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2012 DEC -7 PM 3: 20

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21 UNITED STATES DISTRICT COURT
22 CENTRAL DISTRICT OF CALIFORNIA

FAX FILING

23 ENZO FORCELLATI and LISA
24 ROEMMICH, on Behalf of Themselves
25 and all Others Similarly Situated,

26 Plaintiff,

27 v.

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

Defendants.

Case No. 2:12-CV-01983 GHK
(MRWx)

Hon. George H. King

**CONSOLIDATED AMENDED
CLASS ACTION COMPLAINT**

1 **CLASS ACTION COMPLAINT WITH JURY DEMAND**

2 Plaintiffs Enzo Forcellati and Lisa Roemmich (“Plaintiffs”), by their attorneys,
3 makes the following allegations pursuant to the investigation of their counsel and
4 based upon information and belief, except as to allegations specifically pertaining to
5 themselves and their counsel, which are based on personal knowledge.

6 **NATURE OF ACTION**

7 1. This is a class action against Hyland’s, Inc., Standard Homeopathic
8 Laboratories, Inc., Standard Homeopathic Company and Does 1-100 (collectively
9 “Hyland’s” or “Defendants”) arising out of the sale of homeopathic cold and flu
10 remedies sold over the counter (“OTC”), including Hyland’s Cold ’n Cough 4 Kids
11 (“Cold ’n Cough”), Cough Syrup with 100% Natural Honey 4 Kids (“Cough
12 Syrup”), Sniffles ‘n Sneezes 4 Kids (“Sniffles ‘n Sneezes”), Cold Relief Strips 4
13 Kids with Zinc (“Cold Strips”), Complete Flu Care 4 Kids (“Flu Care”), Nighttime
14 Cold ‘n Cough 4 Kids (“Nighttime Cold”) (collectively “Cold and Flu Remedies”).

15 2. Hyland’s represents that its homeopathic Cold and Flu Remedies offer
16 children “Fast acting,” “Safe & Effective,” “Multi-symptom” relief from cold and flu
17 symptoms, including runny noses, sore throats, coughs, headaches, body aches, flu
18 and congestion. In fact, Hyland’s Cold and Flu Remedies are nothing more than
19 sweetened, flavored water with only highly diluted concentrations of the products’
20 so-called “active ingredients.”

21 3. As a direct and proximate result of Hyland’s false and misleading
22 advertising claims and marketing practices, Plaintiffs and the members of the Class,
23 as defined herein, purchased Hyland’s Cold and Flu Remedies to treat cold and flu
24 symptoms for which the drugs were not fast acting or efficacious as they were
25 marketed and advertised to be.

26 4. Plaintiffs seek relief in this action individually, and on behalf of all
27 purchasers of Hyland’s Cold and Flu Remedies, for Hyland’s violations of the
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1 Magnuson-Moss Act, 15 U.S.C. § 2301, *et seq.*, for unjust enrichment, breach of
2 express warranty, breach of implied warranties of fitness and merchantability,
3 violations of the New Jersey Consumer Fraud Act, N.J.S.A. § 58:8-1, *et seq.*,
4 violation of the California Consumer Legal Remedies Act (“CLRA”), Civil Code §§
5 1750, *et seq.*, Unfair Competition Law (“UCL”), Bus. & Prof. Code §§ 17200, *et*
6 *seq.*, False Advertising Law (“FAL”), Bus. & Prof. Code §§ 17500, *et seq.*, and
7 violation of the Missouri Merchandising Practices Act, Mo. Ann. Stat. §§ 407.010, *et*
8 *seq.*

9 **THE PARTIES**

10 5. Plaintiff Enzo Forcellati is a resident of Bergen County, New Jersey.

11 6. Plaintiff Lisa Roemmich is a resident of Dardenne Prairie, Missouri.

12 7. Hyland’s is a corporation organized under the laws of the State of
13 California, with its principal place of business located at 204 W. 131st Street, Los
14 Angeles, California 90061. Hyland’s is engaged in the business of manufacturing,
15 mass marketing and distributing homeopathic formulas under the Hyland’s brand
16 name. Hyland’s is a wholly owned subsidiary of defendant Standard Homeopathic
17 Company.

18 8. Standard Homeopathic Laboratories is a privately held corporation
19 organized under the laws of the State of Nevada, with its principal place of business
20 located at 154 W. 131st Street, Los Angeles, California 90061. Standard
21 Homeopathic Laboratories is a wholly owned subsidiary of Standard Homeopathic
22 Company. Standard Homeopathic Laboratories’ website maintains that it is a
23 “licensed pharmacy and modern laboratory designed to provide the most
24 comprehensive choice of homeopathic medicines.”

25 9. Standard Homeopathic Company is a privately held corporation
26 organized under the laws of the State of Nevada, with its principal place of business
27 located at 154 W. 131st Street, Los Angeles, California 90061. Standard
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1 Homeopathic Company has four wholly owned subsidiaries: P&S Laboratories dba
2 Hyland's, Inc.; Standard Homeopathic (International), Inc. - a foreign sales
3 corporation; Walker Laboratories, Inc.; and Standard Homeopathic Laboratories.
4 Standard Homeopathic Company has three sales divisions: Pharmacy; Wholesale;
5 and Natural Foods. Standard Homeopathic Company promotes itself and its
6 operating companies as the largest full-service homeopathic firm in the United States
7 in terms of sales and operating results.

8 10. Defendants produce, market, and sell homeopathic products throughout
9 the United States. Defendants have long maintained substantial manufacturing,
10 distribution, marketing and warehousing operations in Los Angeles, California.

11 11. Plaintiffs are unaware of the names and capacities of those defendants
12 sued as DOES 1 through 100 but will seek leave to amend this complaint once their
13 identities become known to Plaintiffs. Upon information and belief, Plaintiffs allege
14 that at all relevant times each defendant, including the DOE defendants 1 through
15 100, was the officer, director, employee, agent, representative, alter ego, parent or
16 subsidiary, or co-conspirator of each of the other defendants.

17 **JURISDICTION AND VENUE**

18 12. This Court has subject matter jurisdiction under 28 U.S.C. § 1331
19 (federal question). This Court has supplemental jurisdiction over state law claims
20 pursuant to 28 U.S.C. § 1367.

21 13. This Court also has jurisdiction over this action pursuant to 28 U.S.C. §
22 1332(d) because there are more than 100 Class members and the aggregate amount
23 in controversy exceeds \$5,000,000.00, exclusive of interest, fees, and costs, and at
24 least one Class member is a citizen of a state different from at least one Defendant.

25 14. Pursuant to 28 U.S.C. § 1391, this Court is the proper venue for this
26 action because a substantial part of the events, omissions and acts giving rise to the
27 claims herein occurred in this District. Defendants reside in this district and
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1 Defendants sold the products which are the subject of the present Complaint, in this
2 District.

3 **FACTUAL ALLEGATIONS COMMON TO ALL CLAIMS**

4 **A. Homeopathy Is A Pseudoscience**

5 15. Homeopathy is a 200-year old system of alternative medicine in which
6 practitioners treat patients using highly diluted preparations that were believed to
7 cause healthy people to exhibit symptoms that are similar to those exhibited by the
8 patient.

9 16. Homeopathy is based on two principles: “Like-Cure-Like” whereby a
10 substance that causes a symptom to manifest in healthy person is used in diluted
11 form to treat the same symptom in a sick person; and “ultra-dilution” whereby the
12 more one dilutes a substance, the more potent that sometimes becomes at treating the
13 symptom (“ultra-dilution” is aided by a specific method of shaking the solutions,
14 termed “succussion” or “succussion”). It is claimed that homeopathy works by
15 stimulating the body’s healing mechanisms. *See* House of Commons, Science and
16 Technology Committee, Evidence Check 2: Homeopathy, Fourth Report, 2009-10,
17 HC 45, ¶ 9 (U.K.).

18 17. The “Like-Cure-Like” principle of homeopathy, also known as the “law
19 of similars,” was first stated by German physician Samuel Hahnemann in 1796.
20 Hahnemann believed that by using drugs to induce symptoms, the artificially
21 induced symptoms would stimulate the “vital force,” causing it to neutralize and
22 expel the original disease and that this artificial disturbance would naturally subside
23 when the dosing ceased. As explained in Hyland’s literature:

24 Basically, [the law of similars] states that a medicinal substance that can
25 create a set of symptoms in a healthy individual can treat a sick
26 individual who is manifesting similar symptoms. This law has been
27 found in writings of Hippocrates as well as in ancient Indian and
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1 Chinese texts. While Hahnemann wasn't the first to discover the law of
2 similars, he was the first physician to conduct extensive systematic
3 experiments that put this law into clinical practice.

4 See <http://www.hylands.com/Cough-Cold-Edu.pdf>
5 [http://www.hylands.com/Cough-](http://www.hylands.com/Cough-Cold-Edu.pdf)
6 [Cold-Edu.pdf](http://www.hylands.com/Cough-Cold-Edu.pdf) (last accessed March 7, 2012).

7 18. As an example of the "law of similars," the consumption of a substance
8 such as coffee before bed keeps children awake, so coffee is used to make a
9 homeopathic remedy to treat insomnia. Indeed, coffee is listed on the label as one of
10 the ingredients of Hyland's Nighttime Cold, and according to Hyland's webpage for
11 this product, is purportedly effective to treat "sleeplessness." See
12 [http://www.hylands.com/products/nighttime-](http://www.hylands.com/products/nighttime-cold.php)
13 [cold.php](http://www.hylands.com/products/nighttime-cold.php)
14 <http://www.hylands.com/products/nighttime-cold.php> (last accessed March
15 7, 2012).



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24 19. The settled view of medical science is that the "law of similars" is
25 theoretically weak and "fails to provide a credible physiological mode of action for
26 homeopathic products." See House of Commons, Science and Technology
27
28

1 Committee, Evidence Check 2: Homeopathy, Fourth Report, 2009-10, HC 45, ¶ 54
2 (U.K.).

3 20. The method homeopaths have used for over 200 years to determine
4 which remedies were suitable for specific symptoms is called a “proving,” after the
5 original German word Prüfung, meaning “test.” Provings involved taking various
6 substances and recording every twitch, sneeze, ache or itch that occurred afterward—
7 often for several days. Followers of homeopathy took for granted that every
8 sensation reported was caused by whatever substance was administered, and that
9 extremely dilute doses of that same substance would then be the correct substance to
10 treat anyone with those specific symptoms.

11 21. As explained in Hyland’s brochure promoting its Cold and Flu
12 Remedies:

13 In his clinical practice, Hahnemann conducted a thorough history and
14 physical examination paying attention to the mental, emotional as well
15 as the physical symptoms of each patient. Hahnemann was a truly
16 holistic physician in that he also questioned his patients about their
17 lifestyle in general - diet, exercise, attitudes, as well as the quality of air
18 and water they were exposed to, and so forth.

19
20 A “symptom picture” would be generated from each patient interview
21 and Hahnemann would then prescribe that substance whose drug picture
22 most closely matched the symptom picture. Hahnemann confirmed in
23 his clinical practice that the more closer the match, the more successful
24 the treatment outcome.

25 See [http://www.hylands.com/Cough-](http://www.hylands.com/Cough-Cold-Edu.pdf)
26 [Cold-Edu.pdf](http://www.hylands.com/Cough-Cold-Edu.pdf) (last accessed March 7, 2012).

1 22. Homeopathy uses many animal, plant, mineral, chemical and poisonous
2 substances in its remedies. Examples of substances used by homeopaths to prepare
3 their remedies include arsenicum album (arsenic oxide), natrum muriaticum (sodium
4 chloride or table salt), lachesis muta (the venom of the bushmaster snake), opium,
5 and thyroidinum (thyroid hormone). Some of Defendants’ homeopathic products for
6 children list belladonna (also known as the “deadly nightshade”), one of the most
7 lethal plants in the Western Hemisphere, as an active ingredient. In addition to
8 various plants and flowers, Hyland’s Cold and Flu Remedies contain such “active
9 ingredients” as sulphur, phosphorous, zinc, potash, soda ash, and extract from duck
10 hearts and liver.

11 23. In producing these remedies, homeopaths use a process called
12 “dynamisation,” “potentisation” or “ultra-dilution” whereby a substance is diluted
13 with alcohol or, more commonly, distilled water. The diluting procedure specific for
14 homeopathy is called potentisation or dynamisation.

15 24. Defendants use the decimal scale to describe the dilution ratio of its
16 “active ingredients.” Under the decimal scale, the active substance is diluted by a
17 factor of 10 at each stage, and is expressed as #D or #X. Dilution often continues
18 until none of the original substance remains. Indeed, the allowable concentration of
19 arsenic in U.S. drinking water is 8X, which is several orders of magnitude less than
20 many of the purportedly “active ingredients” in Defendants’ Cold and Flu Remedies.

21 25. According to homeopathic theory, following each dilution, homeopathic
22 remedies are then vigorously shaken by ten hard strikes against an elastic body, in a
23 process which homeopaths term “succussion” or “succussion.” Each dilution
24 followed by succussion is assumed to increase the effectiveness of the remedy.
25 Homeopaths call this process of ultra-dilution and succussion “potentization.”

26 26. Because they are so heavily diluted, homeopathic remedies may not
27 contain any pharmacologically active molecules, and, therefore, for such remedies to
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1 have pharmacological effect violates fundamental principles of science. Modern
2 homeopaths have proposed that water has a memory that allows homeopathic
3 preparations to work without any of the original substance. As explained by
4 Hyland’s in its brochure promoting its Cold and Flu Remedies, “[t]he most current
5 proposal for how this may work is that water is capable of storing information about
6 substances with which it has previously been in contact.” Medical science considers
7 the notion that ultra-dilutions can maintain an imprint of substances previously
8 dissolved in them to be scientifically implausible. *See* House of Commons, Science
9 and Technology Committee, Evidence Check 2: Homeopathy, Fourth Report, 2009-
10 10, HC 45, ¶ 61 (U.K.).

11 27. The efficacy of homeopathic remedies has been rejected repeatedly by
12 medical science. For example, in a study of homeopathic remedies commissioned by
13 the British Government, medical scientists repeatedly expressed their criticisms of
14 homeopathy and its proponents:

15 We regret that advocates of homeopathy ...choose to rely on, and
16 promulgate, selective approaches to the treatment of evidence base as
17 this risks confusing or misleading the public, the media and policy
18 makers

19 *Id.* at ¶73.

20 In our view, the systematic reviews and meta-analyses conclusively
21 demonstrate that homeopathic products perform no better than placebos.

22 *Id.* at ¶70.

23 There has been enough testing of homeopathy and plenty of evidence
24 showing that it is not efficacious

25 *Id.* at ¶77.

26 For patient choice to be real choice, patients must be adequately
27 informed to understand the implications of treatments. For homeopathy
28

1 this would certainly require an explanation that homeopathy is a
2 placebo. When this is not done, patient choice is meaningless. When it
3 is done, the effectiveness of the placebo – that is, homeopathy – may be
4 diminished.

5 *Id.* at ¶70.

6 28. After its investigation, the British Government found that:
7 [T]he evidence base shows that homeopathy is not efficacious (that is, it
8 does not work beyond the placebo effect) and that explanations for why
9 homeopathy would work are scientifically implausible. ... The [Science
10 and Technology] Committee concluded, given that the existing
11 scientific literature showed no good evidence of efficacy, that further
12 clinical trials of homeopathy could not be justified... In the
13 Committee's view, homeopathy is a placebo treatment and the
14 Government should have a policy on prescribing placebos. Prescribing
15 of placebos is not consistent with informed patient choice, which the
16 Government claims is very important, as it means patients do not have
17 all the information needed to make choice meaningful... Beyond ethical
18 issues and the integrity of the doctor-patient relationship, prescribing
19 pure placebos is bad medicine. Their effect is unreliable and
20 unpredictable and cannot form the sole basis of any treatment on the
21 NHS.

22 *See* Press Release, Science and Technology Committee, MPS Urge Government to
23 Withdraw NHS Funding and MHRA Licensing of Homeopathy (February 22, 2010),
24 available at [http://www.parliament.uk/business/committees/committees-
28 archive/science-technology/s-t-homeopathy-
inquiry/http://www.parliament.uk/business/committees/committees-archive/science-
technology/s-t-homeopathy-inquiry/](http://www.parliament.uk/business/committees/committees-
25 archive/science-technology/s-t-homeopathy-
26 inquiry/http://www.parliament.uk/business/committees/committees-archive/science-
27 technology/s-t-homeopathy-inquiry/) (last accessed March 7, 2012).

1 29. In 2005, Dr. Matthias Egger and colleagues from the University of
2 Berne in Switzerland analyzed 110 placebo-controlled homeopathy trials and
3 compared the results to the same number of trials of conventional drugs. The results,
4 published in the British journal, *The Lancet*, showed that the benefits from
5 the homoeopathic remedies were entirely compatible with the placebo effect. The
6 researchers went on to add that: “the findings were less surprising than the fact that
7 debate over homeopathy continues, despite 150 years of unfavorable findings”
8 Aijing Shang, *Are The Clinical Effects of Homoeopathy Placebo Effects?*
9 *Comparative Study of Placebo-controlled Trials of Homoeopathy and Allopathy*, *The*
10 *Lancet*, Vol. 366, Aug. 27, 2005, at 726-732 (the “Homeopathy Comparative
11 Study”).

12 30. Michael Levy, director of the Food and Drug Administration’s
13 (“FDA’s”) division of new drugs and labeling compliance, has stated that the FDA is
14 “not aware of any evidence that shows homeopathic drugs are effective.” Indeed the
15 American medical establishment has long rejected the science underlying
16 homeopathic studies, saying the compounds are too diluted to have any meaningful
17 or measurable medicinal value. “Science tells us that most of these medicines aren’t
18 useful,” said Dr. Wayne Yankus, a Midland Park pediatrician, discussing the efficacy
19 of homeopathic remedies. See Colleen Diskin, *Parents Look To Homeopathy As*
20 *Alternative To Over-The-Counter Cold Medicines*, *The Record* (Dec. 19, 2010),
21 [http://www.northjersey.com/news/112144649_Over-the-](http://www.northjersey.com/news/112144649_Over-the-counter_alternatives.html)
22 [counter_alternatives.html](http://www.northjersey.com/news/112144649_Over-the-counter_alternatives.html)[http://www.northjersey.com/news/112144649_Over-the-](http://www.northjersey.com/news/112144649_Over-the-counter_alternatives.html)
23 [counter_alternatives.html](http://www.northjersey.com/news/112144649_Over-the-counter_alternatives.html) (last accessed March 5, 2012).

24 **B. The FDA Does Not Regulate Homeopathic Remedies**

25 31. Congress enacted the Federal Food, Drug, and Cosmetic Act (“FDCA”),
26 21 U.S.C. § 301 *et seq.* in 1938, after Congress “became increasingly concerned
27 about unsafe drugs and fraudulent marketing.” *Wyeth v. Levine*, 129 S. Ct. 1187,
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1 1198-99 (2009). Among other things, the FDCA prohibits the sale of adulterated or
2 misbranded drugs, and requires manufacturers to apply to the FDA for premarket
3 approval of new drugs. 21 U.S.C. § 331.

4 32. The FDCA defines “drug” to include articles like Hyland’s Cold and
5 Flu Remedies that are recognized in the official Homeopathic Pharmacopoeia of the
6 United States (“HPUS”) and includes both prescription and OTC drugs. 21 U.S.C. §
7 321(g)(1). Homeopathic OTC drugs, however, are treated as a subset of OTC drugs
8 by the FDCA and its various regulations, and are not subject to the same evaluation,
9 testing and substantiation requirements that the FDA applies to conventional non-
10 homeopathic OTC drugs.

11 33. The FDA subjects non-homeopathic OTC drugs to stringent evaluations
12 and testing to determine whether such drugs are safe, effective and not misbranded
13 using a drug monograph system created by the FDA. *See* 21 C.F.R. §§ 330.1,
14 330.10. In drafting the monographs, the FDA divided the non-homeopathic OTC
15 drugs into drug categories, which were then assigned an advisory review panel of
16 qualified experts who evaluate the safety and effectiveness of the non-homeopathic
17 OTC drugs, as well as reviewing the drugs’ labeling, and advising the FDA
18 Commissioner on the promulgation of monographs establishing conditions under
19 which non-homeopathic OTC drugs listed within each monograph are generally
20 recognized as safe, effective, and not misbranded. *Id.* § 330.10(a).

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

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

4 21 U.S.C. § 355. Moreover, after the FDA approves a new drug application, any
5 change in the drug’s labeling requires a supplement to the application, and further
6 approval by the FDA, either before or after the change. 21 C.F.R. §§ 314.70(b), (c),
7 314.71.

8 35. In stark contrast, unlike non-homeopathic OTC drugs, homeopathic
9 OTC drugs, including the Cold and Flu Remedies, are not approved or authorized by
10 the FDA at all. Indeed, the FDA has “acknowledge[d] that many homeopathic drug
11 products are manufactured and distributed without FDA approval or authorization
12 under [its] enforcement policies.”

13 36. The FDA defines a homeopathic drug as any drug labeled as being
14 homeopathic that is also listed in the HPUS, an addendum, or its supplements. *See*
15 21 U.S.C. § 321(g)(1)(A); FDA, Inspections, Compliance, Enforcement, and
16 Criminal Investigations, Compliance Policy Guides § 400.400, “Conditions Under
17 Which Homeopathic Drugs May be Marketed” (“CPG § 400.400”).¹

18 37. According to the FDA, the HPUS is “[a] compilation of standards for
19 source, composition, and preparation of homeopathic drugs. The HPUS contains
20 monographs of drug ingredients used in homeopathic treatment.” CPG § 400.400.
21 Although the HPUS describes how these ingredients are prepared for homeopathic
22 use, it does not list the drugs as fit to treat specific symptoms, ailments, or
23 conditions. Instead, the HPUS allows the practitioner or manufacturer to set forth
24 the substance’s indications for use.

25 _____
26 ¹ *See*
27 <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074360.htm>
28 <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074360.htm> (Last accessed March 7, 2012).

1 38. Thus, rather than the stringent testing and evaluation applied to other
2 OTC drugs, homeopathic OTC drug substances are included in the HPUS after
3 having been subjected to the “provings” described above, which were conducted in
4 the 1800’s and early 1900’s to establish what types of symptoms resulted from the
5 use of a homeopathic substance in a healthy person.

6 39. The FDA does not impose additional standards for strength, purity,
7 quality, safety, or efficacy on homeopathic OTC remedies. Indeed, the FDA has
8 advised that unless a homeopathic remedy is “being offered for use (or promoted)
9 significantly beyond recognized or customary practice of homeopathy,” federal
10 policies on health fraud do not apply. FDA's Compliance Policy Guide § 400.400
11 (the “CPG”).

12 40. The FDA requires that the labels on homeopathic remedies include at
13 least one major indication (*i.e.*, medical problem to be treated), a list of ingredients,
14 the dilution, and safety instructions. Notably, however, pursuant to FDA
15 Compliance Guidelines, compliance with this labeling requirement or a “product’s
16 compliance with requirements of the HPUS . . . *does not establish that it has been*
17 *shown by appropriate means to be safe, effective, and not misbranded for its*
18 *intended use.”* *Id.* (emphasis added).

19 41. The CPG further provides that only “[h]omeopathic products intended
20 solely for self-limiting disease conditions amenable to self-diagnosis (of symptoms)
21 and treatment may be marketed OTC. *Homeopathic products offered for conditions*
22 *not amenable to OTC use must be marketed as prescription products.”* *Id.*
23 (emphasis added).

24 **C. Background Of Hyland’s**

25 42. In 1903, Hyland’s was founded as a Los Angeles pharmacy when
26 homeopathy was a standard medical practice in the United States. Countless
27 conventional medicines, both prescription and OTC, were developed and began to
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1 dominate the pharmaceutical market in the middle of the 20th Century. In response,
2 Hyland's pharmacists began to develop "combination" homeopathic medicines,
3 which they formulated by combining several single homeopathic remedies believed
4 to be effective for a particular ailment into one tablet.

5 43. In the 1970s, Hyland's began marketing these combination homeopathic
6 remedies in health food stores. By the late 1980s, Hyland's used Hyland's Teething
7 Tablets to break into the chain drugstore market. Since 2000, the company has
8 annually enjoyed double-digit growth, introduced many financially successful new
9 products, put its medicines on the shelves of every major drug retailer and has
10 engaged in aggressive marketing to take advantage of the increasing demand for
11 medicines that are perceived as effective without carrying negative side effects.

12 **D. Hyland's False And Misleading Labels**

13 44. Hyland's has recognized the importance of labeling in capturing the
14 highly competitive OTC market. In fact, Hyland's was featured in a *Nutritional*
15 *Outlook* article entitled "Savvy labeling and container design can ensure a sale at
16 first sight." This article heralded the fact that Hyland's was the first homeopathic
17 company to "collaborate[] with a market research firm to redesign and test bilingual
18 labels for its homeopathic infant products" such as its Cold and Flu Remedies.

19 45. The FDCA prohibits the sale of misbranded drugs, whether they are
20 conventional or homeopathic. *See generally* 21 U.S.C. § 331. Under the FDCA, a
21 drug will be deemed to be misbranded if the label is false or misleading. 21 U.S.C. §
22 352(a). The term "labeling" is defined to include "all labels and other written,
23 printed, or graphic matter (1) upon any article or any of its containers or wrappers, or
24 (2) accompanying such article." *Id.* § 321(m).

25 46. Nevertheless, Hyland's makes numerous false and misleading
26 marketing claims on the labels of its Cold and Flu Remedies promising fast acting
27 and effective relief from cold and flu symptoms. For example, virtually every panel
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1 of the boxes claim Hyland’s Cold and Flu Remedies are “Safe & Effective” and
2 “100% Natural.”

3 47. The packaging materials for Hyland’s Sniffles ‘n Sneezes product
4 claims it provides “Safe and Effective relief of cold symptoms.”

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48. Similarly, Hyland’s Cold Relief with Zinc promises “Fast relief from
cold symptoms,” and the same package claims that it “Relieves: Runny nose,
Sneezing [and] Sore throat.”



1 49. Defendants also claim that “Hyland’s Cold ‘n Cough 4 Kids provides
2 effective and quick relief for the symptoms of the common cold... [and] relieves
3 symptoms of: **Sneezing & runny nose, Nasal congestion, Sore throat, Cough**”
4 (emphasis in original).



16 50. On the packaging for Hyland’s Complete Flu product, Defendants claim
17 that it “Relieves” “Fever & Chills,” “Body Aches,” “Headaches,” and “Coughs and
18 Congestion.”



1 51. Likewise, the label for Hyland’s Cough ‘n Cold claims to offer “Multi-
2 symptom” relief and claims that the product: “Temporarily relieves the symptoms of
3 the common cold,” including “Sore Throat,” “Nasal Congestion,” “Cough,” “Runny
4 nose” and “Sneezing.”

5 52. The outer packaging materials and labels on each of the other Cold and
6 Flu Remedies contain similar representations. Specifically, Hyland’s maintains on
7 the packaging and labels of each of the Cold and Flu Remedies that the product that
8 the product is safe and effective for multiple cold and/or flu symptoms. *See*
9 [http://www.hylands.com/gallery/index.ph](http://www.hylands.com/gallery/index.php)
10 [p](http://www.hylands.com/gallery/index.php) (last accessed March 7, 2012) (including photos of the front packaging of each of
11 the Cold and Flu Remedies).

12 **E. Hyland’s Own Marketing Materials Belie It’s Theory Of Effectiveness**
13 **For The Cold And Flu Remedies**

14 53. Hyland’s does not believe its own homeopathy theory that “Like Cures
15 Like.” When it suits its marketing purposes, Hyland’s promotes its Cold and Flu
16 Remedies based on conventional concepts of chemistry and medical efficacy.

17 54. For instance, Defendants promote Sniffles ‘n Sneezes 4 Kids on their
18 website by claiming that “**Hyland’s New Sniffles ‘n Sneezes 4 Kids Offers Children**
19 **Relief From Uncomfortable Symptoms with an Active Ingredient Proven to Shorten**
20 **the Duration of Colds by Nearly Half.”**
21 [http://www.hylands.com/products/snif](http://www.hylands.com/products/sniffles.php)
22 [fles.php](http://www.hylands.com/products/sniffles.php) (last accessed March 7, 2012).

23 55. Hyland’s product catalogue also contains the same misleading
24 representation concerning the effectiveness of Zinc Gluconate in Hyland’s product,
25 Zinc Strips. *See* [http://www.hylands.com/Hylands-](http://www.hylands.com/Hylands-Catalogue.pdf)
26 [Catalogue.pdf](http://www.hylands.com/Hylands-Catalogue.pdf) (last accessed March
27 5, 2012). The catalogue notes: “Our children’s cold relief formula contains Zinc
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1 Gluconate, an essential mineral with antioxidant effects that has been clinically
2 proven to shorten duration of colds by nearly half.” *Id.*

3 56. These statements are misleading because the clinical study to which
4 Hyland’s refers did not include highly diluted homeopathic concentrations of the
5 active ingredient (Zincum Gluconicum), but a standard non-diluted concentration.
6 Moreover, Hyland’s statements are remarkable because they undermine Hyland’s
7 own theory of efficacy for the Cold and Flu Remedies. *Hyland’s claims to be*
8 *treating cold and flu symptoms homeopathically, by using active ingredients that*
9 *cause the cold symptom in standard concentrations, but the study suggests that*
10 *standard concentrations treat, rather than cause the symptoms of a cold!*

11 **F. Hyland’s Markets Its Cold And Flu Remedies By Creating Fear And**
12 **Distrust Of Conventional OTC Medicines**

13 57. To profit from FDA warnings concerning conventional OTC cold and
14 flu medicines and the near flu hysteria which began in 2009, Hyland’s promoted its
15 Cold and Flu Remedies through false and misleading print advertisements, television
16 advertisements, Internet advertisements and press releases. Not only does each of
17 these advertisements falsely claim that Hyland’s products are fast acting and
18 effective for the treatment of cold and flu symptoms, but many such advertisements
19 also attempt to stoke parents’ fears of competing products that may actually be
20 effective.

21 58. For instance, an edition of Hyland’s online newsletter raises questions
22 about each medically accepted treatment for cold and flu symptoms, including
23 conventional non-homeopathic OTC drugs, antibiotics and even flu shots, which the
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1 United States Center for Disease Control (the “CDC”) recommends to everyone
2 older than 6 months of age² (the “Newsletter”). The Newsletter states:

3 Over-the-counter (OTC) medications for cold and flu may include a
4 pain and fever reducer, such as acetaminophen or ibuprofen,
5 antihistamines, decongestants and/or cough suppressants. Potential side
6 effects of OTC cold and flu medications include: allergic reactions; liver
7 damage; easy or unusual bleeding or bruising; drowsiness; dizziness;
8 fainting; dry eyes, nose, and mouth; blurred vision; difficulty urinating;
9 or excitation in children. *Considering the side effects and possible drug*
10 *interactions, OTC medications should be used with caution.*

11 Antibiotics continue to be overused, but they are not effective treatment
12 against colds and the flu. Antibiotics fight off bacteria, but colds and flu
13 are caused by viruses. *Tamiflu is one antiviral that has been*
14 *recommended by the Centers for Disease Control. However, one of the*
15 *side effects, particularly in children, may be at increased risk for self-*
16 *injury and delirium.* The FDA's safety information and adverse event
17 reporting program has sent alerts to physicians advising them to closely
18 monitor their patients for signs of abnormal behavior.

19 One other option is a flu shot. But *an article in the October 28, 2006*
20 *issue of British Medical Journal questions the evidence of safety and*
21 *effectiveness of the flu shot. Some of the known possible adverse*
22 *effects of flu shots include fever, malaise, muscle aches, irritability,*
23 *insomnia and allergic reactions (e.g., hives, swelling, asthma and*
24 *anaphylaxis).*

25
26 ²
27 <http://www.cdc.gov/flu/about/qa/flushot.htm><http://www.cdc.gov/flu/about/qa/flushot>
28 .htm (last accessed March 5, 2012)

1 See [http://www.hylands.com/news/treatment-for-common-](http://www.hylands.com/news/treatment-for-common-cold.php)
2 [cold.php](http://www.hylands.com/news/treatment-for-common-cold.php) (last
3 accessed March 5, 2012) (Emphasis added).

4 59. The Newsletter goes on to laud the safety and efficacy of Hyland's
5 homeopathic products over the dangerous products recommended by the CDC,
6 noting:

7 Some of the products that appear to be particularly helpful for colds are
8 Hyland's Cold Plus C Tablets and Hyland's Cold 'n Cough 4 Kids.
9 These products contain a group of homeopathic medicines that help
10 relieve symptoms of the common cold. In addition, Hyland's Cough
11 Syrup with 100% Natural Honey 4 Kids is safe for children over 2 years
12 old. For flu, Hyland's Complete Flu Care and Hyland's Complete Flu
13 Care 4 Kids include some of the top remedies for flu symptoms. For
14 example, some of the medicines in Complete Flu Care 4 Kids
15 specifically help relieve body aches associated with fevers. Other
16 ingredients help with weakness, sleepiness and chills and relieving
17 inflamed eyes and runny noses.

18 *Id.*

19 60. Moreover, as set forth above, Hyland's published and distributed a
20 brochure promoting its Cold and Flu Remedies for children. This brochure,
21 maintained on Hyland's website states, in relevant part:

22 In October of 2008, the Food and Drug Administration (FDA)
23 supported labeling of over-the-counter (OTC) cough and cold
24 medications so that they should not be used in children younger than 2
25 years of age. *The FDA was acting in response to lack of data showing*
26 *efficacy of cough and cold medications in children* as well as serious
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1 adverse effects including tachycardia, decreased levels of
2 consciousness, seizures and even death.

3 * * *

4 ***Homeopathy is grounded in a scientific method and supported by***
5 ***clinical research.***

6 * * *

7 OTC cough and cold medications containing phenylephrine,
8 diphenhydramine, psuedoephedrine, clorpheniramine,
9 brompheniramine, dextromethorphan, guaifensisin, and doxylamine are
10 not a safe or effective treatment option for children under 4 years of age.

11 * * *

12 There are also safe alternative approaches, e.g., FDA regulated
13 homeopathic combination medicines that assist the body to begin the
14 healing process, and can be used in young children without having to
15 worry about any side effects.

16 * * *

17 ***Homeopathic medications are widely available over the counter***
18 ***medications.***

19 * * *

20 ***Homeopathic medications are regulated by the FDA*** so are unlikely to
21 contain any toxic components.

22 * * *

23 ***Homeopathic medications are safe to use. . . .*** They support the body's
24 own healing capacity and do not interact with other medications, so they
25 can be given alongside conventional medications without any
26 interactions.

27 * * *

28

1 In daily clinical practice, *combination homeopathic medications can*
2 *be recommended that contain many of the individual homeopathic*
3 *medications that have been known to be effective in alleviating*
4 *different symptoms of colds and coughs.* This takes the guesswork out
5 of prescribing. *Hyland’s provides a complete array of cough and cold*
6 *products that contain many of these medications and are safe and*
7 *effective treatment options that you can recommend with confidence*
8 *to your patients.*

9 <http://www.hylands.com/Cough-Cold-Edu.pdf>
10 <http://www.hylands.com/Cough-Cold-Edu.pdf> (last accessed March 5, 2012)(emphasis added).

11 61. Hyland’s also issued false and misleading press releases to promote its
12 Cold and Flu Remedies and stoke consumers’ fears of conventional treatments based
13 on medically sound principles. For example, on August 20, 2009, Hyland’s issued a
14 press release available on its website, which once again employed scare tactics to
15 raise the concern of parents regarding conventional non-homeopathic OTC cold and
16 flu products, while claiming Hyland’s Cold and Flu Remedies are an “effective”
17 alternative. This press release stated in relevant part:

18 Parents everywhere will be searching for a way to relieve their young
19 children’s cough and cold symptoms as the autumn months approach
20 and children return to school. *Many, though, are leery of some over-*
21 *the-counter (OTC) medications that, this time last year, were under*
22 *discussion as to their safety and efficacy for young children.* Add to
23 that the fact that, according to the Center for Disease Control, 22 million
24 school days are lost annually in the U.S. due to the common cold, it’s
25 easy to see that not treating symptoms is simply not an option. As a
26 result, many parents are opting to treat their children with safer, more
27 natural medicines.

1 In 2007 and 2008, the Food and Drug Administration (FDA) warned
2 parents of children’s OTC medications that contained any of the eight
3 specific, active ingredients of concern, including phenylephrine,
4 diphenhydramine, pseudoephedrine, chlorpheniramine,
5 brompheniramine, dextromethorphan, guaifensin, doxylamine. This
6 year, experts say that many parents want to take control of the issue and
7 make sure that when cold season hits, they’re prepared.

8 “The 2008 cold and cough season resulted in thousands of scared,
9 confused parents unsure of how to help their child get some relief from
10 stubborn symptoms,” said Jim Sears, M.D., expert on pediatric medicine
11 and advocate of natural treatments. ***“I want parents to find comfort in
12 knowing that there are OTC medications in their local drug stores and
13 health food stores that are safe for their children. Known as
14 homeopathic medications, these OTCs are all natural, extremely safe
15 and will effectively relieve a young child’s cold, flu and cough
16 symptoms.”***

17 Hyland’s, Inc. is a leading, national provider of homeopathic
18 medications. They are reaching out to parents this cough and cold
19 season to make sure that children everywhere have access to safe
20 symptom relief. “Families need to know that there are ways to safely
21 treat the symptoms of colds and flu this fall, especially in children,” said
22 J.P. Borneman, Ph.D., chairman and CEO of Hyland’s, Inc. “While
23 persistent or severe symptoms should always be referred to a healthcare
24 professional, ***parents remain their child’s first defense in alleviating
25 symptoms while avoiding the dangers associated with medicines
26 containing the active ingredients of concern to the FDA.*** For this
27 reason, Hyland’s is making time this cough and cold season to educate
28

1 parents on their OTC options, helping them gain access to safe
2 medications for their child.” (emphasis added)

3 *See*

4 <http://www.hylands.com/news/coldcough4kids.php><http://www.hylands.com/news/col>
5 [dough4kids.php](http://www.hylands.com/news/coldcough4kids.php) (last accessed March 5, 2012) (emphasis added).

6 62. Another press release notes: “There’s nothing worse than watching a
7 child suffer from the miserable symptoms that accompany a winter cold.” *See*
8 <http://www.hylands.com/news/snifflesnsneezes.php><http://www.hylands.com/news/sn>
9 [ifflesnsneezes.php](http://www.hylands.com/news/snifflesnsneezes.php) (last accessed March 5, 2012). The press release also attributes
10 the following quote to Mr. Borneman:

11 Sniffles n’ Sneezes 4 Kids tablets dissolve instantly, making it simple to
12 ensure younger children receive the correct dosage. It also eliminates
13 the hassle of trying to get children to take medicines they don’t like ...
14 The medicine is a great option for parents looking to relieve their
15 children’s cold symptoms without turning to medicines that can make
16 them drowsy or have other unpleasant side effects.

17 63. The intended effect of this marketing and advertising campaign is to
18 create a fear of non-homeopathic OTC remedies, particularly for the treatment of
19 small children. Instead, they maintain that their homeopathic products are “fast
20 acting” and “effective”, when in fact the Cold and Flu Remedies are nothing but a
21 placebo. While Hyland’s maintains that there is nothing worse than a parent
22 watching their child suffer, by promoting their Cold and Flu Remedies as a substitute
23 for alternative products that might actually work, Hyland’s dissuades parents from
24 seeking proper medical treatment.

25 **G. Hyland’s Cold And Flu Remedies Are Neither Fast Acting Nor Effective**

26 64. Although the label, packaging and advertisements for Hyland’s Cold
27 and Flu Remedies state that these drugs provide “Fast acting” and “Safe & Effective”
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1 relief from “multiple” cold and flu symptoms, there are no studies which
2 demonstrate that these homeopathic drugs are either fast acting or effective for relief
3 from the symptoms of colds and flu.

4 65. The purportedly “active ingredients” in Hyland’s Cold and Flu
5 Remedies are so highly diluted that there is no scientific basis to support Hyland’s
6 claims that its products are effective. The majority of the “active ingredients” in
7 Hyland’s Cold and Flu Remedies is diluted at a ratio of 1 to 1,000,000, while many
8 are diluted at a ratio of 1 to 1,000,000,000,000. Moreover, the extract of duck liver
9 and heart purportedly contained in Flu Care is diluted at a ratio of 1 to 10 to the 400th
10 power (1 followed by 400 zeros).

11 66. For over 200 years, homeopaths have claimed that with each successive
12 dilution of the active ingredient, when properly shaken, the remedy becomes more
13 potent. There is no scientific explanation, however, of how the water or other
14 substance in which the in which the so-called active ingredients are diluted retains a
15 “memory” or “imprint” which would make these remedies effective.

16 67. When substances are dissolved in water, the water molecules will form
17 structures around the solute molecules, but the hydrogen bonds between water
18 molecules are far too weak and short-lived to hold that structure once the solute has
19 been removed. It is not surprising that experiments that claim to have demonstrated
20 the memory of water have failed to be reproducible. The notion that water could
21 hold imprints of solutions previously dissolved in it is so far removed from current
22 scientific understanding, as opposed to scientific theory 200 years ago, that, as
23 Professor David Colquhoun, Professor of Pharmacology at University College
24 London, put it: “If homeopathy worked the whole of chemistry and physics would
25 have to be overturned.”

26 68. Moreover, properly conducted random clinical trials have repeatedly
27 demonstrated that homeopathic remedies are no more effective than placebos. The
28

1 authors of the Homeopathy Comparative Study, cited above, concluded that “*when*
2 *analyses were restricted to large trials of higher quality there was no convincing*
3 *evidence that homeopathy was superior to placebo.*” (emphasis added).

4 69. Similarly, health organizations such as the American Medical
5 Association and the National Health Service have also issued statements that there is
6 no scientific evidence to support the use of homeopathic treatments in medicine.
7 Even homeopathy’s own supporters, such as the National Center for Complementary
8 and Alternative Medicine has been forced to admit that “[t]here is [] no condition for
9 which homeopathy has been proven effective.”

10 70. In sum, Hyland’s produces expensive sweetened, flavored water or
11 sugar tablets and capitalizes on consumers’ trust and fears. Hyland’s, through its
12 labeling and marketing, misleads consumers into believing that (i) the ingredients in
13 Hyland’s Cold and Flu Remedies have been proven effective and deemed as such by
14 the FDA; (ii) homeopathic medicine and treatment have been proven effective; and
15 (iii) the “active ingredients” in Hyland’s Cold and Flu Remedies are actually present.
16 In fact, however: (i) the FDA has never deemed Hyland’s Cold and Flu Remedies
17 effective against any ailment or condition; (ii) Hyland’s Cold and Flu Remedies have
18 never been proven effective, let alone proven to provide fast acting relief; and (iii)
19 the serial dilutions used by Hyland’s in the preparation of its Cold and Flu Remedies
20 rendered the “active ingredients” virtually non-existent.

21 **J. Hyland’s False And Misleading Claims Are Material**

22 71. All of Hyland’s false and/or misleading claims challenged herein relate
23 to matters that are material and important to a consumer’s purchasing decision, as
24 they concern the effectiveness of Hyland’s Cold and Flu Remedies to blunt the
25 effects, reduce the duration, and treat the symptoms of colds and flu, all of which, if
26 true, would be inherent and material qualities of those products.

1 72. All of Hyland’s marketing and packaging materials were further
2 intended to, and did, induce Plaintiffs and members of the Class to rely upon
3 Hyland’s representations that its Cold and Flu Remedies would provide fast “acting,”
4 “effective,” “multi-symptom” cold and flu relief. These representations were a
5 substantial factor in causing Plaintiffs and members of the Class to purchase
6 Hyland’s Cold and Flu Remedies instead of conventional medication that had been
7 approved or otherwise authorized by the FDA.

8 73. At the time Plaintiffs and members of the Class purchased Hyland’s
9 Cold and Flu Remedies they were unaware of the fact that Hyland’s Cold and Flu
10 Remedies were not generally recognized as effective for their intended uses or that
11 there has been no studies which demonstrated that their “active ingredients” were
12 effective for the treatment of the common cold or flu, and therefore it was a violation
13 of state and federal law for Hyland’s to sell Hyland’s Cold and Flu Remedies and
14 promote those products in a false, misleading, deceptive and/or unconscionable
15 manner.

16 74. If Plaintiffs and members of the Class had been aware of the fact that
17 Hyland’s Cold and Flu Remedies were not effective for their intended uses and that
18 it was illegal for Hyland’s to sell its Cold and Flu Remedies, Plaintiffs and members
19 of the Class would not have purchased the products.

20 75. As a result, Plaintiffs and members of the Class who purchased
21 Hyland’s Cold and Flu Remedies which were not efficacious, effective, and useful
22 for their intended uses and were illegal for sale at the time of the consumer
23 transactions have been injured in fact and have suffered an ascertainable and out of
24 pocket loss. Plaintiffs and members of the Class therefore seek a refund and/or
25 rescission of the transaction and all further equitable and injunctive relief as provided
26 by applicable law.

**PLAINTIFF FORCELLATI'S PURCHASE
OF HYLAND'S COLD 'N COUGH**

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3 76. Plaintiff Enzo Forcellati read Defendants' advertisements on the outside
4 of the Hyland's Cold 'n Cough and read about the product on Hyland's website. Mr.
5 Forcellati purchased Cold 'n Cough over the counter at a CVS store in Bergen
6 County, New Jersey after reading that Hyland's Cold 'n Cough provides safe &
7 effective, fast acting multi-symptom relief for nasal congestion, cough, sore throat,
8 runny nose, sneezing and congestion. His family used the drug as directed, but did
9 not obtain the advertised relief from these symptoms, nor any benefits from using
10 Cold 'n Cough. Mr. Forcellati purchased the Cold 'n Cough product for
11 approximately \$10.00.

12 77. Mr. Forcellati would not have purchased Hyland's Cold 'n Cough if he
13 had known that it was not an effective treatment for these symptoms.

**PLAINTIFF ROEMMICH'S PURCHASE
OF HYLAND'S COLD 'N COUGH**

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15
16 78. Plaintiff Roemmich purchased Hyland's Cold 'n Cough for her child at
17 a Walmart in Dardenne Prairie, Missouri and online at drugstore.com. Ms.
18 Roemmich purchased Cold 'n Cough after reading Defendants' advertisements on
19 the product's packaging label. Ms. Roemmich spent between \$7.00 and \$14.00 in
20 purchasing the Cold 'n Cough...

21 79. In purchasing Cold 'n Cough 4 Kids, Plaintiff Roemmich relied upon
22 various representations Defendants made on the product's label, such as the name of
23 the product itself and statements that Cold 'n Cough 4 Kids will relieve her child of
24 symptoms of the common cold, was 100% natural and contained active ingredients.

25 80. Cold 'n Cough 4 Kids did not work for Plaintiff Roemmich as
26 advertised.
27
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1 81. Absent the misstatements described herein, Plaintiff Roemmich would
2 not have purchased Cold ‘n Cough 4 Kids.

3 **CLASS ACTION ALLEGATIONS**

4 82. Plaintiffs bring this action as a class action under Federal Rule of Civil
5 Procedure 23 on behalf of a Class consisting of all persons in the United States who,
6 within the relevant statute of limitations period, purchased Hyland’s Cold and Flu
7 Remedies.

8 83. Plaintiff Enzo Forcellati also seeks to represent a subclass defined as all
9 members of the Class who purchased mislabeled Hyland’s Cold and Flu Remedies in
10 New Jersey (“the New Jersey Subclass”).

11 84. Plaintiff Lisa Roemmich also seeks to represent a subclass defined as all
12 members of the Class who purchased mislabeled Hyland’s Cold and Flu Remedies in
13 Missouri (“the Missouri Subclass”).

14 85. Plaintiffs reserve the right to amend or modify the Class definition with
15 greater specificity or further division into subclasses or limitation to particular issues
16 as discovery and the orders of this Court warrant.

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

21 87. Also excluded from the Class are persons or entities that purchased
22 Hyland’s Cold and Flu Remedies for purposes of resale.

23 88. Plaintiffs are members of the Class they seek to represent.

24 89. The Class is so numerous that joinder of all members is impractical.
25 Although Plaintiffs do not yet know the exact size of the Class, Hyland’s claims to
26 have its Cold and Flu Remedies in “nearly every pharmacy and grocery store in
27 North America today.” Consequently, Hyland’s represents on its website that
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1 “Standard Homeopathic Company and its operating companies [are] the largest full-
2 service homeopathic firm in the United States in terms of sales and operating
3 results.” Hyland’s claims that in 2007 “an estimated 3.9 million US adults and
4 900,000 children used homeopathy.” Upon information and belief and based upon
5 Hyland’s press releases and public statements, the Class includes more than 1 million
6 members. Accordingly, joinder is impracticable.

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

- 10 (a) Whether Hyland’s violated the Magnuson-Moss Act, 15 U.S.C. §
11 201, *et seq.*;
- 12 (b) Whether Hyland’s breached an express warranty made to Plaintiff
13 and the Class;
- 14 (c) Whether Hyland’s breached the implied warranties of
15 merchantability and/or fitness for a particular purpose made to
16 Plaintiff and the Class;
- 17 (d) Whether Hyland’s marketing of Cold and Flu Remedies is false,
18 misleading, and/or deceptive;
- 19 (e) Whether Hyland’s marketing of Cold and Flu Remedies is unfair;
- 20 (f) Whether Hyland’s Cold and Flu Remedies are efficacious,
21 effective, and useful for the treatment of common cold
22 symptoms;
- 23 (g) Whether Hyland’s Cold and Flu Remedies are efficacious,
24 effective, and useful for the treatment of flu symptoms;
- 25 (h) Whether Hyland’s Cold and Flu Remedies provide fast acting
26 relief;
- 27 (i) Whether Hyland’s was unjustly enriched by its conduct;
- 28

- 1 (j) Whether Hyland’s violated the CLRA;
- 2 (k) Whether Hyland’s violated the UCL;
- 3 (l) Whether Hyland’s violated the FAL;
- 4 (m) Whether Hyland’s violated the New Jersey Consumer Fraud Act;
- 5 (n) Whether Hyland’s violated the Missouri Merchandising Practices
6 Act;
- 7 (o) Whether Class members suffered an ascertainable loss as a result
8 of the Hyland’s misrepresentations; and
- 9 (p) Whether, as a result of Hyland’s misconduct as alleged herein,
10 Plaintiffs and Class members are entitled to restitution, injunctive
11 and/or monetary relief and, if so, the amount and nature of such
12 relief.

13 91. Plaintiffs’ claims are typical of the claims of the members of the Class
14 as all members of the Class are similarly affected by Hyland’s wrongful conduct.
15 Plaintiffs have no interests antagonistic to the interests of the other members of the
16 Class. Plaintiffs and all members of the Class have sustained economic injury
17 arising out of Hyland’s violations of common and statutory law as alleged herein.

18 92. Plaintiffs are adequate representatives of the Class because their
19 interests do not conflict with the interests of the Class members they seek to
20 represent, they have retained counsel competent and experienced in prosecuting class
21 actions, and they intend to prosecute this action vigorously. The interests of the
22 Class members will be fairly and adequately protected by Plaintiffs and their
23 counsel.

24 93. The class mechanism is superior to other available means for the fair
25 and efficient adjudication of the claims of Plaintiffs and the Class members. Each
26 individual Class member may lack the resources to undergo the burden and expense
27 of individual prosecution of the complex and extensive litigation necessary to
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1 establish Hyland’s liability. Individualized litigation increases the delay and expense
2 to all parties and multiplies the burden on the judicial system presented by the
3 complex legal and factual issues of this case. Individualized litigation also presents a
4 potential for inconsistent or contradictory judgments. In contrast, the class action
5 device presents far fewer management difficulties and provides the benefits of single
6 adjudication, economy of scale, and comprehensive supervision by a single court on
7 the issue of Hyland’s liability. Class treatment of the liability issues will ensure that
8 all claims and claimants are before this Court for consistent adjudication of the
9 liability issues.

10 **COUNT I**

11 **(Violation of Magnuson-Moss Act (15 U.S.C. § 2301, *et seq.*)**

12 94. Plaintiffs repeat the allegations contained in the above paragraphs as if
13 fully set forth herein.

14 95. Plaintiffs bring this claim individually and on behalf of the members of
15 the Class, the New Jersey Subclass and the Missouri Subclass.

16 96. The Cold and Flu Remedies are consumer products as defined in 15
17 U.S.C. § 2301(1).

18 97. Plaintiffs and Class members are consumers as defined in 15 U.S.C.
19 § 2301(3).

20 98. Defendants are suppliers and warrantors as defined in 15 U.S.C.
21 § 2301(4) and (5).

22 99. In connection with the sale of the Cold and Flu Remedies, Defendants
23 issued written warranties as defined in 15 U.S.C. § 2301(6), which warranted that the
24 products offer children “Fast acting,” “Effective,” “Multi-symptom” relief from cold
25 and flu symptoms, including runny noses, sore throats, coughs, headaches, body
26 aches, flu and congestion, when in fact, these products are ineffective and do not
27 provide relief for any of these symptoms.
28

1 100. By reason of Defendants’ breach of the express written warranties
2 stating that the Cold and Flu Remedies were “Fast acting,” “Effective”, and provided
3 “Multi-symptom” relief from cold and flu symptoms, Defendants have violated the
4 statutory rights due Plaintiffs and Class members pursuant to the Magnuson-Moss
5 Warranty Act, 15 U.S.C. § 2301 *et seq.*, thereby damaging Plaintiffs and Class
6 members.

7 101. By reason of Defendants’ breach of the express written warranties
8 stating that the Cold and Flu Remedies were “Fast acting,” “Effective”, and provided
9 “Multi-symptom” relief from cold and flu symptoms, Defendants have violated the
10 statutory rights due Plaintiffs and Class members pursuant to the Magnuson-Moss
11 Warranty Act, 15 U.S.C. § 2301 *et seq.*, thereby damaging Plaintiffs and Class
12 members.

13 102. Prior to filing this action, Mr. Forcellati, by and through his counsel,
14 provided Defendants with written notice of his claims pursuant to 15 U.S.C. §
15 2310(e) and also notified Defendants that he was acting on behalf of a Class defined
16 as all persons in the United States who purchased Hyland’s Cold and Flu Remedies.

17 **COUNT II**

18 **(Unjust Enrichment)**

19 103. Plaintiffs repeat the allegations contained in the foregoing paragraphs as
20 if fully set forth herein.

21 104. Plaintiffs bring this Count II individually and on behalf of the members
22 of the Class, the New Jersey Subclass and the Missouri Subclass.

23 105. “Although there are numerous permutations of the elements of the
24 unjust enrichment cause of action in the various states, there are few real differences.
25 In all states, the focus of an unjust enrichment claim is whether the defendant was
26 unjustly enriched. At the core of each state’s law are two fundamental elements –
27 the defendant received a benefit from the plaintiff and it would be inequitable for the
28

1 defendant to retain that benefit without compensating the plaintiff. The focus of the
2 inquiry is the same in each state.” *In re Mercedes-Benz Tele Aid Contract Litig.*, 257
3 F.R.D. 46, 58 (D.N.J. Apr. 24, 2009), quoting *Powers v. Lycoming Engines*, 245
4 F.R.D. 226, 231 (E.D. Pa. 2007).

5 106. Plaintiffs and Class members conferred a benefit on Hyland’s by
6 purchasing Cold and Flu Remedies and by paying a price premium for Cold and Flu
7 Remedies.

8 107. Defendants have been unjustly enriched in retaining the revenues
9 derived from Class members’ purchases of Cold and Flu Remedies, which retention
10 under these circumstances is unjust and inequitable because Defendants
11 misrepresented that Cold and Flu Remedies would provide “Fast acting,” “Safe &
12 Effective”, “Multi-symptom” relief from cold and flu symptoms.

13 108. Because Defendants’ retention of the non-gratuitous benefit conferred
14 on them by Plaintiff and Class members is unjust and inequitable, Defendants must
15 pay restitution to Plaintiffs and the Class members for their unjust enrichment, as
16 ordered by the Court.

17 **COUNT III**

18 **(For Breach Of Express Warranty)**

19 109. Plaintiffs and Class members reallege and incorporate by reference each
20 allegation set forth above and further allege as follows.

21 110. Plaintiff brings this Count III individually and on behalf of the members
22 of the Class, the New Jersey Subclass and the Missouri Subclass.

23 111. Defendants expressly warranted that the Hyland’s Cold and Flu
24 Remedies were effective and would provide fast acting, multi-symptom relief for the
25 symptoms of the common cold and the flu.
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1 112. Defendants breached this warranty because Hyland's Cold and Flu
2 Remedies are neither fast acting nor effective treatments for the cold or flu or any
3 symptoms thereof.

4 113. Plaintiffs and Class Members were injured as a direct and proximate
5 result of Defendants' breach because: (a) they would not have purchased Hyland's
6 Cold and Flu Remedies on the same terms if they had known the true facts; (b) they
7 paid a price premium due to the mislabeling of Hyland's Cold and Flu Remedies;
8 and (c) Hyland's Cold and Flu Remedies did not have the quality, effectiveness or
9 value as promised.

10 **COUNT IV**

11 **Breach of Implied Warranty**

12 **(On Behalf of Plaintiff and the Class)**

13 114. Plaintiffs repeat the allegations contained in the paragraphs above as if
14 fully set forth herein.

15 115. Plaintiffs bring this Count IV individually and on behalf of the members
16 of the Class, the New Jersey Subclass and the Missouri Subclass.

17 116. Defendants, through their acts and omissions set forth herein, in their
18 sale, marketing, and promotion of their Cold and Flu Remedies made implied
19 representations to Plaintiff and the Class that their Cold and Flu Remedies were fast
20 acting and effective for the treatment of cold and flu symptoms and that the Plaintiff
21 and the Class bought the Cold and Flu Remedies manufactured, advertised and sold
22 by Defendants.

23 117. Defendants breached their implied warranties because the Cold and Flu
24 Remedies were not fast acting or effective and as a result of Defendants' conduct,
25 Plaintiffs and the Class did not receive goods as impliedly warranted by Defendants
26 to be merchantable or fit for the purpose they were sold.
27
28

1 118. Plaintiffs and the Class have sustained damages as a proximate result of
2 the foregoing breach of implied warranty in an amount to be determined at trial.

3 **COUNT V**

4 **(Violation of the New Jersey Consumer Fraud Act, N.J.S.A. . § 58:8-1, et seq.)**

5 119. Plaintiff Forcellati repeats the allegations contained in the above
6 paragraphs as if fully set forth herein.

7 120. Plaintiff Forcellati brings this Count V on behalf of the New Jersey
8 Subclass under New Jersey law.

9 121. Defendants violated this provision by representing that Hyland’s Cold
10 and Flu Remedies were fast acting and effective at providing multi-symptom relief
11 from the symptoms of the common cold and flu, when in fact they were not.

12 122. Plaintiff Forcellati and members of the New Jersey Subclass suffered an
13 ascertainable loss caused by Defendants’ misrepresentations because: (a) Plaintiff
14 Forcellati and the New Jersey Subclass would not have purchased the Hyland’s Cold
15 and Flu Remedies on the same terms if they had known the true facts regarding the
16 effectiveness and contents of the products; (b) Plaintiff Forcellati and the New Jersey
17 Subclass paid a price premium due to the mislabeling of Hyland’s Cold and Flu
18 Remedies; and (c) Hyland’s Cold and Flu Remedies did not have the quality,
19 effectiveness or value as promised.

20 **COUNT VI**

21 **(Violation of the Consumer Legal Remedies Act (“CLRA”),**

22 **Civil Code §§ 1750, et. seq.)**

23 123. Plaintiffs and Class members reallege and incorporate by reference
24 each allegation set forth above and further allege as follows.

25 124. Plaintiffs brings this Count VI on behalf of the Class and at all relevant
26 times, Hyland’s Cold and Flu Remedies constituted “goods,” as that term is defined
27 in Civ. Code § 1761(a).
28

1 125. At all relevant times, Defendants were “persons,” as that term is defined
2 in Civ. Code § 1761(c).

3 126. At all relevant times, Plaintiffs’ purchases of Hyland’s Cold and Flu
4 Remedies, and the purchases of other Class and Subclass members constituted
5 “transactions,” as that term is defined in Civ. Code § 1761(e).

6 127. The policies, acts, and practices described in this Complaint were
7 intended to and did result in the sale of Hyland’s Cold and Flu Remedies to Plaintiffs
8 and the Class. Defendants’ practices, acts, policies, and course of conduct violated
9 the CLRA §1750 *et seq.*, in that, as described above.

10 128. Defendants represented that Hyland’s Cold and Flu Remedies have
11 sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which
12 they do not have in violation of California Civil Code § 1770(a)(5). Defendants
13 violated this provision by representing that Hyland’s Cold and Flu Remedies were
14 safe and effective at providing fast acting, multi-symptom relief from the symptoms
15 of the common cold and flu, when in fact they were not.

16 129. Defendants represented that Hyland’s Cold and Flu Remedies were of a
17 particular standard or quality, when Defendants were aware that they were of another
18 in violation of § 1770(a)(7) of the CLRA. Defendants maintained that the Cold and
19 Flu Remedies were fast acting and effective when they were not.

20 130. Defendants advertised Hyland’s Cold and Flu Remedies with intent not
21 to sell them as advertised in violation of § 1770(a)(9) of the CLRA. Defendants
22 intended to not to sell the Cold and Flu Remedies as fast acting and effective
23 products, because they know those products contain so-called active ingredients in
24 inactive homeopathic concentrations that are not fast acting or effective.

25 131. Plaintiffs and Class members suffered injuries caused by Defendants
26 misrepresentations because: (a) Plaintiffs and the Class members would not have
27 purchased Hyland’s Cold and Flu Remedies on the same terms if they had known the
28

1 true facts; (b) Plaintiffs and the Class paid a price premium due to the mislabeling of
2 Hyland’s Cold and Flu Remedies; and (c) Hyland’s Cold and Flu Remedies did not
3 have the level of safety, quality, effectiveness or value as promised.

4 132. Prior to the filing of this Complaint, a CLRA notice letter was served on
5 Defendants which complies in all respects with California Civil Code § 1782(a). On
6 February 29, 2012, Plaintiff Forcellati sent Defendants a letter via certified mail,
7 return receipt requested, advising Defendants that they are in violation of the CLRA
8 and must correct, repair, replace or otherwise rectify the goods alleged to be in
9 violation of § 1770. On June 27, 2012, Plaintiff Roemmich sent Defendants a letter
10 via certified mail, return receipt requested, advising Defendants that they are in
11 violation of the CLRA and must correct, repair, replace or otherwise rectify the
12 goods alleged to be in violation of § 1770. Defendants were further advised that in
13 the event that the relief requested had not been provided within thirty (30) days,
14 Plaintiffs would amend their Complaints to include a request for damages pursuant
15 to the CLRA. Wherefore, Plaintiffs seek damages, restitution, and injunctive relief
16 for this violation of the CLRA.

17 **COUNT VII**

18 **(For Violation of the False Advertising Law, Business & Professions Code**
19 **§17500 et seq.)**

20 133. Plaintiffs and Class members reallege and incorporate by reference each
21 allegation set forth above and further allege as follows.

22 134. Plaintiffs bring this Count VII on behalf of the Class under California
23 law.

24 135. California’s FAL, (Bus. & Prof. Code §§17500, *et seq.*) makes it
25 “unlawful for any person to make or disseminate or cause to be made or
26 disseminated before the public in this state, . . . in any advertising device . . . or in
27 any other manner or means whatever, including over the Internet, any statement,
28

1 concerning . . . personal property or services, professional or otherwise, or
2 performance or disposition thereof, which is untrue or misleading and which is
3 known, or which by the exercise of reasonable care should be known, to be untrue or
4 misleading.”

5 136. Throughout the Class Period, Defendants committed acts of false
6 advertising, as defined by § 17500, by using false and misleading statements to
7 promote the sale of Hyland’s Cold and Flu Remedies, as described above.

8 137. Defendants knew or should have known, through the exercise of
9 reasonable care that the statements were untrue and misleading.

10 138. Defendants’ actions in violation of § 17500 were false and misleading
11 such that the general public is and was likely to be deceived.

12 139. As a direct and proximate result of these acts, consumers have been and
13 are being harmed. Plaintiffs bring this action pursuant to § 17535 for injunctive
14 relief to enjoin the practices described herein and to require Defendants to issue
15 corrective disclosures to consumers.

16 **COUNT VIII**

17 **(For Violation of the Unfair Competition Law, Bus.**

18 **& Prof. Code §§ 17200 et seq.)**

19 140. Plaintiffs and Class members reallege and incorporate by reference each
20 allegation set forth above and further allege as follows.

21 141. Plaintiffs bring this Count VIII on behalf of the Class and the
22 Defendants are subject to the UCL, Bus. & Prof. Code § 17200 et seq. The UCL
23 provides, in pertinent part: “Unfair competition shall mean and include unlawful,
24 unfair or fraudulent business practices and unfair, deceptive, untrue or misleading
25 advertising” The UCL also provides for injunctive relief and restitution for
26 violations.

1 142. Throughout the Class Period, Defendants committed acts of unfair
2 competition, as defined by § 17200, by using false and misleading statements to
3 promote the sale of Hyland’s Cold and Flu Remedies, as described above.

4 143. Defendants’ conduct is unfair in that the harm to Plaintiffs and the Class
5 arising from Defendants’ conduct outweighs the utility, if any, of those practices.

6 144. Defendants’ conduct described herein, violated the “fraudulent” prong
7 of the UCL by representing that Hyland’s Cold and Flu Remedies were fast acting
8 and effective at providing multi-symptom relief from the symptoms of the common
9 cold and flu, when in fact they were not.

10 145. Plaintiffs and members of the Class have suffered injury and actual out
11 of pocket losses as a result of Defendants’ unfair, unlawful, and fraudulent business
12 acts and practices because: (a) Plaintiffs and the Class would not have purchased
13 Hyland’s Cold and Flu Remedies on the same terms if they had known the true facts
14 regarding the effectiveness and contents of the products; (b) Plaintiffs and the Class
15 paid a price premium due to the misrepresentations of Hyland’s Cold and Flu
16 Remedies; and (c) Hyland’s Cold and Flu Remedies did not have the quality and
17 effectiveness or value as promised.

18 146. Pursuant to *California Business & Professions Code §17203*, Plaintiffs,
19 the Class and the Subclasses are therefore entitled to: (a) an Order requiring
20 Defendants to cease the acts of unfair competition alleged herein; (b) full restitution
21 of all monies paid to Defendants as a result of their deceptive practices; (c) interest at
22 the highest rate allowable by law; and (d) the payment of Plaintiffs’ attorneys’ fees
23 and costs pursuant to, inter alia, California Code of Civil Procedure §1021.5.

1 **COUNT IX**

2 **(Violation of the Missouri Merchandising Practices Act, Mo. Ann. Stat. §§**
3 **407.010, et seq.)**

4 147. Plaintiff Roemmich repeats the allegations contained in the above
5 paragraphs as if fully set forth herein.

6 148. Plaintiff Roemmich brings this Count IX on behalf of the Missouri
7 Subclass under Missouri law.

8 149. Missouri Merchandising Practices Act, Mo. Ann. Stat. §§ 407.010, *et*
9 *seq.*, (the “MMPA”) prohibits “deception, fraud, false pretense, false promise,
10 misrepresentation, unfair practice or the concealment, suppression or omission of
11 any material fact in connection with the sale or advertisement of any merchandise in
12 trade or commerce ... in or from the state of Missouri ...” MMPA § 407.020.

13 150. Under the definition provided by MMPA, “trade or commerce” means
14 the “advertising, offering for sale, sale, or distribution or any combination thereof, of
15 any services and any property ...” MMPA § 407.010(7).

16 151. Hyland’s Cold and Flu Remedies are “merchandise” under the MMPA.
17 *See* MMPA § 407.010(4).

18 152. Hyland’s representations regarding the benefits and qualities of its Cold
19 and Flu Remedies constitute “trade or commerce” under the MMPA. MMPA §
20 407.010(7).

21 153. While MMPA, section 407.010(7) further defines the terms “trade” and
22 “commerce” to “include” any trade or commerce “directly or indirectly affecting
23 people of this state,” Missouri courts recognize that this language does not
24 necessarily restrict application of the MMPA to consumer victims domiciled within
25 the State of Missouri, or to business transacted entirely within Missouri’s territorial
26 borders. *See State ex rel. Nixon v. Estes*, 108 S.W.3d 795 (Mo. App. W. D. 2003).

1 154. Plaintiff Roemmich and members of the Class are “persons,” who
2 bought Hyland’s Cold and Flu Remedies “for personal, family or household
3 purposes” under the MMPA. *See* MMPA §§ 407.010(5), 407.025.I.

4 155. In connection with the sale or advertisement of Cold n’ Cough 4 Kids,
5 Defendants represented that the Product “provides quick relief for the symptoms of
6 the common cold,” relieving “nasal congestion,” “cough,” “sore throat,” runny
7 nose,” and “sneezing,” (*See* Ex. 2 for more false representations), and concealed the
8 true nature of the Product, that it is merely an aqueous solution of inert ingredients.
9 Such conduct by the Defendants constitutes deception, fraud, false pretense, false
10 promise, misrepresentation, unfair practice or the concealment, suppression or
11 omission of any material fact, in violation of the MMPA. MMPA § 407.020.

12 156. As a result of Defendants’ unlawful practices in violation of the MMPA,
13 Plaintiff Roemmich and members of the Class suffered an ascertainable loss of
14 money or property. MMPA §§ 407.020; 407.025(1) and (2).

15 157. Pursuant to MMPA sections 407.025(1) and (2), Plaintiff Roemmich
16 and members of the class seek an order of this Court enjoining Defendants from
17 continuing to engage in unfair or deceptive business practices with respect to Cold n’
18 Cough 4 Kids.

19 158. Pursuant to MMPA section 407.025(1) and (2), Plaintiff Roemmich and
20 members of the Class seek an order awarding them damages and punitive damages,
21 and reasonable attorneys’ fees.

22 **WHEREFORE**, Plaintiffs pray for relief and judgment, as follows:

23 A. Determining that this action is a proper class action;

24 B. For an order declaring that the Defendants’ conduct violates the statutes
25 referenced herein;

26 C. Awarding compensatory and punitive damages in favor of Plaintiffs and
27 members of the Class, the New Jersey Subclass and the Missouri Subclass against
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1 Defendants for all damages sustained as a result of the Defendants' wrongdoing, in
2 an amount to be proven at trial, including interest thereon;

3 D. Awarding injunctive relief against Defendants to prevent Defendants
4 from continuing their ongoing unfair, unconscionable and/or deceptive acts and
5 practices;

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

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

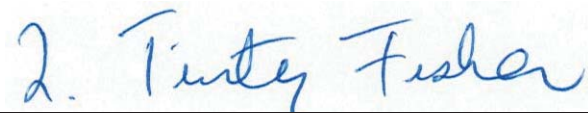
10 **JURY DEMAND**

11 Plaintiffs hereby demand a trial by jury on all claims so triable in this action.

12
13 Dated: November 7, 2012

Respectfully submitted,

14 **BURSOR & FISHER, P.A.**

15
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