, Mr. Spencer Persson, in anticipation of filing the Motion for New Trial and in an attempt to meet and confer. I explained to Mr. Persson our theories to support the new trial and evidence we believed supported our theories. Mr. Persson acknowledged our

position, although he disagreed with our theories. The telephone call was not able to resolve the need for filing a motion for new trial.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed this 13th day of September, 2016, in San Diego, California.

/s/ Deborah S. Dixon

Deborah S. Dixon

EXHIBIT 1

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al.,

Plaintiffs,

VS

HYLAND'S, INC., et al.,

Defendants.

No. 12-1150DMG

Reporter's Transcript of Proceedings
JURY TRIAL - DAY TEN
MORNING SESSION
Los Angeles, California
TUESDAY, SEPTEMBER 15, 2015

ANNE KIELWASSER, CRR, RPR, CSR
Federal Official Court Reporter
312 North Spring Street, Room 432
Los Angeles, California 90012
Telephone: (213) 894-2969
anne.kielwasser@gmail.com
AKtranscripts.com

to be tried.

And the Court defined it as such, and we've prepared for the case as such, and I think we're entitled to have the jury decide the case that the Court certified, not some case as it may have developed into: Well, you should have said something on the label.

This case is about whether the products performed as represented and whether they can provide relief to anyone. And I think to not tell the jury that would be to do disservice to the Court -- to the Court's order and would prejudice us in terms of how we are prepared to try this case.

THE COURT: Well, I tend to agree with that only because I think that that is the unifying theme that causes this to be able to be certified as a class action, because if -- if we were here to decide whether it works for some people but doesn't work for other people, then we would have individualized issues.

And so, the only issue that I certified was that -- and it was the theory that plaintiffs, frankly, said that they were prepared to demonstrate or was that it cannot work, and therefore the representations are false.

MR. GOMEZ: Well, I think it's really, sort of, a matter of semantics.

Counsel said that the representations were

false because the products don't provide relief, you know, we agree with that. And that's the misrepresentation, they don't provide relief -- in other words, they don't relief the symptoms that the representations claim that they do.

You know, to -- I just think to say --

So that makes it falls, if you make a representation that it will relief symptoms, and it doesn't relief symptoms, that's a false representation.

To take the additional step in the jury's mind of saying it cannot relief symptoms, I think is improper, and I think imposes a burden of proof that's inconsistent with the elements of the California Consumer Legal Remedies Act.

And so I think you get into -- it invites speculation by the jury, because we've had all kinds of experts by the defense talking about what we don't know how it really works, but maybe it can work this way or maybe it can work this away. And so, I think it invites speculation.

The question is, whether the representations are false or not. And so, if they do not provide relief as represented, you know, I think we've met our burden. To say they cannot provide relief, I think just grammatically is a more difficult burden that invites speculation, I think.

THE COURT: You mean you would be able to live with it if I said: "Do not relieve symptoms as represented"

as opposed to "cannot relieve"?

MR. GOMEZ: Absolutely. And I -- and I think that's fair.

MR. MARGULIES: Again, Your Honor, your order certifying the class was clear. I think if they're changing their position on this, I realize Mr. Gomez wasn't around for the class certification proceedings, but the Court certified a question, I don't think it's fair to change the question midstream.

THE COURT: Do you think that it's different if it says: "Do not relieve symptoms as represented"?

MR. MARGULIES: I do. Their theory was, these are homeopathy medicine. They cannot provide relief.

THE COURT: For anyone.

MR. MARGULIES: For anyone. That was the theory the Court certified. So, I think Monday morning quarterbacking on whether that was the right question is really improper at this time.

This argument should have been raised then.

MR. GOMEZ: I just -- again, I think there's all sorts of different things that happened at the class certification stage. Not many of these cases are tried. We have jury instructions that set forth the proper standard of proof.

THE COURT: Well, I'm pretty clear on what issue I

certified, and --

MR. GOMEZ: To be sure --

THE COURT: -- frankly, I wouldn't have certified it if it was a question of just of, you know, whether it might work for some people, might not for others.

The issue -- the only issue that was certified was about whether or not, as a matter of proof, it can or cannot work.

And it was meaning that if that answer is answer that it cannot work, it applies to the entire class, not just to individual plaintiffs.

MR. GOMEZ: Well, again, I'm comfortable with that, and we you embrace the notion, and we put on a case that the products provide no relief to anyone. And so, if we want to add to anyone, that's okay; but I think just -- and the Court will use language in an order, but I think if you think about a jury looking at this question in light of the evidence in the case, for them to hypothesize about "cannot," you know, especially given some of the theoretical bases raised by the defendants' experts I think just invites --

THE COURT: Well, if I say simply that the representations are false, what would you be arguing is the falsehood?

MR. GOMEZ: The falsity is that they don't relieve symptoms for anyone. And so is that an important

distinction? In my mind it is, you know, based on the evidence in the case.

I just think for them to hypothesize about it: It can, it cannot. The question is: Did it or did it not? And we're saying within the class period, it provided no relief to anyone. And that's consistent with our theory, and it's consistent with the Court's order.

MR. MARGULIES: I don't know that I have anything more to say. And I am concerned that we've heard a lot of evidence about what things could or should have been on the label which have nothing to do with what the Court certified, things that are not on the label, and how that, you know -- okay, it didn't say that the FDA hasn't approved this, but how does that relate to the Court's question?

And I think if we -- the further we stray from the question the Court certified, the further we've gone from the issue of commonality that the Court certified, and again, they picked their theory. I didn't pick it for them.

And I remember the colloquy that I had with Your Honor at the hearing, when I was arguing that all of these different products, and they weren't common, and I think you said something to the effect: Well wouldn't be it to your advantage to have all of this decided in one question?

It is one question. It's only one question.

These products can't work because -- or don't work because they can't work. That's the theory this case has been --

THE COURT: Well, he wants "don't."

MR. MARGULIES: But -- but the theory was "can't." And I -- I'm sorry, Your Honor, but -- but I don't think it's proper to suggest the theory they convinced the Court to certify it, and then when you go through trial and hear the evidence, say: You know what? That's too much and too hard.

We shouldn't be held to that.

THE COURT: All right. Well, I -- I think that it's fair, given what the issue was, that was certified to indicate that the representations on the packaging were false and cannot relief symptoms as represented.

And I think that was pretty much what I said in my final pretrial conference order, too.

MR. GOMEZ: And so just for clarity of language, would it be -- can we break up into four elements, then? The first being: Defendants made representations about the benefits of the products, one; representations were false because the products cannot relief -- whatever the Court said -- symptoms as represented --

THE COURT: So you want to say: *Defendants made representations about the benefits of the products on the packaging.*

EXHIBIT 2

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al.,

Plaintiffs,

VS

HYLAND'S, INC., et al.,

Defendants.

No. 12-1150DMG

Reporter's Transcript of Proceedings
JURY TRIAL - DAY ELEVEN
9:00 A.M. - 2:30 P.M.
Los Angeles, California
WEDNESDAY, SEPTEMBER 16, 2015

ANNE KIELWASSER, CRR, RPR, CSR
Federal Official Court Reporter
312 North Spring Street, Room 432
Los Angeles, California 90012
Telephone: (213) 894-2969
anne.kielwasser@gmail.com
AKtranscripts.com

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Q. And your expertise is in toxicology; is that not correct?
A. That's correct.
Q. You've never bought or used any of the products at issue here; correct?
A. I'm sure that's correct.
Q. And you are not testifying today to this jury that homeopathy is effective; are you?
A. I am not addressing that question.
Q. And you are not also testifying today that mechanistically any of the products at issue here can provide any form of relief; are you?
A. I have not addressed that question.
Q. You have had some of your theories presented to the Science and Technology Committee of the House of Commons; have you not?

MR. PERSSON: Objection. Foundation.

THE WITNESS: I'm not sure --

THE COURT: Wait. When there is an objection, you have to let me rule.

He can answer if he knows.

THE WITNESS: Somehow I didn't hear in between what you said and what the judge said.

BY MS. NELSON:

Q. Sure. No problem. You're aware, are you not, that the

EXHIBIT 3

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, at all,

Plaintiffs,

VS

HYLAND'S, INC., at all,

Defendants.

No. 12-1150DMG

Reporter's Transcript of Proceedings
JURY TRIAL - DAY TWELVE
JURY CHARGE and CLOSING ARGUMENTS
Los Angeles, California
WEDNESDAY, SEPTEMBER 16, 2015

ANNE KIELWASSER, CRR, RPR, CSR
Federal Official Court Reporter
312 North Spring Street, Room 432
Los Angeles, California 90012
Telephone: (213) 894-2969
anne.kielwasser@gmail.com
AKtranscripts.com

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plaintiffs' alleged harm. A substantial factor in causing harm is a factor that a reasonable person would consider to have contributed to the harm. It must be more than the remote or trivial factor, it does not have to be the only cause of harm.

Plaintiffs claim that they were harmed by defendants' homeopathic products because defendants represented that the products relief symptoms, but the products were not as represented.

To establish this claim, plaintiffs must prove by a preponderance of the evidence the following:

One: Plaintiffs purchased homeopathic products manufactured by defendants.

Two: Defendants through their packaging made representations to plaintiffs that defendants' homeopathic products would relieve certain symptoms.

Three: Defendants' homeopathic products did not perform as promised because they cannot perform as promised.

Four: Plaintiffs were harmed.

And five: The failure of defendants' products performed as represented was a substantial factor in causing plaintiffs' harm.

Defendants are not responsible for any harm to plaintiffs if defendants prove that statements on the

EXHIBIT 4

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, at all,

Plaintiffs,

VS

HYLAND'S, INC., at all,

Defendants.

No. 12-1150DMG

Reporter's Transcript of Proceedings
JURY TRIAL - DAY TWELVE
JURY CHARGE and CLOSING ARGUMENTS
Los Angeles, California
WEDNESDAY, SEPTEMBER 16, 2015

ANNE KIELWASSER, CRR, RPR, CSR
Federal Official Court Reporter
312 North Spring Street, Room 432
Los Angeles, California 90012
Telephone: (213) 894-2969
anne.kielwasser@gmail.com
AKtranscripts.com

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Plaintiffs allege defendants violated provisions of the California's Consumer Legal Remedies Act.

To establish this claim, plaintiffs must prove by a preponderance of the evidence the following:

One: Defendants made representations about the benefits of the products on the packaging.

Two: The represents were false because the products at issue cannot relieve symptoms as represented.

Three: Defendants' representations were material to the reasonable consumer.

Four: Defendants' representations were a substantial factor in causing plaintiffs' harm.

You will be asked to evaluate whether representations on the labels of the defendants' products are material to a reasonable consumer's decision to purchase defendants' homeopathic products.

A representation is material if a reasonable consumer would attach importance to its existence or nonexistence in determining his or her choice of action in the transaction in question.

A reasonable consumer is the ordinary consumer acting reasonably under the circumstances and is neither the most nor least sophisticated consumer.

You will be asked to evaluate whether certain conduct by defendants was a substantial factor in causing

EXHIBIT 5

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al.,

Plaintiffs,

VS

HYLAND'S, INC., et al.,

Defendants.

No. 12-1150DMG

Reporter's Transcript of Proceedings
JURY TRIAL - DAY TEN
MORNING SESSION
Los Angeles, California
TUESDAY, SEPTEMBER 15, 2015

ANNE KIELWASSER, CRR, RPR, CSR
Federal Official Court Reporter
312 North Spring Street, Room 432
Los Angeles, California 90012
Telephone: (213) 894-2969
anne.kielwasser@gmail.com
AKtranscripts.com

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******

false because the products don't provide relief, you know, we agree with that. And that's the misrepresentation, they don't provide relief -- in other words, they don't relief the symptoms that the representations claim that they do.

You know, to -- I just think to say --

So that makes it falls, if you make a representation that it will relief symptoms, and it doesn't relief symptoms, that's a false representation.

To take the additional step in the jury's mind of saying it cannot relief symptoms, I think is improper, and I think imposes a burden of proof that's inconsistent with the elements of the California Consumer Legal Remedies Act.

And so I think you get into -- it invites speculation by the jury, because we've had all kinds of experts by the defense talking about what we don't know how it really works, but maybe it can work this way or maybe it can work this away. And so, I think it invites speculation.

The question is, whether the representations are false or not. And so, if they do not provide relief as represented, you know, I think we've met our burden. To say they cannot provide relief, I think just grammatically is a more difficult burden that invites speculation, I think.

THE COURT: You mean you would be able to live with it if I said: "Do not relieve symptoms as represented"

EXHIBIT 6

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

THE HON. JUDGE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al., on behalf of themselves, all others similarly situated and the general public,	)	
Plaintiffs,	)	
vs.	)	NO. 13-CV-5102-DMG
HYLAND'S, INC., a California corporation; and STANDARD HOMEOPATHIC COMPANY,	)	
Defendants.	)	

JURY TRIAL - DAY 9 (P.M. Session)

Los Angeles, California

Monday, September 14, 2015

LISA M. GONZALEZ, CSR No. 5920, CCRR
U.S. District Courthouse
312 North Spring Street - Room 438
Los Angeles, California 90012
213.894.2979
www.lisamariecsr.com

I N D E X

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yourself; right?
A Yes.
Q Common table salt; right?
A Yes.
Q And could you describe to the jury exactly what you did.
A I took it -- bought it from a homeopathic pharmacy and took it in a homeopathic diluted form.
Q For what condition?
A Something called tropical sprue.
Q I'm sorry?
A Tropical sprue, s-p-r-u-e.
Q Is it true that this table salt within the homeopathic literature is also recognized to be effective to relieve the pangs and hurts of life which are most often hidden from others?
A That is a slightly poetic description, but it is one of the ones that we use for depression, for instance.
Q Table salt?
A Yes.
Q In what dilution?
A This would have been 30C or 200C.
Q Which one? 30C or 200C?
A I can't remember now. This is many years ago.
Q So again just to be clear, we have one part of table

EXHIBIT 7

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al.,

Plaintiffs,

VS

HYLAND'S, INC., et al.,

Defendants.

No. 12-1150DMG

Reporter's Transcript of Proceedings
JURY TRIAL - DAY TEN
MORNING SESSION
Los Angeles, California
TUESDAY, SEPTEMBER 15, 2015

ANNE KIELWASSER, CRR, RPR, CSR
Federal Official Court Reporter
312 North Spring Street, Room 432
Los Angeles, California 90012
Telephone: (213) 894-2969
anne.kielwasser@gmail.com
AKtranscripts.com

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to be tried.

And the Court defined it as such, and we've prepared for the case as such, and I think we're entitled to have the jury decide the case that the Court certified, not some case as it may have developed into: Well, you should have said something on the label.

This case is about whether the products performed as represented and whether they can provide relief to anyone. And I think to not tell the jury that would be to do disservice to the Court -- to the Court's order and would prejudice us in terms of how we are prepared to try this case.

THE COURT: Well, I tend to agree with that only because I think that that is the unifying theme that causes this to be able to be certified as a class action, because if -- if we were here to decide whether it works for some people but doesn't work for other people, then we would have individualized issues.

And so, the only issue that I certified was that -- and it was the theory that plaintiffs, frankly, said that they were prepared to demonstrate or was that it cannot work, and therefore the representations are false.

MR. GOMEZ: Well, I think it's really, sort of, a matter of semantics.

Counsel said that the representations were

false because the products don't provide relief, you know, we agree with that. And that's the misrepresentation, they don't provide relief -- in other words, they don't relief the symptoms that the representations claim that they do.

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And so I think you get into -- it invites speculation by the jury, because we've had all kinds of experts by the defense talking about what we don't know how it really works, but maybe it can work this way or maybe it can work this away. And so, I think it invites speculation.

The question is, whether the representations are false or not. And so, if they do not provide relief as represented, you know, I think we've met our burden. To say they cannot provide relief, I think just grammatically is a more difficult burden that invites speculation, I think.

THE COURT: You mean you would be able to live with it if I said: "Do not relieve symptoms as represented"

as opposed to "cannot relieve"?

MR. GOMEZ: Absolutely. And I -- and I think that's fair.

MR. MARGULIES: Again, Your Honor, your order certifying the class was clear. I think if they're changing their position on this, I realize Mr. Gomez wasn't around for the class certification proceedings, but the Court certified a question, I don't think it's fair to change the question midstream.

THE COURT: Do you think that it's different if it says: "Do not relieve symptoms as represented"?

MR. MARGULIES: I do. Their theory was, these are homeopathy medicine. They cannot provide relief.

THE COURT: For anyone.

MR. MARGULIES: For anyone. That was the theory the Court certified. So, I think Monday morning quarterbacking on whether that was the right question is really improper at this time.

This argument should have been raised then.

MR. GOMEZ: I just -- again, I think there's all sorts of different things that happened at the class certification stage. Not many of these cases are tried. We have jury instructions that set forth the proper standard of proof.

THE COURT: Well, I'm pretty clear on what issue I

certified, and --

MR. GOMEZ: To be sure --

THE COURT: -- frankly, I wouldn't have certified it if it was a question of just of, you know, whether it might work for some people, might not for others.

The issue -- the only issue that was certified was about whether or not, as a matter of proof, it can or cannot work.

And it was meaning that if that answer is answer that it cannot work, it applies to the entire class, not just to individual plaintiffs.

MR. GOMEZ: Well, again, I'm comfortable with that, and we you embrace the notion, and we put on a case that the products provide no relief to anyone. And so, if we want to add to anyone, that's okay; but I think just -- and the Court will use language in an order, but I think if you think about a jury looking at this question in light of the evidence in the case, for them to hypothesize about "cannot," you know, especially given some of the theoretical bases raised by the defendants' experts I think just invites --

THE COURT: Well, if I say simply that the representations are false, what would you be arguing is the falsehood?

MR. GOMEZ: The falsity is that they don't relieve symptoms for anyone. And so is that an important

EXHIBIT 8

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

THE HON. JUDGE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al., on behalf of themselves, all others similarly situated and the general public,	)	
Plaintiffs,	)	
vs.	)	NO. 13-CV-5102-DMG
HYLAND'S, INC., a California corporation; and STANDARD HOMEOPATHIC COMPANY,	)	
Defendants.	)	

JURY TRIAL - DAY 11

(2:45 p.m. - 3:24 p.m.)

Los Angeles, California

Wednesday, September 16, 2015

LISA M. GONZALEZ, CSR No. 5920, CCRR
U.S. District Courthouse
312 North Spring Street - Room 438
Los Angeles, California 90012
213.894.2979
www.lisamariecsr.com

I N D E X

CHRONOLOGICAL INDEX OF WITNESSES

DEFENDANTS' WITNESS	DIRECT	CROSS	REDIRECT	RECROSS	VOIR DIRE VOL
Daniel Krombach	4	9	13		

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(none)	

instructions?

MS. DIXON: Your Honor, I think the only stipulated fact that we have is a stipulation that we were prepared to provide to you which is as to the defendants being the same. Other than that --

THE COURT: I think there were actually two whole stipulations in the final pretrial conference order. I don't remember what they were, but they were so overwhelming in their voluminousness.

MR. GOMEZ: I guess the final thing is, you know, after having had the discussion with the language of the liability instructions being derived from the class cert order, we had prepared a couple more instructions that deal with placebo effect, which is also from the class cert order, essentially saying that the jury cannot consider a placebo effect in determining whether the products are effective and cannot consider that in damage calculation. And so I know it's late in the game, but, you know, given that we were -- so relied upon the language in the class cert order, we have a couple more proposed instructions.

THE COURT: Have you shared those with opposing counsel?

MS. DIXON: Yes, Your Honor. We emailed them last night after we received your instructions.

THE COURT: All right. Can you give me a copy?

MS. DIXON: Yes.

THE COURT: Defendants do you have a position?

MR. MARGULIES: Yes, Your Honor. We would object to these as arguing facts to the jury and not stating them the law.

THE COURT: Well, I think it's definitely something that you can argue, but I don't think that I need to give it as an instruction.

MR. GOMEZ: Thanks, Your Honor.

THE COURT: My law clerk may have emailed you the revised verdict form and instructions. If he did, I am going to have to revise them again, based on what we just discussed, so stay tuned for another email with a copy on them.

MR. MARGULIES: Your Honor, just for purposes of anticipating tomorrow morning, are we planning to then just instruct the jury first thing and go right into closings?

THE COURT: Correct. I'll be instructing the jury first thing at 9:00 o'clock, and then after that we'll go with the plaintiffs' closing -- well, opening. And if it goes for the hour that Mr. Gomez projects, we'll probably have a break, and then we'll go with the defendants' closing, and then the plaintiffs' final closing.

MR. MARGULIES: Thank you.

MR. GOMEZ: Thanks so much, Your Honor.

EXHIBIT 9

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al.,

Plaintiffs,

VS

HYLANDS, INC., et al.,

Defendants.

No. 12-1150DMG

Reporter's Transcript of Proceedings
JURY TRIAL - DAY TWO
MORNING SESSION
Los Angeles, California
WEDNESDAY, SEPTEMBER 2, 2015

ANNE KIELWASSER, CRR, RPR, CSR
Federal Official Court Reporter
312 North Spring Street, Room 432
Los Angeles, California 90012
Telephone: (213) 894-2969
anne.kielwasser@gmail.com
AKtranscripts.com

more than Dr. Taylor, but I am claiming to know what happened.

Q. Initially, is it fair to say that the study didn't come out the way you wanted it to?

A. No. The study wasn't completed.

Q. Let's talk about Teething Tablets. Are you familiar with that study?

A. I am.

Q. And how did that one come out?

A. Strangely. The --

Q. Go ahead. Keep talking. How did it come out?

A. I answered it. It came out strangely.

(Discussion off the record.)

MR. GOMEZ: One moment. I got a little lost.

BY **MR. GOMEZ:**

Q. She's going to go try to find something for me, but you say it came out strangely. What do you mean?

A. So, when you do a clinical trial, as you've discussed, you have two groups. You have a active group, and you have a placebo group. Trials generally consider to be successful if the active group shows different activity than the placebo group does. A trial is generally considered a fail if the placebo group and the active group are the same.

In this trial the placebo group showed more activity than the active group did, which is not only sort of

EXHIBIT 10

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al.,

Plaintiffs,

VS

HYLANDS, INC., et al.,

Defendants.

No. 12-1150DMG

Reporter's Transcript of Proceedings
JURY TRIAL - DAY THREE
MORNING SESSION
Los Angeles, California
THURSDAY, SEPTEMBER 3, 2015

ANNE KIELWASSER, CRR, RPR, CSR
Federal Official Court Reporter
312 North Spring Street, Room 432
Los Angeles, California 90012
Telephone: (213) 894-2969
anne.kielwasser@gmail.com
AKtranscripts.com

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******

MR. GOMEZ: Oh, right. Yes, I'm trying to get him to skip to the second sentence. I'm sorry.

THE WITNESS: So, the primary analysis were, we were on 62 participants? Is that where you want me to go?

BY MR. GOMEZ:

Q. Sure, read that whole paragraph to yourself.

MR. MARGULIES: Objection. Hearsay.

THE COURT: Yes, you should not read from the document until I've admitted the document. And it's not yet admitted; and moreover, please don't speak so quickly, my court reporter will keel over and pass out before the end of the day.

THE WITNESS: My apologies, Your Honor.

THE COURT: All right.

BY MR. GOMEZ:

Q. So, read it to yourself. Just without talking.

A. (Reads document.) Okay.

Q. Okay, does that refresh your memory that this in fact is the report of the study that Dr. Bell conducted that demonstrated placebos performed better than your Teething Tablets?

MR. MARGULIES: Objection. Lacks foundation.

THE COURT: He can answer if this refreshes his memory.

THE WITNESS: To be honest with your, I'd like to

be able to review the document, because I found something else in the document that I think does refresh my memory.

BY MR. GOMEZ:

Q. Where is that?

A. On page 7. It says: "Participants in the placebo group tend to have better outcomes."

Q. Okay, great. So, does that refresh your memory?

A. Well, I haven't gone through the entire document, but that was what was at issue with the broken trial.

Q. Correct. Okay, and so would you now agree that this document provided to us that talks about a study comparing Teething Tablets and placebos is in fact the report of the study we have been discussing?

A. Mr. Gomez, I've already told you, it's undated, there is no header on it, I don't know who it came from. So, it's hard for me to tell you what this is without studying it.

Q. Would you assume that a report of an executive summary, and then further reports of a study conducted by your employee or contractor, Dr. Bell, your medical director, would in fact be the document that reported those results?

MR. MARGULIES: Objection. Lacks foundation and calls for speculation.

THE COURT: Sustained. As to the question starting with: "Will you assume."

BY MR. GOMEZ:

EXHIBIT 11

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al.,

Plaintiffs,

VS

HYLAND'S, INC., et al.,

Defendants.

No. 12-1150DMG

Reporter's Transcript of Proceedings
JURY TRIAL - DAY SIX
Los Angeles, California
WEDNESDAY, SEPTEMBER 9, 2015

ANNE KIELWASSER, CRR, RPR, CSR
Federal Official Court Reporter
312 North Spring Street, Room 432
Los Angeles, California 90012
Telephone: (213) 894-2969
anne.kielwasser@gmail.com
AKtranscripts.com

THE COURT: All right. Let's call the jurors in.

(Following held in the presence of the jury.)

THE COURT: All right, are plaintiffs ready with their next witness?

MS. DIXON: Yes, Your Honor, the plaintiffs call Dr. James Taylor via video deposition.

THE COURT: All right.

(Videotape viewed.)

THE COURT: All right, that concludes our testimony for today.

All right, we will resume tomorrow at 9:00 o'clock A.M.

COURT CLERK: All rise.

THE COURT: Oh, yes, let me remind you again not to talk to each other or with anyone else about this case. Thank you and good night.

(Following proceedings held outside the presence of the jury.)

THE COURT: Please be seated.

When I reviewed the designations, it was not my understanding that the highlighted items were all that was going to be played. I thought these were items that you had disputes about whether they were objectionable.

So the question I have is, why were there so many excerpts where you were just identifying documents, but

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

ENZO FORCELLATI and LISA ROEMMICH, on Behalf of Themselves and All Others Similarly Situated,

Plaintiffs,

vs.

HYLAND'S, INC., STANDARD HOMEOPATHIC LABORATORIES, INC., and STANDARD HOMEOPATHIC COMPANY,

Defendants.

No. 2:12-CV-01983-GHK

Deposition Upon Oral Examination Of

JAMES TAYLOR, MD

12:41 p.m.

June 19, 2014

4333 Brooklyn Avenue NE

Seattle, Washington

REPORTED BY: Yvonne A. Southworth, CCR No. 2129.

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In Allen v. Hyland's, Inc.

is the page with the Bates number SHCFORC 9861. Do you have that? 01:01:00 01:01:08

A Yes. 01:01:09

Q Do you see an inch from the bottom of the page, there's a bold heading analysis? 01:01:10 01:01:13

A Yes. 01:01:15

Q And underneath that heading it says, the primary study outcome is improvement, slash, no improvement in each of the four URI symptoms, open paren, cough, runny nose, nasal congestion, and sneezing closed paren, one hour after a dose of study medication based on the data recorded in the symptom log. Do you see that? 01:01:17 01:01:20 01:01:23 01:01:29 01:01:36 01:01:39 01:01:44

A Yes. 01:01:47

Q Did you write that? 01:01:47

A Yes. 01:01:48

Q That was the primary study outcome, right? 01:01:51

A Yes. 01:01:53

Q So to try to translate that into simpler English, you wanted to study whether Cold 'n' Cough for Kids would result in improvement in the four symptoms listed here, right? 01:01:57 01:02:06 01:02:09 01:02:11

A That's correct. 01:02:15

Q And specifically, you wanted to see if the Cold 'n' Cough for Kids would produce a different 01:02:21 01:02:25

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In Allen v. Hyland's, Inc.

result than a placebo with respect to these four symptoms, is that right? 01:02:31 01:02:35

A Yes. 01:02:37

Q Why is it important to use a placebo control in a study like this? 01:02:40 01:02:45

A Because if somebody has a positive response to a medication, you don't know if it's because of the medication, because they're just getting better by themselves, or because of what would be called the placebo effect, the fact that people think they are getting better because they are taking something. And so when you do a placebo, it controls for that. 01:02:46 01:02:50 01:02:52 01:02:56 01:02:58 01:03:01 01:03:04

Q The placebo effect is something that's well known in the field of medicine, right? 01:03:07 01:03:10

A That's correct. 01:03:12

Q It's been well known for many decades, right? 01:03:12 01:03:14

A Yes, it has. 01:03:15

Q It's been demonstrated through many scientific studies, right? 01:03:16 01:03:18

A I don't know about that exactly. There are some classic studies on placebo effects that were done a long time ago. I think that people sometimes accept it, but sometimes argue about the magnitude of it. And I don't know how many specific studies have been 01:03:22 01:03:24 01:03:27 01:03:32 01:03:36

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In Allen v. Hyland's, Inc.

A Yes. It could be a symptom of children's colds. 03:21:18 03:21:20

Q And that's why you've measured it? 03:21:20

A That's why we've measured it. 03:21:22

Q So what were the results with respect to appetite? 03:21:25 03:21:27

A After 31.1 percent of doses of placebo, there was at least slight improvement in appetite. And with the cold remedy, there was improvement in appetite after 36.3 percent of the doses. And the P value for that is .779, which is statistically nonsignificant. 03:21:28 03:21:31 03:21:33 03:21:36 03:21:37 03:21:40

Q So with respect to the secondary outcome of appetite, you were not able to detect that Cold 'n' Cough for Kids had any effect that could be distinguished from the placebo effect, correct? 03:21:41 03:21:44 03:21:51 03:21:55

A That's correct. 03:21:58

Q Those were the results you reported on April 22? 03:21:58 03:22:00

A Those were the results that we reported on April 22nd, yeah. 03:22:01 03:22:03

Q And so with respect to the four primary outcomes and then the four secondary outcomes measured one hour after dose, none of those eight produced a significant result, right? 03:22:05 03:22:09 03:22:16 03:22:20

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In Allen v. Hyland's, Inc.

1	A That's correct.	03:22:22
2	Q So there wasn't any symptom for which you	03:22:22
3	found that Cold 'n' Cough for Kids had an effect that	03:22:27
4	you could measure that could be distinguished from the	03:22:35
5	placebo effect?	03:22:38
6	A Just to clarify that a little bit. We	03:22:41
7	couldn't -- for any of the symptoms we measured, we	03:22:43
8	couldn't find that there was any change one hour after	03:22:46
9	the dose that was different with the cold medicine and	03:22:48
10	with the placebo.	03:22:51
11	Q And one hour after the dose was the	03:22:52
12	primary --	03:22:54
13	A That was the primary study outcome.	03:22:55
14	Q I want to ask you a question about the	03:23:05
15	generalized estimating equation.	03:23:08
16	A Yes.	03:23:10
17	Q What kind of training do you have in	03:23:12
18	statistics?	03:23:14
19	A Taking courses in biostatistics at the	03:23:17
20	University of Washington School of Public Health.	03:23:19
21	Q That was a requirement of your degree at	03:23:22
22	that school?	03:23:23
23	A I didn't get a degree. It was just part of	03:23:24
24	my training when I was here as a general academic	03:23:26
25	fellow, pediatric fellow in the late '80s.	03:23:29

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In Allen v. Hyland's, Inc.

between placebo and the cold remedy. 03:29:45

Q So your final conclusion with respect to 03:29:47

each of the four primary outcomes was that you could 03:29:50

not find that Cold 'n' Cough for Kids had any effect 03:29:55

on those cold symptoms that could be distinguished 03:30:01

from the placebo effect. Is that accurate? 03:30:04

A When they were measured one hour after a 03:30:06

dose of medicine, yes, that's accurate. 03:30:09

Q And with respect to the four secondary 03:30:22

outcomes that we've identified that you report on in 03:30:24

the same table, irritability, lethargy, fussiness, and 03:30:27

appetite, the results were the same, right? 03:30:31

A That's correct. 03:30:35

Q Meaning that in your final report, you 03:30:36

concluded that you could not find that Cold 'n' Cough 03:30:39

for Kids had any effect with respect to any of those 03:30:44

symptoms that could be distinguished from the placebo 03:30:49

effect? 03:30:52

A That is -- when we use the outcome of 03:30:53

measuring them one hour after the dose. 03:30:55

Q And is measuring them one hour after the 03:31:01

dose, that was the measurement that you agreed upon at 03:31:05

the outset of the study, right? 03:31:07

A That's correct. 03:31:09

Q With the folks at Hyland's, right? 03:31:10

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In Allen v. Hyland's, Inc.

EXHIBIT 12

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al.,

Plaintiffs,

VS

HYLAND'S, INC., et al.,

Defendants.

No. 12-1150DMG

Reporter's Transcript of Proceedings
JURY TRIAL - DAY SIX
Los Angeles, California
WEDNESDAY, SEPTEMBER 9, 2015

ANNE KIELWASSER, CRR, RPR, CSR
Federal Official Court Reporter
312 North Spring Street, Room 432
Los Angeles, California 90012
Telephone: (213) 894-2969
anne.kielwasser@gmail.com
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THE COURT: All right. Let's call the jurors in.

(Following held in the presence of the jury.)

THE COURT: All right, are plaintiffs ready with their next witness?

MS. DIXON: Yes, Your Honor, the plaintiffs call Dr. James Taylor via video deposition.

THE COURT: All right.

(Videotape viewed.)

THE COURT: All right, that concludes our testimony for today.

All right, we will resume tomorrow at 9:00 o'clock A.M.

COURT CLERK: All rise.

THE COURT: Oh, yes, let me remind you again not to talk to each other or with anyone else about this case. Thank you and good night.

(Following proceedings held outside the presence of the jury.)

THE COURT: Please be seated.

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UNITED STATES DISTRICT COURT

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No. 2:12-CV-01983-GHK

Deposition Upon Oral Examination Of

JAMES TAYLOR, MD

12:41 p.m.

June 19, 2014

4333 Brooklyn Avenue NE

Seattle, Washington

REPORTED BY: Yvonne A. Southworth, CCR No. 2129.

CONFIDENTIAL-Restricted Information For Use Only
In Allen v. Hyland's, Inc.

it was 49.3 percent, with a P value of .892, which is statistically nonsignificant. 03:16:15 03:16:20

Q So with respect to the primary outcome of improvement in nasal congestion, you were not able to find any effect from Cold 'n' Cough for Kids that was different from the placebo effect, correct? 03:16:23 03:16:29 03:16:32 03:16:40

A That's correct. 03:16:44

Q And so with respect to all four primary outcomes that you set out to measure, Cold 'n' Cough for Kids did not show any effect that was any different from placebo, correct? 03:16:44 03:16:49 03:16:53 03:16:57

A That's correct. 03:16:59

Q Now, you have four additional symptoms, results for four additional symptoms. Irritability, lethargy, fussiness, and appetite that you reported in April, correct? 03:17:05 03:17:15 03:17:21 03:17:25

A That's correct. 03:17:26

Q And those were not the primary study outcomes, right? 03:17:27 03:17:28

A That's correct. 03:17:29

Q And I can't remember the term that you used to describe them. Were they secondary outcomes? 03:17:30 03:17:33

A You can call them secondary outcomes. That's -- yes. 03:17:36 03:17:38

Q I don't want to characterize them. I want 03:17:39

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In Allen v. Hyland's, Inc.

EXHIBIT 13

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

THE HON. JUDGE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al., on behalf of themselves, all others similarly situated and the general public,	)	
Plaintiff,	)	
vs.	)	NO. 13-CV-5102-DMG
HYLAND'S, INC., a California corporation; and STANDARD HOMEOPATHIC COMPANY,	)	
Defendants.	)	

JURY TRIAL - DAY 1 (P.M. Session)

Los Angeles, California

Tuesday, September 1, 2015

LISA M. GONZALEZ, CSR No. 5920, CCRR
U.S. District Courthouse
312 North Spring Street - Room 438
Los Angeles, California 90012
213.894.2979
www.lisamariecsr.com

I N D E X

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PLAINTIFFS' WITNESS	DIRECT	CROSS	REDIRECT	RECROSS	VOIR DIRE VOL
John P. Borneman	62				

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A I do.

MR. GOMEZ: May I display that, Your Honor? It was already shown to the jury.

THE COURT: Is this an exhibit?

MR. GOMEZ: It's a demonstrative at this point. I just want to ask him about it.

THE COURT: All right.

BY MR. GOMEZ: Apparently it needs some time to warm up. There it goes.

Is that on your screen?

A It is.

Q And so, do you see the active ingredients?

A Yes.

Q They're listed for each of these products?

A Yes.

Q And do you recall me saying, in my opening statement, that the active ingredients of the Hyland's for kids -- which is marketed for ages two to 12 and has the picture of the little boy with the teddy bear on it -- have the exact same active ingredients as your company markets to adults for the same product?

A Yes, sir, that's correct.

Q Is that true what I said, that you sell the same product in one package for kids and one package for adults?

A Yes, in fact, we do that.

in the store is different.
Q So "yes"?
A Yes.
Q And again product's completely identical; correct?
A From a formulation perspective, yes.
Q And that's just fancy for saying what's in the bottle is exactly the same for a two-year-old as a 72-year-old?
A Yes, that's correct.
Q How does that make sense? Can you explain it to us.
A Sure. The condition is identical, whether it be runny nose or cold or the cough or whatever, the age of the organism, it doesn't make any difference. The symptoms are the same whether the person is 2 or the person is 22 or they're 42 or they're 62.

So the fact of the matter is that the product is identical, it's just in a different location in the store, because people without children can find it in the adult section and vice versa.
Q You used the word "organism." We're talking about human beings --
A People, yes.
Q So is it your position as president of this company that I can take any medicine that's appropriate for an adult and give it to a kid?
A That's not what I said. I said that, in this case, the

EXHIBIT 14

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

THE HON. JUDGE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al., on behalf of themselves, all others similarly situated and the general public,	)	
Plaintiffs,	)	
vs.	)	NO. 13-CV-5102-DMG
HYLAND'S, INC., a California corporation; and STANDARD HOMEOPATHIC COMPANY,	)	
Defendants.	)	

JURY TRIAL - DAY 7 (P.M. Session)

Los Angeles, California

Thursday, September 10, 2015

LISA M. GONZALEZ, CSR No. 5920, CCRR
U.S. District Courthouse
312 North Spring Street - Room 438
Los Angeles, California 90012
213.894.2979
www.lisamariecsr.com

I N D E X

CHRONOLOGICAL INDEX OF WITNESSES

PLAINTIFFS' WITNESS	DIRECT	CROSS	REDIRECT	RECROSS	VOIR DIRE VOL
Dr. Iris Bell, Ph.D. (Continued)	4	59	109		

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not been tested at this point; true?

MR. MARGULIES: Your Honor, I would repeat my objection, and it is grounded in the Court's motion in limine regarding the scope of expert testimony. I didn't go into topics like this with Dr. Bell, given the ruling, and I don't think it's appropriate on cross to allow that to occur as well.

THE COURT: I believe that during the direct you asked her whether it was in some ways similar to a vaccine. Is that not questioning about like?

MR. MARGULIES: In the context of -- correct, but I believe that the questioning here goes to data beyond which we discussed on direct on topics that the Court excluded.

THE COURT: Well, I'm going to allow some cross on it. We're not going to go into it in great depth.

MR. GOMEZ: Thank you, Your Honor. And I'll suggest that the only questioning about the particular products was in the last ten minutes.

BY MR. GOMEZ:

Q So, Doctor, is it true that the data does not confirm definitely that this core principle works in the entire field of homeopathy? That has not been tested at this point?

A It has not been tested other than through the evidence

which is in the literature, in the research literature, that homeopathically prepared material can trigger hermetic-type reactions, which go in opposite directions, low doses versus high doses.

Q Okay. And we learned, I think, through Dr. Borneman and Dr. Phillips that age doesn't matter, and I think we heard that from you. Do you agree with that?

A In what context?

Q In the context of providing medication to a Hyland's consumer, a homeopathic medication.

A Well, as a geriatric psychiatrist, I would say that there are certain clinical guidelines that one tries to avoid if you have a very vulnerable patient who's at risk from a very serious medical condition that would guide your decision about what to use.

Q To be sure. And what I'm limiting my question to, Doctor, is the issue of homeopathic products like those at issue in this case. It doesn't matter how old or young the person is, the homeopathic product will have the same effect on the person; true?

A Homeopathy rarely has the exact same effect on two different people.

Q And so is it your testimony that -- and I think there was some testimony by you that I found interesting about -- let me find it -- homeopathic constitutional types. Do you

A Well, these are not all independent theories. These are things that are published by other people with experimental findings where they did studies and reported their data.

Q And what you've done is looked at those studies and tried to explain to this jury how these products could work relying upon those studies; true?

A In part.

Q How about memory of the water? Have you relied upon that theory in the past?

A No.

Q We're running out of time, so I want to finish with you. Can you go to page 1. Are you familiar with the House of Commons evidence check two on homeopathy?

A Yes. I believe it was done in the United Kingdom.

Q Yes. And so you certainly are a person that keeps up on the literature and you're aware of this document; correct?

A Yes.

Q And did you see that the House of Commons considered the input of Dr. Peter Fisher and Professor Edward Calabrese in looking at this issue?

A Yes.

Q You understand that those are both experts that we'll hear from in this case?

EXHIBIT 15

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

THE HON. JUDGE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al., on behalf of themselves, all others similarly situated and the general public,	)	
Plaintiffs,	)	
vs.	)	NO. 13-CV-5102-DMG
HYLAND'S, INC., a California corporation; and STANDARD HOMEOPATHIC COMPANY,	)	
Defendants.	)	

JURY TRIAL - DAY 9 (P.M. Session)

Los Angeles, California

Monday, September 14, 2015

LISA M. GONZALEZ, CSR No. 5920, CCRR
U.S. District Courthouse
312 North Spring Street - Room 438
Los Angeles, California 90012
213.894.2979
www.lisamariecsr.com

I N D E X

CHRONOLOGICAL INDEX OF WITNESSES

DEFENDANTS' WITNESS	DIRECT	CROSS	REDIRECT	RECROSS	VOIR DIRE VOL
Peter Fisher	4	68	79		
Edward Miracco	86	108			

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to my expert report, it is the larger single group. I have to look up the numbers, but actually there are many such studies and probably now they make up the majority of the clinical trials.

Q And you believe that the majority of the clinical trials you cited to the jury are combination mass-marketed homeopathic products?

A Yes, and that is in the appendices. I would need to look up which appendix, but those are in the appendices to my expert report.

Q In terms of -- we heard some testimony by you about nanoparticles, nano bubbles, intense heat and physical reactions of water. Do you recall that?

A Yes.

Q You have no opinion in this case as to the mechanism of action for any of the ingredients at issue in this case; true?

A We don't fully understand -- I do not fully understand the mechanisms of action, which is not to say that I have no inkling, no idea of how they might work.

Q Setting aside an inkling of how they might work, you can't provide expert testimony to this jury about how any of these products actually work; true?

A Yes, that is true.

Q There was some discussion by you of -- let me see if I

EXHIBIT 16

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al.,

Plaintiffs,

VS

HYLAND'S, INC., et al.,

Defendants.

No. 12-1150DMG

Reporter's Transcript of Proceedings
JURY TRIAL - DAY FOUR
MORNING SESSION
Los Angeles, California
FRIDAY, SEPTEMBER 4, 2015

ANNE KIELWASSER, CRR, RPR, CSR
Federal Official Court Reporter
312 North Spring Street, Room 432
Los Angeles, California 90012
Telephone: (213) 894-2969
anne.kielwasser@gmail.com
AKtranscripts.com

LOS ANGELES, CALIFORNIA; THURSDAY, SEPTEMBER 4, 2015;
P.M.
-oOo-

THE COURT: All right. Are Plaintiffs ready to call their next witness?

MS. NELSON: Yes, Your Honor. The Plaintiffs would like to call Dr. Noel Rose to the stand, please.

THE CLERK: Sir, if you would please approach the witness stand.

And if you'd remain standing and raise your right hand for me.

*DR. NOEL ROSE, Ph.D.,
Plaintiffs' Witness, was duly sworn, and testified as follows:

THE CLERK: And, sir, could you please state your full name, spelling both first and last for the record?

THE WITNESS: Noel Richard Rose, N-O-E-L, R-O-S-E.

DIRECT EXAMINATION

BY MS. NELSON:

Q Good afternoon, Dr. Rose.

A Good afternoon.

Q And welcome to Los Angeles.

Q And let me ask you now, if you would, tell the jury what is your overarching opinion that you -- we will discuss further, with respect to the issues here?
A Well, with respect to the products that are under consideration and of concern in this -- in this event, it is my opinion that there is no sound scientific or medical evidence that they provide any benefit to patients with medical conditions such as those described and indicated on the labels, beyond the placebo effect.
Q And within your opinion, do you have an opinion as to whether or not there exists any firm, reproducible evidence that the ingredients in the products in this case are effective?
A Again, I think that there is a lack of evidence, a lack of firm, reproducible evidence that the products involved in this case are of benefit to patients with the medical conditions described.
Q And do you have an opinion as to whether there exists any scientific evidence to demonstrate that homeopathic treatments are effective beyond their placebo effect?
A I believe the scientific evidence does not support the claim that the homeopathic medicines are effective beyond their placebo effect.
Q And there has been some testimony, during the course of this trial, regarding a study that Dr. James Taylor at the

who undertake to put together all of the many randomized trials in a particular area. They may be, for example, all trials of the same drug or all trials of the same kind of patient or whatever it may be, to assemble the world's literature, all the articles published relating to a particular treatment, to analyze them and see which ones represent sound clinical trials, bring those results together, analyze them, compile the results, and make recommendations to physicians and other health specialists as to whether a particular form of treatment is likely to be beneficial or not beneficial, whether it's beneficial for a certain disease and not for another disease, and what the possible adverse effects may be.

Q And did you review any Cochrane reports relating to homeopathy?

A Yes, I did.

Q And what did they show?

A Well, they really show uniformly the same phenomenon. And that is, when we compare homeopathic treatment with a placebo -- getting back now to the placebo -- sometimes the homeopathic drug is a teeny weeny bit better. Sometimes the placebo is a teeny weeny bit better. But most of the time the two are the same.

So we say that any benefit that could come from giving or receiving a homeopathic drug almost certainly

comes from the placebo effect, not from the drug itself.

Q And also in preparing to testify today, did you review any governmental statements on studies or reports that have been prepared on homeopathic remedies?

A Yes, I did.

MR. MARGULIES: Your Honor, I would just note for the record our prior objections under 801 and 803(8) to these governmental reports.

THE COURT: Yes. He's not going to testify as to the contents of those reports; is he?

MS. NELSON: I was going to have --

THE COURT: At opposed to his opinion, having reviewed them.

MS. NELSON: I was going to actually have gun review them, and I was actually going to ask to introduce them into evidence.

THE COURT: All of them?

MS. NELSON: There are only three. One is the physician that we talked about from the National Institutes of Health, National Center for Complementary and Integrative Health, the report from the Australian government and the other from the British government, the House of Commons. Is that acceptable, Your Honor?

THE COURT: What was the date of the first one?

MS. NELSON: The date of the first one, I think it

National Center for Complementary and Integrative Health?
A Well, that is one of the institutes and centers of the National Institutes of Health. There are about 30 of them that are concerned with different aspects of medicine and biomedical research, and this particular one is, as the name suggests, a particular agency that's responsible for fostering knowledge and fostering public understanding of alternative and complementary medicine.
Q And does homeopathy fall within the structure of the National Center for Complementary and Integrative Health?
A Yes, it does.
Q And am I correct that the National Center has published that several key concepts of homeopathy are inconsistent with fundamental concepts of chemistry and physics?
A That is correct.
Q And do you agree with that opinion?
A I do agree with that.
Q And is it also true that the National Center for Complementary and Integrative Health takes the position that there is little evidence to support homeopathy as an effective treatment for any specific condition?
A I do agree with that.
MS. NELSON: Your Honor, I would like to move admission of Exhibit 139.
MR. MARGULIES: I would just note my continuing

all people interested, including the homeopathic community?
A They did.
Q And ultimately did the National Health and Medical Research Council of Australia come to a conclusion regarding the evidence that had been presented to them?
A Yes, they did.
Q And if I may ask you to take a look at page 18, Exhibit 409, page 18, which appears, Dr. Rose, at the bottom right-hand corner of each page.
A Okay.
Q And this table summarizes the evidence from various studies of homeopathy; does it not?
A Yes, it does.
Q And did the National Health and Medical Research Council come to the conclusion that homeopathy is not more effective than a placebo for the treatment of anxiety and stress-related conditions?
A That's correct.
Q And did they also come to the conclusion that homeopathy is not more effective than placebo for the treatment of headache and migraine?
A Yes. That's correct.
Q And did they also come to that same conclusion with respect to upper respiratory tract infections otherwise known as a cold?

A Yes, they did.
Q And did they come to the conclusion that there is no reliable evidence that homeopathy is more effective than a placebo for the treatment of allergic rhinitis?
A They did.
Q And did they also come to the conclusion that there was no reliable evidence that homeopathy is more effective than a placebo in the treatment of influenza, sinusitis, and sleep disturbances?
A They did indeed.
Q And do you agree with those conclusions?
A I do agree.
Q And if you'll turn to page 19, which is the next page.
A (Witness complies.)
Q Did the National Health and Medical Research Council of the Australian government come to the conclusion that there is no reliable evidence on which to draw a conclusion about the effectiveness of homeopathy compared with a placebo for the treatment of a cough?
A Treatment of what?
Q Of a cough.
A Of a cough. That's correct.
Q And the overall conclusion of the National Health and Medical Research Council was that homeopathy is not an effective treatment; is that correct?

A It is not an effective treatment for any human condition. That's correct.

Q Thank you.

MS. NELSON: Your Honor, I'd like to move into evidence Exhibit 409.

MR. MARGULIES: Your Honor, subject to our objections under 801 and 803(8).

THE COURT: It is admitted subject to those objections.

(Exhibit No. 409 received)

BY MS. NELSON:

Q Finally, Dr. Rose, after all of the work that you have done in this case, is it your opinion that the underlying principles of homeopathy are biologically implausible?

A That is my opinion.

Q And is it also your opinion based on the work that you've done in this case that the products at issue here do not provide any effective relief for the symptoms described other than the potential placebo effect?

A That is my opinion.

MS. NELSON: Thank you.

I have nothing further at this time, Your Honor.

THE COURT: Cross-examination.

MR. MARGULIES: Yes. Thank you, Your Honor.

One moment.

MR. MARGULIES: Thank you very much, Dr. Rose.

THE WITNESS: Thank you.

THE COURT: Ms. Nelson.

MS. NELSON: Very briefly.

BY MS. NELSON:

Q It has to be very briefly because I'm told that Dr. Rose's wife of 65 years will tell him to leave if he doesn't make his flight.

I just have one question. You were asked some questions about the products here. You are aware, are you not, that these products are manufactured as homeopathic products; correct?

A That's my understanding.

Q And your testimony that homeopathy does not work applies equally to these products; does it not?

A Yes, it does.

MS. NELSON: Thank you very much.

THE COURT: Recross.

MR. MARGULIES: No. Thank you, Your Honor.

THE COURT: All right.

Thank you, Dr. Rose. You may be excused.

THE WITNESS: Thank you, Your Honor.

THE COURT: And at this time we will adjourn and resume on Tuesday at 9:00 o'clock because Monday is a holiday. All right. Have a good weekend, and again I

EXHIBIT 17

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al.,

Plaintiffs,

VS

HYLAND'S, INC., et al.,

Defendants.

No. 12-1150DMG

Reporter's Transcript of Proceedings
JURY TRIAL - DAY FOUR
MORNING SESSION
Los Angeles, California
FRIDAY, SEPTEMBER 4, 2015

ANNE KIELWASSER, CRR, RPR, CSR
Federal Official Court Reporter
312 North Spring Street, Room 432
Los Angeles, California 90012
Telephone: (213) 894-2969
anne.kielwasser@gmail.com
AKtranscripts.com

LOS ANGELES, CALIFORNIA; THURSDAY, SEPTEMBER 4, 2015;
P.M.
-oOo-

THE COURT: All right. Are Plaintiffs ready to call their next witness?

MS. NELSON: Yes, Your Honor. The Plaintiffs would like to call Dr. Noel Rose to the stand, please.

THE CLERK: Sir, if you would please approach the witness stand.

And if you'd remain standing and raise your right hand for me.

*DR. NOEL ROSE, Ph.D.,
Plaintiffs' Witness, was duly sworn, and testified as follows:

THE CLERK: And, sir, could you please state your full name, spelling both first and last for the record?

THE WITNESS: Noel Richard Rose, N-O-E-L, R-O-S-E.

DIRECT EXAMINATION

BY MS. NELSON:

Q Good afternoon, Dr. Rose.

A Good afternoon.

Q And welcome to Los Angeles.

the treatment is effective.
Q Correct.
A Am I restating your question?
Q You are.
A All right. Then the answer is probably yes.
Q Okay. And it's just a matter of judgment by them that they don't think it's reliable; is that right -- or sufficiently reliable?
A I think that's the strength of the report. I think we would agree it is the judgment of the examiners.
Q Based on what you told me, that the absence of a trial showing an effect doesn't mean it doesn't work, okay, would the Australian agency be wrong in stating that homeopathy is not more effective than placebo in this report?
A No.
Q Well, how are both statements correct? Help me out.
A Because I think one has to take -- in issuing a report one has to take the entire body of the report. And certainly the overwhelming preponderance of evidence clearly states that homeopathy is not effective treatment.
Q Homeopathy doesn't work because it can't work. Is that your opinion?
A No, no. Homeopathy doesn't work because it doesn't work.
Q And if the studies don't allow you to reach that

conclusion as you've told us today, how do you reach it?
A How do you reach what conclusion?
Q The conclusion that it doesn't -- you just told us that studies don't allow you to conclude a product or a drug doesn't work; right?
A When the drug doesn't work, it's because it doesn't work. It's not because we don't know what the mechanism is.
Q I'm sorry, sir. I don't mean to confuse things. I'm not asking about how it works. I think you told us that a study that shows no effect doesn't show the drug doesn't work; is that right?
A That's right. I'm responding to the statement that homeopathy doesn't work because it can't work, and I'm not indicating that that is the gist of my own opinion or my own testimony. I'm saying that the -- that homeopathy doesn't work because when it has been put to trial, the preponderance, the overwhelming preponderance of evidence is that it does not work.
Q The same studies that you say can't prove whether a particular drug works or doesn't work?
A That's right. You can carefully say that it is possible that some homeopathic drug some day somewhere under certain conditions may be beneficial.
Q And as you sit here today, sir, you can't tell me whether this Defend Cold 'n Cough product is effective or

EXHIBIT 18

FILED
CLERK, U.S. DISTRICT COURT
June 16, 2016
CENTRAL DISTRICT OF CALIFORNIA
BY: IV DEPUTY

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

CHRISTOPHER LEWERT, individually and on behalf of all other similarly situated,

Plaintiffs,

v.

BOIRON, INC. and BOIRON, USA, INC.,

Defendants.

Case No. CV 11-10803-AB (JPRx)

CLOSING JURY INSTRUCTIONS

The following sets forth the Court's concluding jury instructions which will guide your consideration of the evidence in this case.

Dated: June 16, 2016

HONORABLE ANDRÉ BIROTTE JR.
UNITED STATES DISTRICT COURT JUDGE

6. CALIFORNIA CONSUMER LEGAL REMEDIES ACT, CIVIL CODE §§ 1750, *ET SEQ.*

Plaintiff alleges that Defendants violated provisions of California's Consumer Legal Remedies Act, also known as the CLRA. To establish this claim, Plaintiff must provide affirmative evidence to prove each of the following, by a preponderance of the evidence:

1. Defendants represented that Oscillo relieves flu-like symptoms;
2. Defendants' representations that Oscillo relieves flu-like symptoms were false;
3. Plaintiff Christopher Lewert purchased Oscillo in reliance on Defendants' representations that Oscillo relieves flu-like symptoms;
4. The members of the class that Plaintiff represents purchased Oscillo in reliance on Defendants' representations that Oscillo relieves flu-like symptoms; and
5. Plaintiff Christopher Lewert, and the members of the class he represents, were harmed by Defendants' representations that Oscillo relieves flu-like symptoms.

Plaintiff may prove that the class members relied on Defendants' representations by establishing that Defendants' representations that Oscillo relieves flu-like symptoms were material to the reasonable consumer.

A reasonable consumer is an ordinary consumer acting reasonably under the circumstances, and is neither the most nor least sophisticated consumer.

A representation is material if a reasonable consumer would attach importance to its existence or nonexistence in determining whether to purchase Defendants' product.

EXHIBIT 19

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al.,

Plaintiffs,

VS

HYLAND'S, INC., et al.,

Defendants.

No. 12-1150DMG

Reporter's Transcript of Proceedings
JURY TRIAL - DAY FOUR
MORNING SESSION
Los Angeles, California
FRIDAY, SEPTEMBER 4, 2015

ANNE KIELWASSER, CRR, RPR, CSR
Federal Official Court Reporter
312 North Spring Street, Room 432
Los Angeles, California 90012
Telephone: (213) 894-2969
anne.kielwasser@gmail.com
AKtranscripts.com

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*****

EXHIBITS

Exhibit No. 6.1 received in evidence	14
Exhibit No. 6-2 received in evidence	15
Exhibit No. 42-33 received in evidence	46

******

Q. Tell the jury which ones you purchased.
A. I have purchased four different Hyland's products. The first one is some Colic Tablets, and I'm not sure if that's pertinent to this trial because it was so long ago. The other products I've purchased have been Calms Forte, Leg Cramp medicine, and Migraine Relief.
Q. Okay. We're going to go through each of those together. But let's just talk a little bit about your shopping habits.

Where do you go to buy nonprescription drugs?

A. I go to a variety of places. I go to big box stores, like Wal-Mart and Target, I go to grocery stores. I've gone to pharm -- drugstores like Walgreens or CVS, health food stores, and occasionally I'll shop online.
Q. In this case, the products that we're going to be talking about -- let's start with Calms Forte.

Where do you remember purchasing Calms Forte?

A. I purchase Calms Fore in Publix of Sarasota. Publix is a grocery store, southeastern grocery store chain.
Q. Do you remember where it was that you saw the Calms Forte in the grocery store?
A. Yes. It was in the health -- health and beauty aids aisle.
Q. Do you know whether you needed a prescription for the Calms Forte?

A. I was hoping, and I was intending, yes.
Q. In 2009, did you purchase any other Hyland's products?
A. Yes, I did.
Q. Let's talk about the other products that you purchased.

Which ones did you purchase in 2009?

A. I purchased the Leg Cramp medicine, and I purchased the Migraine Relief medicine.

Q. I'm going to ask you to turn to Exhibit 1012 in your binder.

Do you see that Exhibit in front of you?

A. Yes, I do.
Q. Can you tell me -- do you recognize it?
A. Yes, I do.
Q. What is it?
A. This is the Hyland's Migraine Headache Relief packaging.
Q. Is it -- does it look like Hyland's Migraine packaging that you purchased in 2009?
A. Yes, it does.

MS. DIXON: Your Honor, I believe Exhibit 1012 is already in evidence.

THE COURT: It is.

MS. DIXON: May I publish to the jury?

THE COURT: Yes.

EXHIBIT 20

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al.,

Plaintiffs,

VS

HYLAND'S, INC., et al.,

Defendants.

No. 12-1150DMG

Reporter's Transcript of Proceedings
JURY TRIAL - DAY FOUR
MORNING SESSION
Los Angeles, California
FRIDAY, SEPTEMBER 4, 2015

ANNE KIELWASSER, CRR, RPR, CSR
Federal Official Court Reporter
312 North Spring Street, Room 432
Los Angeles, California 90012
Telephone: (213) 894-2969
anne.kielwasser@gmail.com
AKtranscripts.com

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EXHIBITS

Exhibit No. 6.1 received in evidence	14
Exhibit No. 6-2 received in evidence	15
Exhibit No. 42-33 received in evidence	46

******

A. Yes.
Q. Can you tell the jury why?
A. Because I'm a representing a class against the Hyland's medications.
Q. Can you tell the jury if you've ever purchased Hyland's medications?
A. Yes.
Q. Do you remember which ones?
A. It was the Leg Cramp.
Q. Okay. We're going to talk a little bit about your purchase of the Leg Cramps. But, in general, do you buy medications at the stores?
A. Yes. Usually Target and Wal-Mart and sometimes Henry Sprouts.
Q. Are these nonprescription medications?
A. Yes.
Q. What kind of nonprescription medications have you used in the last eight years?
A. Allergy medications like Claritin and aspirin and ibuprofen and Aleve and stuff like that.
Q. When you've used aspirin and Ibuprofen and Aleve, have they helped you?
A. Yes.
Q. I want to talk to you a little bit today about the specific products that you bought from Hyland's.

EXHIBIT 21

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al.,

Plaintiffs,

VS

HYLAND'S, INC., et al.,

Defendants.

No. 12-1150DMG

Reporter's Transcript of Proceedings
JURY TRIAL - DAY SIX
Los Angeles, California
WEDNESDAY, SEPTEMBER 9, 2015

ANNE KIELWASSER, CRR, RPR, CSR
Federal Official Court Reporter
312 North Spring Street, Room 432
Los Angeles, California 90012
Telephone: (213) 894-2969
anne.kielwasser@gmail.com
AKtranscripts.com

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Exhibit No. 210-1 received in evidence	23
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******

education? Did you graduate college?

A. Yes, I graduated at UCSD.

Q. What was your degree?

A. Computer engineering.

Q. Have you had any formal training in homeopathy or in homeopathic medicines?

A. No.

Q. Have you had any formal training in medicine?

A. No.

Q. Do you know why you're here today?

A. Yes, to testify in Hyland's trial.

Q. And are you a party in the trial?

A. Yes. I believe I represent myself and a class or -- yeah.

Q. You mentioned that you're here to testify in the Hyland's trial. Do you know what Hyland's is?

A. Umm, they're a company that makes homeopathic products.

Q. And how do you know that? Have you purchased those products?

A. Yes.

Q. Tell the jury which products of Hyland's you purchased.

A. Umm, I purchased their cough -- their cough products, and then an allergy product, and a -- there was a kids cough

and cold product.

Q. Let's start with the allergy product. Approximately when did you purchase the allergy product?

A. The allergy product, approximately 2012.

Q. Who were you purchasing the allergy product for?

A. For myself.

Q. What kind of -- what was the reason that you were purchasing the allergy product?

A. I was having some itchy, runny eyes and some runny nose and some symptoms similar to allergy issues, so I...

Q. Had you had symptoms like that before 2011?

A. Yes.

Q. Where did you go to -- to purchase the allergy product?

A. I went to a store called Henry's. Now called Sprout's.

Q. Was that in San Diego?

A. Yes.

Q. I'd like you -- I'd like to ask you to turn to the binder that's in front of you to Exhibit 1019. Do you have that in front of you?

A. Yes.

Q. Can you tell us what Exhibit 1019 is?

A. It's a picture of the box with Seasonal Allergy Relief.

EXHIBIT 22

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al.,

Plaintiffs,

VS

HYLAND'S, INC., et al.,

Defendants.

No. 12-1150DMG

Reporter's Transcript of Proceedings
JURY TRIAL - DAY FOUR
MORNING SESSION
Los Angeles, California
FRIDAY, SEPTEMBER 4, 2015

ANNE KIELWASSER, CRR, RPR, CSR
Federal Official Court Reporter
312 North Spring Street, Room 432
Los Angeles, California 90012
Telephone: (213) 894-2969
anne.kielwasser@gmail.com
AKtranscripts.com

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EXHIBITS

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******

Hyland's to change their labels.

Q. Have you purchased Hyland's products?

A. I have.

Q. Which products did you purchase that were Hyland's?

A. I did the Cold -- Cold & Flu, Night Day, and the Migraine Medicine.

Q. Where did you purchase the Cold & Flu, Night & Day?

A. CVS.

Q. Approximately when?

A. Over a long time ago. Umm --

Q. I'll ask for your estimate if you have one.

A. I'm going to -- 2011.

Q. And what about the migraine. Do you remember when you purchased the migraine medicine?

A. I think the same year.

Q. Where?

A. In another CVS.

Q. Have you purchased other nonprescription medications?

A. Yes.

Q. What other types of nonprescription medications have you purchased?

A. The gamut. Like NyQuil, DayQuil, Tylenol.

Q. Where do you purchase those products?

A. Just like the grocery or CVS.

Q. When you purchased Hyland's Day Night Cold Medicine,

both of them, what aisle were they in?

A. The medicine aisle.

Q. What about the migraine medicine?

A. Same aisle.

Q. Were those in San Diego?

A. Yes.

Q. I'm going to ask you about some of the products that you purchased. If you can turn in the binder that should be in front of you still, not the black one, the white one.

A. Oh, found it.

Q. Let's start with the Cold 'n Cough. Can you turn to Exhibit 1016? And it should be dash -1 and -2.

A. Okay.

Q. Looking at Exhibit 1016-1 and -2, do you recognize what this is?

A. I do.

Q. What is it?

A. It's the Cold 'n Cough, Defend, whatever, medicine.

Q. How do you recognize this Exhibit 1016?

A. Because I purchased it.

Q. Does the picture in 1016 look similar to the package of the Cold 'n Cough that you purchased in 2011?

A. Yes.

MS. DIXON: Your Honor, we would move Exhibit 1016-1 and -2 into evidence.

A. I just read the directions.
Q. So you read the directions on the back of the box?
A. Yeah.
Q. Let's look at the directions.
At the time you were an adult; right?
A. Yes.
Q. So we're only going to talk about the adult directions.
Did you follow the directions?
A. Well, I took -- I took it at night and then went to bed and then took in the morning and gave up on it.
Q. And there wasn't any indication on this medication that you would not be able to take it at night, right?
A. Oh, I'm so sorry. We're in the day 1? The day 1 I took it in the morning.
Q. Yes. Let's just be clear because that was my mistake.
Did you buy the products together at the same time?
A. I did.
Q. Okay. So when you were talking earlier that you took it in the morning, you took the Cold 'n Cough in the morning.
A. Correct. And the night one at night.
Q. Okay. Let's look at 1017-1 and -2. Do you recognize the pictures identified in 1017?
A. Yes.

Q. What are they?

A. That's the nighttime one of the daytime thing.

Q. Is this a fair and accurate picture of the product that you bought in 2011?

A. Yes.

MS. DIXON: Your Honor, they've already been admitted into evidence.

THE COURT: Yes.

BY MS. DIXON:

Q. What did you read on --

What did you look at when you were deciding to purchase the Defend Cold 'n Cough Night?

A. The same exact thing as I did on the other ones. I'm seeing it's a hundred percent natural, I see it's going to relieve the symptoms that I currently had, it's going to help me sleep because it's nighttime.

Q. And why did you believe that it was going to relieve the symptoms that you had?

A. Because it says it's effective to those symptoms. It says: "Safe and effective relief."

Q. Is this the product that you took at night when you got home?

A. Yes.

Q. And did you -- how did you know how much to take of the product?

EXHIBIT 23

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

THE HON. JUDGE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al., on behalf of themselves, all others similarly situated and the general public,	)	
Plaintiff,	)	
vs.	)	**NO. 13-CV-5102-DMG**
HYLAND'S, INC., a California corporation; and STANDARD HOMEOPATHIC COMPANY,	)	
Defendants.	)	

JURY TRIAL - DAY 3 (P.M. Session)

Los Angeles, California

Thursday, September 3, 2015

LISA M. GONZALEZ, CSR No. 5920, CCRR
U.S. District Courthouse
312 North Spring Street - Room 438
Los Angeles, California 90012
213.894.2979
www.lisamariecsr.com

I N D E X

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Q And you said that you and your family live in Northern California?
A Correct.
Q Did you travel down here today to be with the jury?
A I did. I left last night and here today.
Q Do you know why you're here today talking to the jury?
A The plaintiff for a lawsuit for Hyland's.
Q And do you know what Hyland's is?
A I know it's a company that produces two of the products that I did use.
Q Okay. I want to talk to you a little bit about the products that you used. Where do you go if you're going to shop for non-prescription products?
A So I shop -- we're a very small town, so we shop a lot at Target and Rite-Aid, are the two big places that we do shop.
Q And what kind of products do you buy, non-prescription products do you buy for you and your family?
A We buy aspirin for headaches, NyQuil. We also buy Benadryl, Claritin. So those types.
Q On occasion have you purchased products that were made by Hyland's?
A I did, yes.
Q Let's talk a little bit about those times that you purchased those products. What is your memory as far as

what specific products you purchased that were made by Hyland's?

A The first product that I did purchase was the teething tabs for my daughter. About eight, nine months after she was born, she had a ton of pain, very irritable. So I found that on the shelf and I did buy that for her during that time.

Q Which store did you purchase the teething tablets at if you remember?

A That was at Target.

Q Where were the teething tablets located?

A So they were located right on the shelf right next to I think children's Tylenol at the time.

Q Do you remember why it was that you decided to purchase the teething tablets?

A I do. The children's Tylenol, she was not old enough at the time for that, and I was looking for relief, any sort of relief for the irritability of teething.

Q Was there another product that you purchased that were made by Hyland's?

A There was a Calms Forté that I did purchase for my son, but I did not buy that for my daughter.

Q When do you remember buying the Calms Forté for your son?

A So the Calms Forté was -- he was born in 2007, so 2008

EXHIBIT 24

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al.,

Plaintiffs,

VS

HYLANDS, INC., et al.,

Defendants.

No. 12-1150DMG

Reporter's Transcript of Proceedings
JURY TRIAL - DAY TWO
MORNING SESSION
Los Angeles, California
WEDNESDAY, SEPTEMBER 2, 2015

ANNE KIELWASSER, CRR, RPR, CSR
Federal Official Court Reporter
312 North Spring Street, Room 432
Los Angeles, California 90012
Telephone: (213) 894-2969
anne.kielwasser@gmail.com
AKtranscripts.com

A. Yes. It's a salt. It's classified as a salt.
Q. And does it have a common word that people go by when they describe this salt or types of assault?
MR. MARGULIES: Objection, Your Honor. Lacks foundation.
THE COURT: He can answer if he knows.
THE WITNESS: I don't know where you're going. I don't understand the question.
BY **MR. GOMEZ:**
Q. All right. So, at least with the leg cramps to relief the cramp being consumers are paying for one in one millionth part of salt, a type of salt.
A. They're paying for magnesium phosphates 6X.

Q. Now, in terms of your products -- you get to finish this little soliloquy --
A. You wish.
Q. -- or I guess discussion, then we'll take a break.
In terms of these products, you're not claiming that you are selling them as a placebo or intended for use as a placebo to customers, correct?
A. Certainly not.
Q. Do you agree if customers paid money for your products and those products provided no more relief than a placebo, then those customers would not be receiving the benefit of

EXHIBIT 25

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

THE HON. JUDGE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al., on behalf of themselves, all others similarly situated and the general public,	)	
Plaintiff,	)	
vs.	)	NO. 13-CV-5102-DMG
HYLAND'S, INC., a California corporation; and STANDARD HOMEOPATHIC COMPANY,	)	
Defendants.	)	

JURY TRIAL - DAY 2 (P.M. Session)

Los Angeles, California

Wednesday, September 2, 2015

LISA M. GONZALEZ, CSR No. 5920, CCRR
U.S. District Courthouse
312 North Spring Street - Room 438
Los Angeles, California 90012
213.894.2979
www.lisamariecsr.com

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THE COURT: Withdraw -- if you're going to withdraw your question --

MR. GOMEZ: I'll withdraw it.

MR. MARGULIES: Thank you.

MR. GOMEZ: That's fine.

MR. MARGULIES: No problem.

BY MR. GOMEZ:

Q And so as we look at it, this product, the Leg Cramps without the quinine on the packaging, makes the same representations and promises to consumers as the other product did, correct?

Fair to say?

A I would have to compare the -- the -- the -- the labeling, but I assume that they do, yeah.

Q Right. And so we can see on -- Exhibit 1015 claims that this product will stop the pain and relax calf and foot cramps; correct?

A Yes, sir.

Q And so those are claims and promises that you make to consumers that will buy this product, that this product will provide relief for these medical conditions; correct?

A That's what we say it will do.

Q And so looking at Exhibit 1015-2, which is going to be in your book there --

I'll offer 1015-2, which I think is without

A Yes.
Q And so you understand and agree that on the front of your packaging for this product, you are representing to consumers that may or may not purchase your product, that this product, if they pay money to purchase it, will provide medical relief for teething children; correct?
A Yes, subject to what I said before, which is that sometimes all products don't work for all people, but this is a very -- this is a product that people like very, very much, so, yes, I'm -- I'm -- I'm saying that.
Q You keep saying that not all products work for all people.
A At all times.
Q Right. Is it your intent that you design these products, to work for as many people as they possibly can?
A Most certainly.
Q And so you don't put on here, for example, "This product may or may not work for you," do you?
A Certainly not.
Q You don't disclose to her, as she is walking down the aisle, contemplating what to buy for her unhappy child, that "This" -- "These Teething Tablets may or may not work"?
You don't say that on the box, do you?
A Certainly not.
Q You basically make a promise and representation to her,

that if she purchases these Teething Tablets for her child, they will provide symptomatic relief; correct?

A Yes, we do.

Q And that's the basis of the bargain --

A Yes.

Q -- am I right? Okay.

And so -- I think we discussed the clinical trial that Dr. Jacobs performed on your behalf, previously.

Do you recall that?

A I do.

Q And so my question to you is: Did you conduct such a clinical trial with this combination of ingredients, prior to offering it for sale to moms?

A No, this is an old -- old -- old, old product. I believe, probably the 1940's.

Q And so the answer's, no; correct?

A I said, "No."

Q And that would be the same with regard to all your products, you performed no clinical testing of these combined ingredients, to determine whether these products could provide the relief that they promised, before you put them on the market?

A The answer is, yes. I stipulated to that before.

Q Right. And so it was after you started selling these products, including these Teething Tablets -- it sounds like

Q And so it looks like on here (indicating), on the front of the box, where we're about to put the label -- not very good.

Can you -- there we go. Do it down, maybe, or circle it or something.

Do you see where we're trying to -- not very well -- to indicate that you've indicated to consumers that this is a homeopathic product?

A Yes.

Q And do you believe that that is a conspicuous way to indicate to consumers that this is a homeopathic product?

A Yes, I do.

Q And so, as we look at this product, the -- the name of the product is Defend Cough & Cold; correct?

A Yes.

Q And so the promise to consumers is that if they take this product, it will, I guess, provide some medical relief for a cold and cough; is that right?

A Yes.

Q What does "defend" mean? How is that word used?

A Defend was -- was a -- an attempt, I'll say, to create a sub-brand from Hyland's, to have a line of products under the name Defend?

Q And so whose idea was that?

A It came from our marketing team.

BY MR. GOMEZ:

Q All right. That's fine for now. And so 42-15 is a product that you offer consumers during our class period entitled "Cough"; is that right?

A Yes.

Q And so in terms of this product, can you explain to us in a nutshell how this differs from Defend Cough 'n Cold?

A Well, first off, it's a tablet, not a liquid. And I don't know if the formula -- I think the formula's different actually. If you give me a second, I could compare them. But this is a solid, a tablet versus the Defend, which is liquid.

Q And let's just go through this. The claim to consumers and promises that if they buy this product from you, it will help relieve the medical condition of a cough; correct?

A That's correct.

Q And that this product will provide medical relief for coughs due to colds; correct?

A Yes.

Q And you understand again that when you make these claims and representations on your packaging, that you are attempting to encourage consumers to purchase your product?

A Yes, it's a great product.

Q So "yes"?

A Yes.

Q And you would agree that you are making them certain promises and that forms the basis of the bargain they choose to purchase your products for?
A That's correct.
Q Let's look at the back of that. And I have, I think -- I don't know.

Do we have the back? Is it going to be legible if we pull it up? That's not bad.

And so here we see -- and do you remember our discussion of the different dosages and how it would be important to give a child, I guess, from zero to some age this dose; and from six to this age, this dose?

And so here we have a dosing for children from six to 12 years old, the adult dose. Do you see that?
A It says children 6 to 12 years old, one-half the adult dose.
Q I'm sorry. One-half the adult dose. Do you see that?
A Yes.
Q So would that be consistent with what's on your other products?
A I don't know that we updated -- this is a very old tradedress. You can see that there's no drug facts box on it. It's pretty old. I don't know that that was changed, but that dosage is a very standard dosage.

THE COURT: For the record, is this Exhibit 42-16?

A Yeah. This is very old tradedress, and I think the word "homeopathic" is now larger on the existing one, but, yeah, we -- this was updated a number of years ago.

Q You understand that this is the packaging that our consumers relied upon in determining whether or not to purchase your product?

A Yes.

Q And so is it your position that this packaging, with this small font of "homeopathic," is insufficient to alert a consumer they're purchasing a homeopathic product?

A No, in fact, if you read it together, it says "Homeopathic Calms Forte."

Q So you think this is just fine?

A This is okay.

Q But you took great pains to explain to us how you've updated to make the homeopathic indication different in your new trade dress.

A And personally speaking, I hate that moon.

Q Okay. And so it says "Calms Forte"; right? And sleep aid; correct?

A Yes.

Q And so you understand that the promise that you are making to consumers is that taking this medication will help them sleep?

A Yes.

your products? It sounds like you have.
A I'm not aware of any formal studies, but I think that, you know, we've thought about it over time.
Q Okay. So it's something you have considered; that is, what you put on the packaging, how you put it on there, and whether consumers will notice it or not; correct?
A Right. And you will see next to it is the QR code which was another idea that we had to help people to learn about homeopathy. So they could hit the QR code with their -- with their cell phone, and then that would go to a Website, and the Website would give more information about the product, about homeopathic medicine.
Q The front of the tablet, do you see that? You see it looks like a picture of a baby?
A Yes.
Q And you understand that what you were doing on this package was making promises to moms, to her, maybe sometimes dad -- hopefully if he's helping out -- that this product would provide effective medical relief to infants suffering from colic, gas pain, and irritability?
A Yeah, it's a great product.
Q And, again, Colic Tablets is mentioned prominently; correct?
A Yes.
Q And so if we go to Exhibit 42-14 --

EXHIBIT 26

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

THE HON. JUDGE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al., on behalf of themselves, all others similarly situated and the general public,	)	
Plaintiff,	)	
vs.	)	**NO. 13-CV-5102-DMG**
HYLAND'S, INC., a California corporation; and STANDARD HOMEOPATHIC COMPANY,	)	
Defendants.	)	

JURY TRIAL - DAY 3 (P.M. Session)

Los Angeles, California

Thursday, September 3, 2015

LISA M. GONZALEZ, CSR No. 5920, CCRR
U.S. District Courthouse
312 North Spring Street - Room 438
Los Angeles, California 90012
213.894.2979
www.lisamariecsr.com

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and help him feel better.
Q Why did you believe that it was three times the product?
A It's on the box. I believe what is marketed and what is in the store, and I would assume it's got to be regulated to some point that there's truth to it.
Q Do you know now what three times is?
A I do after this, yes.
Q What is your understanding if you have one of three times?
A So it's diluted. I don't know the exact, but I know now that three X is three X diluted versus three times increased, which is what I thought it was.
Q Did you believe at the time when you purchased the product that you thought it was three times the dilution?
A I thought it was three times increased.
Q Is it fair to say, then, that you thought it was higher strength?
A Higher strength.
Q When you were purchasing the teething tablets for your son, were you intending to purchase a placebo?
A No.
Q Do you know what that is?
A So I don't know the actual definition, but a placebo to me if I have a headache, I take a pill. My headache is

EXHIBIT 27

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al.,

Plaintiffs,

VS

HYLAND'S, INC., et al.,

Defendants.

No. 12-1150DMG

Reporter's Transcript of Proceedings
JURY TRIAL - DAY FOUR
MORNING SESSION
Los Angeles, California
FRIDAY, SEPTEMBER 4, 2015

ANNE KIELWASSER, CRR, RPR, CSR
Federal Official Court Reporter
312 North Spring Street, Room 432
Los Angeles, California 90012
Telephone: (213) 894-2969
anne.kielwasser@gmail.com
AKtranscripts.com

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******

A. No.
Q. You told us that you took a couple of boxes of the product; is that correct?
A. That's correct.
Q. Why did you take it -- why did you buy another box if the first box wasn't helping you?
A. I usually like to switch things up. I know that sometimes the instructions aren't as clear. I didn't know if it meant take it exactly as the cramps came, or you're supposed to take it throughout the day, and it kind of builds up in your system and makes it go away eventually.
Q. Do you remember how much you spent on purchasing a couple of boxes of the Leg Cramps?
A. About 7 to $9 a box. So double that, whatever that is.
Q. When you were purchasing the Leg Cramps what -- what was it -- why were you buying them?
A. I wanted something natural, and I also wanted something that would not make me groggy in the morning.
Q. When you were purchasing the Leg Cramps, did you believe that you were purchasing a placebo?
A. No.
Q. Do you know what a placebo is or have some understanding of what you think it means?
A. My understanding is that it's something that doesn't

EXHIBIT 28

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al.,

Plaintiffs,

VS

HYLAND'S, INC., et al.,

Defendants.

No. 12-1150DMG

Reporter's Transcript of Proceedings
JURY TRIAL - DAY FOUR
MORNING SESSION
Los Angeles, California
FRIDAY, SEPTEMBER 4, 2015

ANNE KIELWASSER, CRR, RPR, CSR
Federal Official Court Reporter
312 North Spring Street, Room 432
Los Angeles, California 90012
Telephone: (213) 894-2969
anne.kielwasser@gmail.com
AKtranscripts.com

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*****

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******

A. I had none.
Q. Do you know what the word "placebo" means?
A. Yes, I do.
Q. Can you just tell the jury what your understanding of the word is?
A. My understanding of the word "placebo" is a substance that one has taken to relieve symptoms, and it's mind over matter. It's the belief that -- that it will help solve your problem, but there may not necessarily be anything in the pill, tablet, whatever the substance that one is taking, that is actually effective.
Q. At the time that you were purchasing the migraine relief in 2009, did you believe you were purchasing a placebo?
MR. MARGULIES: Objection. Objection. Lacks foundation, improper witness testimony.
THE COURT: Overruled.
THE WITNESS: I did not believe I was purchasing a placebo.
BY MS. DIXON:
Q. Is that why you were buying the migraine medicine, was for a placebo?
A. No, I was not buying it as a placebo.
Q. Okay. I'm going to have you talk a little bit about the Leg Cramps that you purchased as well, the product Leg

EXHIBIT 29

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al.,

Plaintiffs,

VS

HYLAND'S, INC., et al.,

Defendants.

No. 12-1150DMG

Reporter's Transcript of Proceedings
JURY TRIAL - DAY FOUR
MORNING SESSION
Los Angeles, California
FRIDAY, SEPTEMBER 4, 2015

ANNE KIELWASSER, CRR, RPR, CSR
Federal Official Court Reporter
312 North Spring Street, Room 432
Los Angeles, California 90012
Telephone: (213) 894-2969
anne.kielwasser@gmail.com
AKtranscripts.com

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*****

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Exhibit No. 42-33 received in evidence	46

******

was the intent?

A. To relieve the symptoms that were on the box which were my symptoms at the time.

Q. Do you know what the word placebo means?

A. Yes.

Q. What does it mean to you?

A. Well, to me it means a sugar pill. It means someone is taking a sugar pill and hopefully some psychosomatic thing will work for them.

Q. Is that what you thought you were buying when you purchased this product?

A. No, I thought I was actually buying the ingredients that was going to help my symptoms. I don't want to buy a sugar pill.

Q. What about with the Defend Cold 'n Cough? Did you think that you were buying a placebo for that product?

A. No, I would never buy a sugar pill. That's silly.

Q. Let's look at the --

We just talked about the Night. So let's look at the data that you bought at the same time in 2011, which is Exhibit 1016.

A. Okay.

Q. You mentioned to us earlier that you took this in the day after you took the Night product, right?

A. Yes.

EXHIBIT 30

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

THE HON. JUDGE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al., on behalf of themselves, all others similarly situated and the general public,	)	
Plaintiff,	)	
vs.	)	NO. 13-CV-5102-DMG
HYLAND'S, INC., a California corporation; and STANDARD HOMEOPATHIC COMPANY,	)	
Defendants.	)	

JURY TRIAL - DAY 2 (P.M. Session)

Los Angeles, California

Wednesday, September 2, 2015

LISA M. GONZALEZ, CSR No. 5920, CCRR
U.S. District Courthouse
312 North Spring Street - Room 438
Los Angeles, California 90012
213.894.2979
www.lisamariecsr.com

I N D E X

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done by way of clinical trials?

A No. In fact -- in fact, a -- a -- a clinical trial would be too narrow.

What -- what you want are case series, so that there are actually observational studies as opposed to a clinical trial, which is an interventional study.

Q And is it true with regard to each of the products that we're talking about in this case?

Do you recall those?

A Yes.

Q And so -- you say, "these observational trials."

Is that what you called them?

A Yeah.

Q And so is it true that -- it's true --

A Actually, observational studies. They're not trials.

Q Observational studies.

We've now discussed all the observational or clinical studies that your company performed with regard to each of the products at issue in this case; right?

There's -- there's nothing else out there; right?

A Ask me that question again.

Q You're talking about there are these continued observational trials, and my question to you is: You have conducted no observational trials of these particular products, to justify their effective relief of any medical

symptoms?

A That's correct.

Q And the clinical trials, we've already discussed; correct?

A I guess. I think so.

Q And so now we turn to the proof of claims, and for each of the ingredients in each of your products, there's a citation to a number of references in *materia medica*; correct?

A Yes.

Q And we agree that the references here are, generally speaking, around the beginning of the 20th Century?

In other words, early 1900, late 1800?

A Yeah, the -- the -- well, actually -- just so that we're clear about it, the -- the Clarke and Boericke and Hering books, which was specified by FDA, are older.

The Jouanny book is -- is 1980s.

Q How old are the other ones?

A Well, I -- I think we agreed that they are early 20th or late -- late 19 -- I don't know.

I mean, I can look that up very simply. It's and online --

Q And so there's references to these various *medica* -- *materia medica* and the HPUS that we talked about earlier; correct?

EXHIBIT 31

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

THE HON. JUDGE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al., on behalf of themselves, all others similarly situated and the general public,	)	
Plaintiff,	)	
vs.	)	**NO. 13-CV-5102-DMG**
HYLAND'S, INC., a California corporation; and STANDARD HOMEOPATHIC COMPANY,	)	
Defendants.	)	

JURY TRIAL - DAY 5 (P.M. Session)

Los Angeles, California

Tuesday, September 8, 2015

LISA M. GONZALEZ, CSR No. 5920, CCRR
U.S. District Courthouse
312 North Spring Street - Room 438
Los Angeles, California 90012
213.894.2979
www.lisamariecsr.com

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DEFENDANTS' WITNESS	DIRECT	CROSS	REDIRECT	RECROSS	VOIR DIRE VOL
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conducts any clinical tests prior to releasing its products to determine whether or not the statements made as to the relief that will be provided for the symptoms are accurate?

A Could you repeat the question, please.

Q Sure. I'm correct, am I not, that neither Standard or Hyland's does any clinical testing prior to releasing its products to determine whether or not the statements that are made as to the relief that will be provided for symptoms are accurate?

A I believe that is correct.

Q And then lastly, Mr. Phillips, since you were involved in the company as a president for a period of time and had been at Standard from 1979, I'm correct, am I not, that between 1979 and 2010 gross revenue for the company increased from about $2 million in 1979 to about $30 million in 2010?

A Roughly, yes.

MS. NELSON: Thank you very much, Mr. Phillips. I appreciate it.

THE COURT: Cross-examination or direct, whichever it may be.

MR. MARGULIES: Thank you, Your Honor. Hopefully it will be direct.

THE WITNESSS: Are we done with this book?

MS. NELSON: I am done with that book, yes. Thank

EXHIBIT 32

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al.,

Plaintiffs,

VS

HYLANDS, INC., et al.,

Defendants.

No. 12-1150DMG

Reporter's Transcript of Proceedings
JURY TRIAL - DAY TWO
MORNING SESSION
Los Angeles, California
WEDNESDAY, SEPTEMBER 2, 2015

ANNE KIELWASSER, CRR, RPR, CSR
Federal Official Court Reporter
312 North Spring Street, Room 432
Los Angeles, California 90012
Telephone: (213) 894-2969
anne.kielwasser@gmail.com
AKtranscripts.com

case reports, you begin to see patterns and themes. And so, what happens is that the materia medica, as a general concept right now, is a dynamic document. It's being added to pretty much all the time. What we use are symptoms that have been shown to be cured by these homeopathic medicines over a long period of time.

Q. In the materia medica will I find reference to this -- this combination of ingredients providing relief for leg cramps?

A. Of course not.

Q. No?

A. No.

Q. Okay. And so, nowhere in the HPUS, nowhere in the materia medica, and nowhere in the history of homeopathy prior to you placing this substance on the market will I find a support for the proposition that combining these ingredients will provide relief for leg cramps?

MR. MARGULIES: Objection. Compound.

THE COURT: Overruled. He can answer if he can understand it.

MR. GOMEZ: I could barely understand it myself. I'll ask it again.

BY **MR. GOMEZ:**

Q. And so, I'm not going to find this combination in the HPUS, correct?

A. That's correct.
Q. I'm not going to find this combination in the materia medica, correct?
A. You will find no combinations in either document.
Q. I'm not going to find any clinical testing of this combination, right?
A. No. We've not done a trial on this, no.
Q. And you're not aware of anyone ever doing a trial on this combination, right?
A. I don't know of any.
Q. Okay.

THE COURT: This might be a good time to break for lunch.

MR. GOMEZ: Yes, Your Honor. Thank you very much.

THE COURT: All right, so, we will return at 1:15. We are in recess.

(Recess taken.)

EXHIBIT 33

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

THE HON. JUDGE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al., on behalf of themselves, all others similarly situated and the general public,	)	
Plaintiff,	)	
vs.	)	NO. 13-CV-5102-DMG
HYLAND'S, INC., a California corporation; and STANDARD HOMEOPATHIC COMPANY,	)	
Defendants.	)	

JURY TRIAL - DAY 2 (P.M. Session)

Los Angeles, California

Wednesday, September 2, 2015

LISA M. GONZALEZ, CSR No. 5920, CCRR
U.S. District Courthouse
312 North Spring Street - Room 438
Los Angeles, California 90012
213.894.2979
www.lisamariecsr.com

BY MR. GOMEZ:

Q So now I'd like to turn to the proof of claims for Defend Cold & Cough Night. Okay.

And you'll find that at 1027-1. Do you have that, sir?

A I do.

Q So, again, without belaboring the point, but we just have to run through this with regard to each of the products. You performed no testing on human beings before you put this product on the market to confirm that it would provide actual relief for colds or coughs or help people sleep; correct?

A That's correct.

Q And in terms of your support in the bibliography, if you see that at 1027-3, for each of the products again --

And this is the same for each of your products.

-- you cite to the HPUS and a number of references in the materia medica for each of the active ingredients; true?

A That's correct.

Q And so, again, hopefully I made this point and let's just make it and move on.

Nowhere in the HPUS are any of these combination-ingredient products recognized; true?

MR. MARGULIES: Objection. Asked and answered.

EXHIBIT 34

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

THE HON. JUDGE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al., on behalf of themselves, all others similarly situated and the general public,	)	
Plaintiff,	)	
vs.	)	**NO. 13-CV-5102-DMG**
HYLAND'S, INC., a California corporation; and STANDARD HOMEOPATHIC COMPANY,	)	
Defendants.	)	

JURY TRIAL - DAY 5 (P.M. Session)

Los Angeles, California

Tuesday, September 8, 2015

LISA M. GONZALEZ, CSR No. 5920, CCRR
U.S. District Courthouse
312 North Spring Street - Room 438
Los Angeles, California 90012
213.894.2979
www.lisamariecsr.com

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any clinical trials to support the statement that taking Calms Forté will provide somebody sleep?

A I'm not.

Q The statement, you'll agree with me, is also made in the teething tablet product that we just looked at; right?

MR. PERSSON: Objection. Vague.

THE COURT: Sustained.

BY MS. DIXON:

Q We can look back at the teething tablet slide which is 1011. You'll agree with me that Hyland's is making claims on the front of this package that it will help with certain symptoms; correct?

A That's correct.

Q And you're aware of no studies, clinical trials that support the statements that are made on the front of the teething tablets box; are you?

A The Materia Medica is clinical information.

Q Right, but my question was specific as to clinical trials. You're aware of no clinical trials?

A In the modern sense of randomized clinical trials, no, I'm not.

Q You're aware that Hyland's did do a clinical trial about the teething tablets; right?

A Yes. That was not under my direction. I'm not familiar with the study.

EXHIBIT 35

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

THE HON. JUDGE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al., on behalf of themselves, all others similarly situated and the general public,	)	
Plaintiff,	)	
vs.	)	**NO. 13-CV-5102-DMG**
HYLAND'S, INC., a California corporation; and STANDARD HOMEOPATHIC COMPANY,	)	
Defendants.	)	

JURY TRIAL - DAY 5 (P.M. Session)

Los Angeles, California

Tuesday, September 8, 2015

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www.lisamariecsr.com

I N D E X

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through some form of shaking -- succussion is the word I think we've been told -- am I correct that at least as of 2012 Standard would utilize or was essentially shaking its product by hand?

A The succussion was a manual process.

Q And by manual you mean that some individual in the manufacturing plant actually took a two-ounce jar and shook that jar and also incorporated into the shaking some form of impact, either striking it on some felt table; correct?

A Yes. In some cases, yes.

Q Okay. And that was done because that's how it had been done traditionally for years; correct?

A Correct.

Q And you took the position I believe previously that it avoids any potential complications from using machines; correct?

A Yes, from an automated process.

Q Turning back now to the marketing department, I have a couple of questions for you on that. I'm correct, am I not, that it was the marketing department that made the decisions as to the information that was going to be put on the packaging, including what the purpose was next to the particular active ingredients?

A Yes.

Q And am I correct that neither Standard or Hyland's

conducts any clinical tests prior to releasing its products to determine whether or not the statements made as to the relief that will be provided for the symptoms are accurate?

A Could you repeat the question, please.

Q Sure. I'm correct, am I not, that neither Standard or Hyland's does any clinical testing prior to releasing its products to determine whether or not the statements that are made as to the relief that will be provided for symptoms are accurate?

A I believe that is correct.

Q And then lastly, Mr. Phillips, since you were involved in the company as a president for a period of time and had been at Standard from 1979, I'm correct, am I not, that between 1979 and 2010 gross revenue for the company increased from about $2 million in 1979 to about $30 million in 2010?

A Roughly, yes.

MS. NELSON: Thank you very much, Mr. Phillips. I appreciate it.

THE COURT: Cross-examination or direct, whichever it may be.

MR. MARGULIES: Thank you, Your Honor. Hopefully it will be direct.

THE WITNESSS: Are we done with this book?

MS. NELSON: I am done with that book, yes. Thank

EXHIBIT 36

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al.,

Plaintiffs,

VS

HYLAND'S, INC., et al.,

Defendants.

No. 12-1150DMG

Reporter's Transcript of Proceedings
JURY TRIAL - DAY FIVE
MORNING SESSION
Los Angeles, California
TUESDAY, SEPTEMBER 8, 2015

ANNE KIELWASSER, CRR, RPR, CSR
Federal Official Court Reporter
312 North Spring Street, Room 432
Los Angeles, California 90012
Telephone: (213) 894-2969
anne.kielwasser@gmail.com
AKtranscripts.com

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person who made the decision.

Q. That's right, you provided the information on particular ingredients to put into a product, but it was the marketing department that made the decision of which ingredients to go into the product, correct?

A. That is correct.

Q. And the marketing department is the department at Standard Homeopathic that makes the decision about how to market the products that are being sold by Hyland's, correct?

A. Yes.

Q. And the marketing department is a department that is in Standard Homeopathic as opposed to Hyland's, correct?

A. I don't know.

Q. Do you know who employs the marketing department?

A. No, I don't know.

Q. Are you currently the vice chairman of the board of Standard Homeopathic?

A. I am.

Q. How long have you held that position?

A. Approximately one year.

Q. And am I correct that you have testified that Hyland's is a consumer brand and is the sales division of Standard Homeopathic, correct?

A. Correct.

Q. Do you know whether or not Hyland's has a separate

how that ingredient is manufactured, correct?

A. (No response).

Q. In other words, it doesn't -- HPUS doesn't tell you about combination of products, correct?

A. It's incorrect.

Q. The HPUS has combination ingredients in it?

A. No.

Q. Okay. So the HPUS has a series of monographs, I think we have been told, and those monographs relate to a particular single ingredient, correct?

A. Correct.

Q. So you would look at the HPUS to see how a particular ingredient is manufactured, correct?

A. Correct.

Q. And then you would look at the materia medica to determine what symptoms that particular ingredient may be useful for, correct?

A. Correct.

Q. And based upon that work, you would then go to the marketing department and provide the marketing department with a list of potential ingredients, correct?

A. Correct.

Q. And the marketing department made the decision at the end of the day as to which ingredients would be put into a particular product, correct?

A. Correct.

Q. In the course of the conversations that you had with consumers who called, did you form an understanding that many of those consumers had no idea what the dilution levels meant that were on the packages of Hyland's products?

MR. MARGULIES: Objection. Relevance.

THE WITNESS: I just --

THE COURT: Overruled. You may --

BY **MS. NELSON:**

Q. Go ahead, Mr. Phillips. Sorry, there is a -- you have to give a little bit of a wait for the Court to issue a ruling on an objection.

THE COURT: You may proceed.

THE WITNESS: Like I say, I disagree with the premise. Some had those questions. I think you used the term "many." Not necessarily.

BY **MS. NELSON:**

Q. But there were consumers, were there not, who were confused by the dilution levels on the packaging, correct?

A. Some had that question.

Q. And the dilution levels that are on the packaging are what we have seen so far in this trial to be things like 3X, 6X, 12X. Do you understand that to be true?

A. Yes.

Q. Okay. And so you weren't even the person that made

EXHIBIT 37

Final 213

EXHIBIT
PENGAD 800-631-6989
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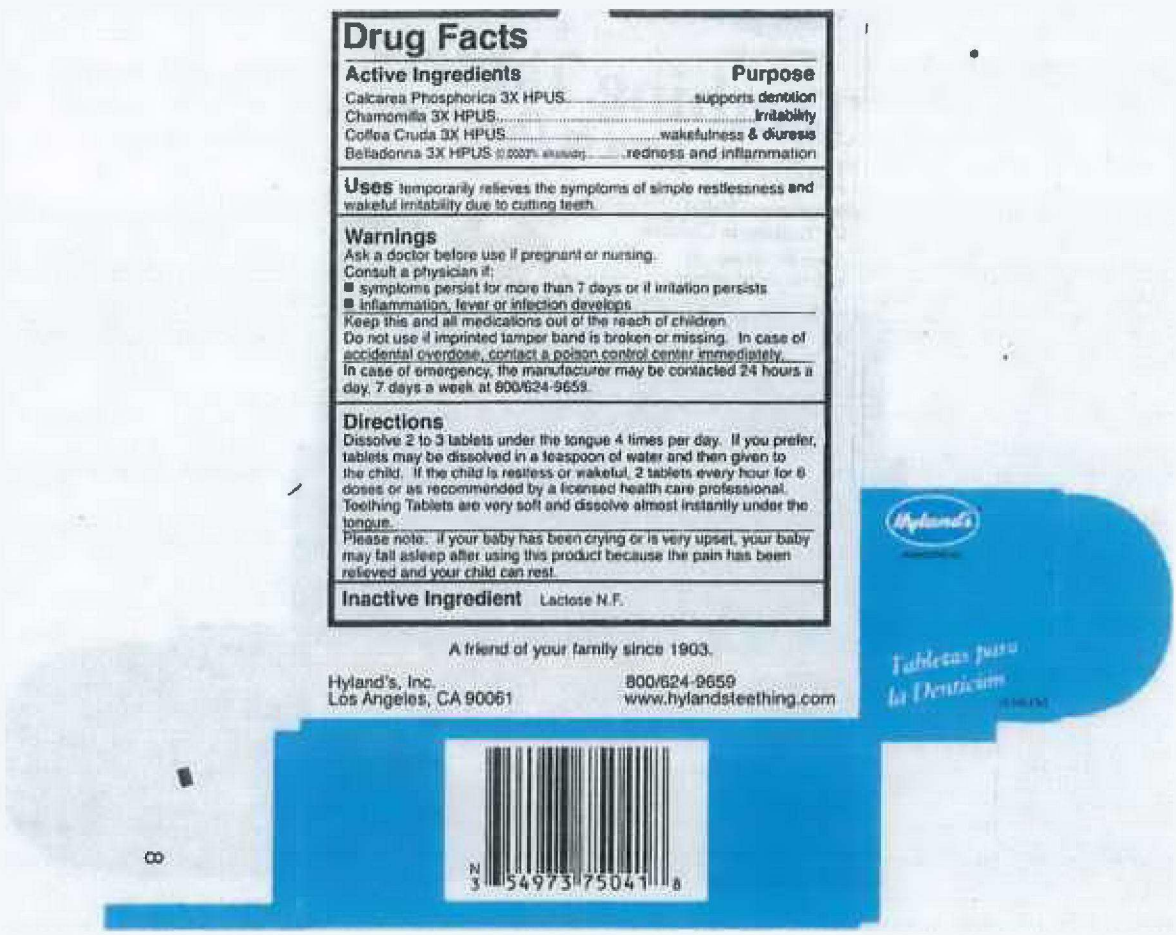
6/1/12

TR. EX. 15-1

SHC000037

TR. EX. 42-37



Drug Facts

Active Ingredients	Purpose
Calcarea Phosphorica 3X HPUS	supports dentition
Chamomilla 3X HPUS	irritability
Coffea Cruda 3X HPUS	wakefulness & diuresis
Belladonna 3X HPUS	redness and inflammation

Uses temporarily relieves the symptoms of simple restlessness and wakeful irritability due to cutting teeth.

Warnings

Ask a doctor before use if pregnant or nursing.

Consult a physician if:

- symptoms persist for more than 7 days or if irritation persists
- inflammation, fever or infection develops

Keep this and all medications out of the reach of children.

Do not use if imprinted tamper band is broken or missing. In case of accidental overdose, contact a poison control center immediately.

In case of emergency, the manufacturer may be contacted 24 hours a day, 7 days a week at 800/624-9659.

Directions

Dissolve 2 to 3 tablets under the tongue 4 times per day. If you prefer, tablets may be dissolved in a teaspoon of water and then given to the child. If the child is restless or wakeful, 2 tablets every hour for 6 doses or as recommended by a licensed health care professional. Teething Tablets are very soft and dissolve almost instantly under the tongue.

Please note: if your baby has been crying or is very upset, your baby may fall asleep after using this product because the pain has been relieved and your child can rest.

Inactive Ingredient Lactose N.F.

A friend of your family since 1903.

Hyland's, Inc.
Los Angeles, CA 90061

800/624-9659
www.hylandsteething.com

Hyland's

Tabletas para la Dentición

N 3 54973 75041 8

SHC000038

TR. EX. 42-38

EXHIBIT 38

TO: Jay Borneman
FROM: Iris Bell, MD PhD
DATE: 9/5/06
RE: Dr. Jennifer Jacobs' proposed teething tablet study project 2

As we discussed, here is a summary of the protocol, key differences from the last project, and my recommendations.

New Protocol Summary:
This project would recruit families with children between the ages of 3 to 18 months from public parks and shopping malls for a study of a "new" natural teething product. Parents would receive a randomly-assigned packet of either active Hyland's Teething Tablets or indistinguishable placebo tablets for use when their child exhibits symptoms of breaking a tooth. Neither parents nor research staff who interact with the families will know the contents of the packets when they are assigned and given to the children. In order to reduce the chance that parents will confuse another health problem with teething symptoms, they will receive a screening symptom form requiring the presence of at least one symptom from each of two categories (A. physical symptoms such as biting on things and B. behavioral symptoms such as fussiness or crying) to decide that the child is teething.

Parents will rate the severity of common symptoms before and for up to one hour after administration of each dose of test tablets, considering no change after one hour to be a lack of response. Data will include the amount of time to observing a noticeable beneficial effect or no effect, as well as an open-ended question on any adverse effects. Parents will also rate their impression of the overall effect of the tablets and their interest in giving the study medicine at a later time. Families receive free study medication and a $25 gift certificate to Toys R Us at the end of their participation.

Statistical analysis will be performed on a consulting basis under supervision of Dr. Bell. The study will be performed in stages to pilot the new procedures and proceed to full recruitment when there is confidence that the protocol is capable of capturing what consumers report from the field.

Key Differences from Previous Project:
- Wording of teething symptoms is based directly on open-ended survey data by the Hyland's Marketing team, obtained from 25 consumers who had used the tablets in their teething children, rather than on investigator-chosen wording from the medical literature.
- The symptom rating system has also been refined for consumer use and sensitivity to change.
- Timing of assessments will be immediately before and for up to one hour after administration of each tablet, rather than on an arbitrary schedule of once every 12 hours. Survey findings and re-analysis of data from the previous study suggest that the fixed schedule of assessments may have kept down subject questionnaire burden, but may have missed effects that did occur within only a few minutes, but which may have required repeated dosing at variable points in time.
- Biases or expectations of participants in both groups will be reduced by presenting the test medication as a "new" product. There were concerns that the parents in the previous study already were favorably inclined towards Hyland's teething tablets, knew that the study focused on this medicine, and wanted to "help" the company (in both the active and placebo groups).

Recommendations:
- This protocol is ready for implementation and should be funded. It has the advantage of an experienced principal investigator with an established research staff team. The PI has the ability to obtain rapid approval of the current protocol at her local Institutional Review Board as a modification of the previously approved study.
- The study sample size can go up to 200 families, once piloting of procedures is done. The larger sample with more sensitive outcome measures will improve ability to detect effects, if present, thereby reducing the need for as large a sample as originally considered. Re-analysis of the prior study suggests characteristics of the subset of definite responders that the current study design should help detect. Interim analysis points will be after 60 and 120 subjects are completed, to evaluate for trends and effect size. This will minimize costs while permitting adjustment of the protocol to optimize chances of finding effects, if present, as the pilot data confirm the feasibili[illegible]h.

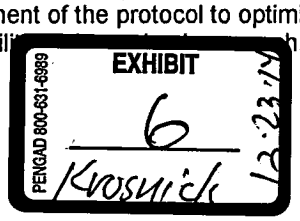


EXHIBIT 39

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

THE HON. JUDGE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al., on behalf of themselves, all others similarly situated and the general public,	
Plaintiff,	
vs.	**NO. 13-CV-5102-DMG**
HYLAND'S, INC., a California corporation; and STANDARD HOMEOPATHIC COMPANY,	
Defendants.	

JURY TRIAL - DAY 5 (P.M. Session)

Los Angeles, California

Tuesday, September 8, 2015

LISA M. GONZALEZ, CSR No. 5920, CCRR
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www.lisamariecsr.com

I N D E X

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above policy. We're going to blow that up.
A Uh-huh.
Q Do you see that, Ms. Le?
A Yes.
Q The statement says: A product's compliance with requirements of the HPUS, USP, or NF does not establish that it has been shown by appropriate means to be safe, effective, and not misbranded for its intended use.
Do you see that?
A Yes.
Q Hyland's doesn't put that statement on its label; right?
A No, we don't.
Q But you're aware in speaking with your counsel about what other competitors put on their labels. We went through those, that some of your competitors do put a statement like that on their labels?
MR. PERSSON: Objection. Lacks foundation.
THE WITNESS: I have not --
THE COURT: Wait. Wait. When there's an objection, you can't answer the question. You need to let me rule on it. And then if I sustain the objection, you won't answer it. If I overrule the objection, then you can answer it.
As to that, I don't remember now what your

EXHIBIT 40

consumers as extemporaneously compounded OTC products but, may only be prepared pursuant to a prescription order.

7 Health Fraud: The deceptive promotion, advertisement, distribution or sale of articles, intended for human or animal use, that are represented as being effective to diagnose, prevent, cure, treat, or mitigate disease (or other conditions), or provide a beneficial effect on health, but which have not been scientificall proven safe and effective for such purposes. Such practices may be deliberate, or done without adequate knowledge or understanding of the article.

*A proving is synonymous with the homeopathic procedure (identified in HPUS as a "Research Procedure") which is employed in healthy individuals to determine the dose of a drug sufficient to produce symptoms.

DISCUSSION:

Section 201(g)(1) of the Act defines the term "drug" to mean articles recognized in the official United States Pharmacopeia (USP), the official Homeopathic Pharmacopeia of the United States (HPUS), or official National Formulary (NF) or any supplement to them; and articles intended for use in the diagnosis, cure, mitigation, treatment, or the prevention of disease in man or other animals; articles (other than food) intended to affect the structure or any function of the body of man or other animals; and articles intended for use as a component of any articles specified in the above. Whether or not they are official homeopathic remedies, those products offered for the cure, mitigation, prevention, or treatment of disease conditions are regarded as drugs within the meaning of Section 201(g)(l) of the Act.

Homeopathic drugs generally must meet the standards for strength, quality, and purity set forth in the Homeopathic Pharmacopeia. Section 501(b) of the Act (21 U.S.C. 351) provides in relevant part:

Whenever a drug is recognized in both the United States Pharmacopeia and the Homeopathic Pharmacopeia of the United States it shall be subject to the requirements of the United States Pharmacopeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of th Homeopathic Pharmacopeia of the United States and not to those of the United States Pharmacopeia.

A product's compliance with requirements of the HPUS, USP, or NF does not establish that it has been shown by appropriate means to be safe, effective, and not misbranded for its intended use.
A guide to the use of homeopathic drugs (including potencies, dosing, and other parameters) may be found by referring to the following texts: A Dictionary of Practical Materia Medica by John Henry Clarke, M.D., (3 volumes; Health Science Press) and A Clinical Repertory to the Dictionary of Materia Medica by John Henry Clarke, M.D. (Health Science Press). These references must be reviewed in conjunction with other available literature on these drug substances.

POLICY:

LABELING

Homeopathic drug product labeling must comply with the labeling provisions of Sections 502 and 503 of the Act and Part 201 Title 21 of the Code of Federal Regulations (CFR), as discussed below, with certain provisions applicable to extemporaneously compounded OTC products. Those drugs in bulk packages intended for manufacture or preparation of products, including those subsequently diluted to various potencies, must also comply with the provisions of Section 502 of the Act and Part 201 (21 CFR 201).

General Labeling Provisions

Name and Place of Business: Each product must bear the name and place of business of the manufacturer, packer, or distributor in conformance with Section 502(b) of the Act and 21 CFR 201.1.

Directions for Use: Each drug product offered for retail sale must bear adequate directions for use in conformance with Section 502(f) of the Act and 21 CFR 201.5. An exemption from adequate directions for use under Section 503 is applicable only to prescription drugs.

Statement of Ingredients: Ingredient information shall appear in accord with Section 502(e) of the Act and 21 CFR 201.10. Labeling must bear a statement of the quantity and amount of ingredient(s) in the product in conformance with Section 502(b) of the Act, as well as 21 CFR 201.10, expressed in homeopathic terms, e.g., lx, 2x.

Documentation must be provided to support that those products or ingredients which are not recognized officially in the HPUS, an addendum to it, or its supplements are generally recognized as homeopathic products or ingredients.

Established Name: The product must be in conformance with Section 502(e)(1) of the Act and must bear an established name in accord with Section 502(e)(3) of the Act and 21 CFR 201.10. Many homeopathic products bear Latin names which correspond to listings in the HPUS. Since Section 502(c) of the Act and 21 CFR 201.15(c)(1) require that all labeling be in English, the industry is required to translate these names from Latin to their common English names as current labeling stocks are depleted, or by June 11, 1990, whichever occurs first. It is permissible for industry to include in the labeling both English and Latin names.

EXHIBIT 41

68. Professor Ernst also commented on the BHA's claims about reviews that offered positive reviews for allergies,[83] upper respiratory tract infections[84] and rheumatic diseases[85] were equally flawed: the "review" on allergies was a lecture series, not a systematic review; the "reviews" on upper respiratory tract infections were health technology assessments, not systematic reviews, and mostly contained uncontrolled data; and the "review" on rheumatic diseases was not conclusive.[86] Finally, he pointed out that the BHA had omitted several systematic reviews and meta-analyses, each of which "must have been known to the BHA" and "all of them arrived at negative conclusions".[87]

69. The review which we consider the most comprehensive to date is that by Shang *et al.*[88] The review compared 110 placebo-controlled trials of homeopathy matched according to disorder and type of outcome to trials of conventional medicine. The study only included trials that were controlled, included randomised assignment to treatment or placebo groups and were accompanied by sufficient data for odds ratio calculations.[89] The authors concluded that "when analyses were restricted to large trials of higher quality there was no convincing evidence that homeopathy was superior to placebo".[90]

70. **In our view, the systematic reviews and meta-analyses conclusively demonstrate that homeopathic products perform no better than placebos.** The Government shares our interpretation of the evidence. We asked the Minister, Mike O'Brien, whether the Government had any credible evidence that homeopathy works beyond the placebo effect and he responded: "the straight answer is no".[91]

71. We were troubled that the Chief Scientist at the DH seemed to be out of step with the accepted scientific consensus on the question of efficacy. Unlike the Minister,[92] he did not agree that there was no credible evidence that homeopathy worked beyond the placebo effect. He stated that "the majority of independent scientists feel that the evidence is weak or absent"[93] and that there are "real difficulties" in drawing conclusions on efficacy because of a "lack of agreement between experts working in the field".[94] However, we could find no

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83 P Bellavite, R Ortolaini, F Pontarolo *et al*, "Immunology and homeopathy. 4. Clinical studies–Part 2", *eCAM*, vol 3 (2006), pp 397–409

84 G Bornhöft, U Wolf, K von Ammon, M Righetti, S Maxion-Bergemann, S Baumgartner *et al*, "Effectiveness, safety and cost-effectiveness of homeopathy in general practice–summarised health technology assessment", *Forsch Komplementmed*, vol 13 (Suppl 2), 2006, pp 19–29; and P Bellavite, R Ortolaini, F Pontarolo *et al*, "Immunology and homeopathy. 4. Clinical studies–Part 1", *eCAM*, vol 3 (2006), pp 397–409

85 W B Jonas, K Linde,G Ramirez, "Homeopathy and rheumatic disease", *Rheum Dis Clin North Am*, vol 26 (2000), pp 117–123

86 Ev 53, para 4

87 Ev 53, para 5

88 A Shang, K Huwiler-Muntener, L Nartey, P Juni, S Dorig, J A Sterne *et al*. "Are the clinical effects of homoeopathy placebo effects? Comparative study of placebo-controlled trials of homoeopathy and allopathy", *Lancet*, vol 366 (2005), pp 726–732

89 An odds ratio indicates how likely it is that an event will occur compared to likelihood that the event will not happen. This can be used to show the strength of a relationship between treatment and outcome.

90 Shang A *et al*, *as above*

91 Q 175

92 Qq 174–75

93 Q 176

94 Q 177

EXHIBIT 42

accepted method, and recorded the number and type of studies that were included in the systematic reviews. Using the information provided by the systematic reviews, the reviewers also assessed the quality of each individual study and its number of participants, taking into account factors that could bias the results in favour of homeopathy, placebo or another treatment.

Additional information was submitted to NHMRC, for consideration as part of its review of homeopathy, by homeopathy interest groups and the public on two occasions: before the commissioned overview of evidence (preliminary submitted literature) and during the review of the draft Information Paper (public consultation submitted literature). The preliminary and public consultation submitted literature was assessed using a similar method to that applied in the overview.

Where a clinical condition had already been considered in the overview, the results from the submitted literature were compared to the conclusions of the overview to examine the consistency of results against the body of evidence. Where a clinical condition had not been considered in the overview, the results of the submitted literature were assessed with regards to their study design, size and different kinds of bias to see if any comment on the effectiveness of homeopathy could be made.

Findings

There was no reliable evidence from research in humans that homeopathy was effective for treating the range of health conditions considered: no good-quality, well-designed studies with enough participants for a meaningful result reported either that homeopathy caused greater health improvements than placebo, or caused health improvements equal to those of another treatment.

For some health conditions, studies reported that homeopathy was not more effective than placebo. For other health conditions, there were poor-quality studies that reported homeopathy was more effective than placebo, or as effective as another treatment. However, based on their limitations, those studies were not reliable for making conclusions about whether homeopathy was effective. For the remaining health conditions it was not possible to make any conclusion about whether homeopathy was effective or not, because there was not enough evidence.

Conclusions

Based on the assessment of the evidence of effectiveness of homeopathy, NHMRC concludes that there are no health conditions for which there is reliable evidence that homeopathy is effective.

Homeopathy should not be used to treat health conditions that are chronic, serious, or could become serious. People who choose homeopathy may put their health at risk if they reject or delay treatments for which there is good evidence for safety and effectiveness. People who are considering whether to use homeopathy should first get advice from a registered health practitioner. Those who use homeopathy should tell their health practitioner and should keep taking any prescribed treatments.

EXHIBIT 43

backgrounder

Homeopathy: An Introduction

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Homeopathy, also known as homeopathic medicine, is an alternative medical system that was developed in Germany more than 200 years ago. This fact sheet provides a general overview of homeopathy and suggests sources for additional information.

Key Points

- There is little evidence to support homeopathy as an effective treatment for any specific condition.
- Although people sometimes assume that all homeopathic remedies are highly diluted and therefore unlikely to cause harm, some products labeled as homeopathic can contain substantial amounts of active ingredients and therefore could cause side effects and drug interactions.
- Homeopathic remedies are regulated by the U.S. Food and Drug Administration (FDA). However, FDA does not evaluate the remedies for safety or effectiveness.
- Several key concepts of homeopathy are inconsistent with fundamental concepts of chemistry and physics. There are significant challenges in carrying out rigorous clinical research on homeopathic remedies.
- Tell all your health care providers about any complementary health approaches you use. Give them a full picture of all you do to manage your health. This will help ensure coordinated and safe care.

Overview

The alternative medical system of homeopathy was developed in Germany at the end of the 18th century. Supporters of homeopathy point to two unconventional theories: "like cures like"—the notion that a disease can be cured by a substance that produces similar symptoms in healthy people; and "law of minimum dose"—the notion that the *lower* the dose of the medication, the *greater* its effectiveness. Many homeopathic remedies are so diluted that no molecules of the original substance remain.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary and Integrative Health

NIH National Center for Complementary and Integrative Health

EXHIBIT 44

consistently eliminate such misperceptions is an open question; however, this research shows the persistence of mistaken consumer beliefs about government approval for homeopathic products.

The copy test results also showed that consumers mistakenly believed that the manufacturers of homeopathic products tested their products on people in order to show their effectiveness.[58] After controlling for "yea saying," the copy test results showed that about 20% to 30% (22.8% to 33.6%) of respondents exposed to the original product packaging for the three products indicated that they believed the manufacturers had tested the products on people to show their effectiveness.[59] These results support the conclusion that consumers have incorrect perceptions about human efficacy testing for homeopathic products.[60]

C. Additional Observations

In addition to what we found in our copy test and focus group research, the FTC staff has observed other potential causes of consumer confusion in the marketing of homeopathic remedies. We believe that consumer confusion likely is created by the retail store shelf placement of homeopathic products side-by-side with conventional medicine that, in fact, has been approved by the FDA and tested on humans for efficacy. Confusion is likely created, as well, by the terminology used in homeopathy product labeling. In current labeling for homeopathic products, a manufacturer normally states that a product contains a particular substance in an amount that is expressed as a number followed by an "X," such as "2X." For

[58] *Id.* at 14.
[59] *Id.* at 11; *see supra* note 13. Before controlling for "yea saying," responses ranged from approximately 45% to 57%.
[60] Few homeopathic remedies have been subjected to human clinical trials under controlled conditions, and the vast majority of those that have been have not shown positive results. *See, e.g.,* Evidence on the effectiveness of homeopathy for treating health conditions, Australian Government National Health and Medical Research Council (NHMRC) (Mar. 2015), *available at* http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/cam02a_information_paper.pdf (last visited June 2, 2015).

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

KIM ALLEN, et al., on behalf of themselves, all others similarly situated and the general public,

Plaintiffs,

v.

HYLAND'S, INC., et al.,

Defendants.

Case No: 12-cv-1150-DMG-MAN

CLASS ACTION

[PROPOSED] ORDER GRANTING PLAINTIFFS' MOTION FOR NEW TRIAL

Judge: Honorable Dolly M. Gee
Date: October 21, 2016
Time: 9:30 a.m.
Location: Courtroom 7, 2nd Floor

Plaintiffs Kim Allen, Melissa Nigh, Nancy Rodriguez, Diana Sisti, Sherrell Smith, Daniel Xenos and Yuanke Xu ("Plaintiffs") on behalf of themselves and the class, Motion for New Trial came on for hearing on October 21, 2016 at 9:30 a.m., or as soon thereafter as the matter could be heard.

After hearing all arguments and considering Plaintiffs' motion, the Court hereby **GRANTS** Plaintiffs' Motion for a New Trial.

IT IS SO ORDERED.

Dated: _____

_____
Honorable Judge Dolly M. Gee
United States District Judge

LAW OFFICES OF RONALD A. MARRON
RONALD A. MARRON (175650)
ron@consumersadvocates.com
SKYE RESENDES (278511)
skye@consumersadvocates.com
651 Arroyo Drive
San Diego, California 92103
Telephone: (619) 696-9006
Facsimile: (619) 564-6665

KREINDLER & KREINDLER, LLP
GRETCHEN M. NELSON (112566)
gnelson@kreindler.com
707 Wilshire Boulevard, Suite 3600
Los Angeles, California 90017
Telephone: (213) 622-6469
Facsimile: (213) 622-6019

GOMEZ TRIAL ATTORNEYS
JOHN H. GOMEZ (171485)
jgomez@gomeztrialattorneys.com
DEBORAH S. DIXON (248965)
ddixon@gomeztrialattorneys.com
655 W. Broadway Suite 1700
San Diego, California 92101
Telephone: (619) 237-3490
Facsimile: (619) 237-3496

Class Counsel

UNITED STATES DISTRICT COURT

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CERTIFICATE OF SERVICE

JUDGE: The Honorable Dolly M. Gee
Trial Date: September 1, 2015

CERTIFICATE OF SERVICE

I hereby certify that on September 13, 2016, I caused the following documents to be electronically filed with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the Electronic Mail Notice List:

- **PLAINTIFFS' NOTICE OF MOTION AND MOTION FOR NEW TRIAL;**
- **PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION FOR NEW TRIAL; and**
- **DECLARATION OF DEBORAH S. DIXON IN SUPPORT OF PLAINTIFFS' MOTION FOR NEW TRIAL**

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on August 14, 2015.

Dated: September 13, 2016

By: */s/ Deborah S. Dixon*
John H. Gomez, Esq.
Deborah S. Dixon, Esq.
GOMEZ TRIAL ATTORNEYS