EXHIBIT 11

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HYLAND'S, INC. and STANDARD HOMEOPATHIC COMPANY

IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

KIM ALLEN, DANIELE XENOS, RODGER HUTCHINSON, MELISSA NIGH, SHERRELL SMITH, YUANKE XU, DIANA SISTI, and NANCY RODRIGUEZ, on behalf of themselves and all others similarly situated and the general public,

Plaintiffs,

v.

HYLAND'S, INC., a California corporation; and STANDARD HOMEOPATHIC COMPANY,

Defendants.

Civil Action No. 2:12-CV-1150 DMG (MANx)

CLASS ACTION

DECLARATION OF DR. PETER A. G. FISHER IN SUPPORT OF DEFENDANTS' OPPOSITION TO CLASS CERTIFICATION

Judge: Hon. Dolly M. Gee
Date: July 13, 2012
Time: 9:30 a.m.
Location: Courtroom 7

I, Peter A.G. Fisher, declare as follows:

1. I am Clinical Director and Director of Research at the Royal London Hospital for Integrated Medicine (RLHIM). The RLHIM is the largest centre for integrated medicine in Europe and part of University College London Hospitals NHS Foundation Trust (UCLH), one of the UK's leading academic medical centres. I am also Physician to Her Majesty Queen Elizabeth II. I am a Fellow of the Royal College of Physicians, accredited as a specialist in both homeopathy and rheumatology (Board certified), and am a Fellow of the Faculty of Homeopathy. I was awarded my Bachelor of Arts in Medical Sciences from Emmanuel College, Cambridge University in 1972, and my Bachelor of Medicine, Bachelor of Surgery (British medical degree, equivalent of US MD) from Cambridge University in 1975.

2. I am an Expert Advisor on Complementary and Alternative Medicine to the UK National Institute of Health and Clinical Excellence (NICE) and was previously Clinical Lead of NICE NHS Evidence - complementary and alternative medicine. I was reappointed a member of the Advisory Board on the Registration of Homoeopathic Products, an advisory committee to the Medicines and Healthcare products Regulatory Agency (a UK government agency approximately equivalent to the FDA), in November 2011. I am Clinical Lead of the Complementary and Alternative Medicine Library and Information Service (CAMLIS, www.cam.nhs.uk). I am a member of World Health Organisation's (WHO) Expert Advisory Panel on Traditional and Complementary Medicine chaired WHO'sworking group on homeopathy and. I have previously served as Lead, National Cancer Research Institute Complementary and Alternative Medicine Clinical Studies Development Group, Disease Management Subgroup (2004-2010); Member and Deputy Chair of the Advisory Board on the Registration of Homoeopathic Products, Medicines Control Agency, UK Department of Health and

as a Member of the European Commission Homoeopathic Medicine Group, European Commission Directorate-General XII, Brussels.

3. I have published many papers on research in Complementary and Alternative Medicine and its integration. I am also Editor-in-Chief of the international journal *Homeopathy*. I am a member of advisory and editorial boards including: Cochrane Collaboration Complementary and Alternative Medicine Field, Alzheimer's Society Specialist Review Panel, Evidence-based Complementary Medicine (eCAM), European Journal of Integrative Medicine (Berlin), Focus on Alternative and Complementary Therapies.

4. Attached as Exhibit A is a true and correct copy of my current curriculum vitae.

5. I have been retained by Defendant's Hyland's, Inc. and Standard Homeopathic Company to provide my expert opinion regarding the issues raised in plaintiff's complaint and motion for class certification. In addition to my background, training, and experience in medicine and homeopathy, I have reviewed the following materials in order to provide my opinions in this case:

- The plaintiffs' Second Amended Complaint
- The plaintiff's motion for class certification
- A wide range of scientific publications, as discussed in more detail below.

6. Homeopathy is based on the concept of 'treating like with like' (in Latin *similia similibus curentur*). The word homeopathy and the systematic application of this concept to medicine are due to the German physician Samuel Christian Hahnemann (1755-1843). However the idea of treating disease on the basis of similarity can be traced to much earlier in the history of medicine, for instance to the works of Hippocrates (approximately 450 BCE). The concept is also prominent in the work of Theophrastus Bombastus von Hohenheim (better

known as Paracelsus) in the late 15th century, and in the medical traditions of several Asian countries.

7. Homeopathic treatment aims to stimulate and direct the body's self-healing capacity by triggering a reaction. The body reacts to stimuli which have physiological effects (drugs or toxins) by attempting to maintain homoeostasis (a stable internal environment); it is this effect that is exploited in homeopathy. There is substantial overlap with other area of pharmacology and toxicology including the widely observed phenomenon of hormesis (the paradoxical, stimulatory or beneficial effects of small doses of toxins).[1, 2, 3, 4] An hormetic dose response curve is non-linear: typically it is J or hockey stick shaped with a linear dose response relationship at relatively high doses (the shaft of the stick) but a reversed dose response curve (the hook) at low dose. Other related phenomena include rebound effects (where withdrawal of a drug produces the reverse effect, so for instance, blood pressure is higher than it was before the prescription of a drug after its withdrawal), dose-dependent reverse effects and paradoxical pharmacology.[5, 6, 7]

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[1] Stebbing ARD (1982). Hormesis - the stimulation of growth by low levels of inhibitors. *Science of the Total Environment*, 22:213-234

[2] Calabrese EJ, Blain R (2005). The occurrence of hormetic dose responses in the toxicological literature, the hormesis database: An overview. *Toxicology and Applied Pharmacology*, 202:289–301.

[3] Calabrese EJ, Staudenmayer J, and Stanek EJ (2006). Drug development and hormesis. Changing conceptual understanding of the dose response creates new challenges and opportunities for more effective drugs. *Current Opinion in Drug Discovery & Development*, 9:117–123.

[4] Calabrese,EJ Staudenmayer JW, Stanek EJ, Hoffmann GR (2006).Hormesis Outperforms Threshold Model in National Cancer Institute Antitumor Drug Screening Database. *Toxicological Sciences*, 94:368–378

[5] Bond RA (2001). Is paradoxical pharmacology a strategy worth pursuing? *Trends in Pharmacological Sciences*, 22:273–276.

[6] Teixeira MZ (2006). Evidence of the principle of similitude in modern fatal iatrogenic events. *Homeopathy*, 95:229–236.

[7] Teixeira MZ (2007). Bronchodilators, fatal asthma, rebound effect and similitude *Homeopathy*, 96:135–137

'Postconditioning hormesis' refers to a small dose of noxious stimulus exerting a beneficial effect after a biological system has been exposed to a harmful stress of similar nature.[8, 9] These phenomena have in common that they are secondary, reverse or paradoxical reactions to drugs or toxins by living organisms, as a function of dose and/or time.

8. In order to minimise the primary action of the drug or toxin while still stimulating the secondary reaction of the body, homeopathic medicines are used at minimum dose. Homeopathic medicines are prepared by a process known as potentization which involves repeated dilutions, usually in steps of 1:10 or 1:100, with succussion (vigorous shaking) between each dilution. Dilutions are denoted for instance 3X for the 3rd decimal (i.e. 3 x 1:10 dilutions) or 200C for the 200th centesimal (200 x 1:100 dilutions). Clean glassware (test tube and pipettes) is used for each step of dilution. Some homeopathic medicines, particularly those made from insoluble substances are prepared by a long period of grinding (known as trituration) with lactose, in the early stages of dilution.[10]

9. It is known from the work of the 19th century scientists Amadeo Avogadro and Johann Josef Loschmidt that, since matter is particulate, it is unlikely that dilutions above 23X or 12C (corresponding to dilutions of 10^{-23} and 10^{-24} respectively) to contain any molecules of the starting substance. Homeopathic medicines in which a molecule of the starting substance is unlikely to be present are variously referred to as 'ultramolecular' or ultra low dilutions (ULD), or BRAN

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[8] Calabrese EJ, Bachmann KA, Bailer AJ, et al. (2007). Biological stress response terminology: Integrating the concepts of adaptive response and preconditioning stress within a hormetic dose–response framework. *Toxicology and Applied Pharmacology*, 222:122–128.

[9] Van Wijk R, Wiegant FA. Postconditioning hormesis and the similia principle. *Front Biosci* 2011; 3:1128-38.

[10] German Homoeopathic Pharmacopoeia (Homöopathische Arzneibuch), 5th supplement to 1978 Edition, English translation (1993). London, British Homoeopathic Association, pp31–38.

(Beyond the Reciprocal of Avogadro's Number). Classical pharmacological actions in-vivo have been reported with dilutions as high as 10^{-22} mol/L and repeatedly with dilutions of $10^{-17} - 10^{-18}$.[11] Homeopathic medicines are used in low dilutions, below the 'molecular threshold', in which some of the original substance is present, and in high dilutions, in which material quantities of the starting substance are unlikely to be present.

10. Many objections to homeopathy are based on the argument 'it doesn't work because it can't work'; since there is no established mechanism whereby the ultramolecular dilutions sometimes used in homeopathy could act, they must be inactive. While it is true that the mechanism of action of Homeopathic high dilutions is not fully understood, this is not a valid objection in the face of evidence that they do have actions which are not due to 'placebo' effects, are not mediated by psychological mechanisms such as expectation, suggestion or conditioned reflexes.

11. There is a substantial body of research using animal models, human cells, plants and other organisms. The HomBRex Database on Fundamental Homeopathy Research includes details of about 1500 basic research experiments in homeopathy. Of these 830 experiments employed ultramolecular dilutions in 745 of these at least one positive result was reported. Animals were the most often used model system (n = 371), followed by plants (n = 201), human material (n = 92), bacteria and viruses (n = 37) and fungi (n = 32).[12]

12. A meta-analysis led by Prof Claudia Witt of the Charité University Medical Center in Berlin, Germany evaluated 67 *in vitro* biological experiments in

[11] Eskinazi D (1999). Homeopathy re-revisited – is homeopathy compatible with biomedical observations? *Archives of Internal Medicine*, 159;1981–1986.
[12] www.carstensstiftung.de/hombrex

75 research publications and found high-potency effects were reported in nearly 75% of all replicated studies.[13]

13. The best established and most repeated series of in-vitro experiments in homeopathy is a test tube model of the allergic response using human basophils, a type of white blood cell. The human basophil degranulation test (HBDT) is a well-established *in vitro* model of allergic response. There are now at least 17 publications based on this method, spanning over 25 years and including multi-centre and independent replications.[14] There is a consistent peak at 16C (10^{-32}), well into the ultramolecular range. These experiments have yielded insights into possible mechanisms of action. For instance it is highly specific to histamine; the effect is not induced by histidine, a close structural analogue of histamine, and it appears to be mediated by H2 receptors, since it is partly blocked by the H2 receptor antagonist drugs ranitidine and cimetidine.[15]

14. Another cellular system which has been the subject of repeated experiments over a long period is the effect of ultramolecular dilutions of aspirin on blood clotting. The effect is hormetic: ultramolecular dilutions promote clotting, the reverse of substantial doses.[16, 17] Recent work with 'knock-out' mice suggests

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[13] Witt CM, Bluth M, Albrecht H, et al. (2007). The in vitro evidence for an effect of high homeopathic potencies – A systematic review of the literature. *Complementary Therapies in Medicine*, 15:128–138.

18. Brizzi M, Lazzarato L, Nani D, et al. (2005). Biostatistical insight into the As_2O_3 high dilution effects on the rate and variability of wheat seedling growth. *Forschende Komplementärmedizin und Klassische Naturheilkunde*, 12:277–283.

[14] Endler PC, Thieves K, Frass M, Bonamin L, Scherr C, Baumgartner S. Repetitions of fundamental research models for homeopathically prepared dilutions beyond 10^{-23}: a bibliometric study. *Homeopathy* (2010);99:25-36.

[15] Belon P, Cumps J, Ennis M, Mannaioni PF, Roberfroid M, Sainte-Laudy J, Wiegant FAC. Histamine dilutions modulate basophil activation. *Inflamm Res* 2004, 53, 181-8.

[16] Lalanne M, Doutremepuich C, De Seze O, Belon P. What is the effect of acetylsalicylic acid at ultra low dose on the interaction platelets/vessel wall? *Thrombosis Res* 1990 60: 231-236.

that the effect is due to inhibition of COX-2 mediated PGI_2 production in the vascular endothelium.[18]

15. The question of how such effects might be mediated is, at present, unanswered. However there has been important progress towards an understanding in recent times. One might think that shaking water is an innocuous process, but it in fact unleashes very violent, but highly localised, processes. Homeopathic succussion causes microcavitation within water, these microcavities are very shortlived (a few microseconds), but as they implode they generate temperatures of thousands of degrees Kelvin followed by extremely rapid cooling and very high pressures (in the region 1000 atm). This in turn generates intense shock waves which propel particles in the solution at high velocity. Empirical evidence of the occurrence of microcavitation and very high, but very localised, energies, during homeopathic potentisation has recently been published.[19]

16. Another recently discovered effect of the dilution process concerns dissolved silicates. The process of succussion produces small colloidal particles of silica of around 20-40 micrometers diameter, derived from the glassware, in the water. These concentrations of silica are too low to have any direct physiological effect but have strong enzyme stabilising effects.[20]

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[17] Eizayaga FX, Aguejouf O, Desplat V, Belon P, Doutremepuich C. Modifications produced by indomethacin and L-NAME in the effect of ultralow-dose aspirin on platelet activity in portal hypertension. *Pathophysiol Haemostasis Thrombosis*. 2007; 35: 357-363

[18] Aguejouf O, Eizayaga FX, Desplat V, Belon P, Doutremepuich C. Prothrombotic and Hemorrhagic Effects of Aspirin. *Clinical Appl Thrombosis/Hemostas*, 2008 doi:10.1177/1076029608319945.

[19] Chikramane PK, Suresh AK, Bellare JR, Kane SG. Extreme homeopathic dilutions retain starting materials: A nanoparticulate perspective. *Homeopathy* (2010) 99, 231-242.

[20] Ives JA, Moffett JR, Arun P et al. Enzyme stabilization by glass-derived silicates in glass-exposed aqueous solutions. *Homeopathy* (2010) 99, 15–24

17. Recent discoveries in the area of nanotechnology, a rapidly advancing area of science which involves the use of extremely small particles (of the order of nanometres), are relevant to the homeopathic production process of trituration. Procedures used to prepare nanoparticles are very similar to trituration, involving long periods of grinding. Reducing particle size increases surface area and modifies important physicochemical properties, so that nanoparticles have a wide range of potential applications in medicine and elsewhere. A number of studies have demonstrated enhanced hormetic responses to materials in nanoparticulate form. [21]

18. Experiments using a range of physical and physico-chemical methods have reported results suggesting structural anomalies in dilutions prepared by the homeopathic method. Methods include low temperature thermoluminesence, flux calorimetry, conductometry, pHmetry Raman and Ultra-Violet–Visible (UV–VIS) spectroscopy and Nuclear Magnetic resonance (NMR).Low temperature thermoluminesence involves freezing water to the temperature of liquid nitrogen, bombarding it with x- or γ rays. Its use to investigate highly diluted preparations was pioneered by Louis Rey. The 'signature' of lithium is detectable in ultramolecular lithium chloride by this method. [22] This result has been independently verified.[23]

19. The group led by Vitorio Elia at the University of Naples has, over more than a decade, published series of papers investigating physico-chemical

[21] Iavicoli I, Calabrese EJ, Nascarella MA. Exposure to nanoparticles and hormesis. *Dose Response* (2010) 8:501-517.
[22] Rey L (2003). Thermoluminescence of ultra-high dilutions of lithium chloride and sodium chloride. *Physica (A)*, **323**:67–74.
[23] van Wijk R, Bosman S, van Wijk EP. Thermoluminescence in ultra-high dilution research. *J Alternative Complementary Med* 2006; 12: 437–443.

properties of ultramolecular dilutions. They have detected, using standard methods, anomalies of specific conductivity, heat of mixing and other parameters.[24, 25, 26]

20. Work from the Materials Research Institute of Pennsylvania State University, led by the late Prof Rustum Roy, shows that ultradilute homeopathic medicines can be distinguished from controls and each other by Raman and Ultra-Violet–Visible (UV–VIS) spectroscopy.[27, 28] These effects may be due to epitaxy, the transfer of information, not material, from the surface of one material, usually solid, to another, usually liquid. Measurement of 20MHz T1 and T2 water proton nuclear magnetic resonance relaxation rates can distinguish homeopathic dilutions of histamine from solvent at ultramolecular dilutions .[29, 30]

21. These findings suggest the existence of extended, ordered dynamics involving liquid water molecules, in the form of dissipative structures, within such

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[24] Elia V, Niccoli M. Thermodynamics of extremely diluted aqueous solutions. *Ann NY Acad Sci* 1999; 879: 241.

[25] Elia V, Napoli E, Niccoli M, et al. New physico-chemical properties of extremely diluted aqueous solutions. A calorimetric and conductivity study at 25 1C. *J Therm Anal Calorimetry* 2004; 78: 331–342.

[26] Elia V, Elia L, Marchettini N, Napoli E, Niccoli M, Tiezzi E. Physico-chemical properties of aqueous extremely diluted solutions in relation to ageing. *J Therm Anal Calorim* 2008; 93:1003-1011.

[27] Roy R, Tiller WA, Bell I, Hoover MR. The structure of liquid water; novel insights from material research; potential relevance to homeopathy. *Mater Res Innovations* 2005; 9: 93–124.

[28] Rao ML, Roy R, Bell I. Characterization of the structure of ultra dilute sols with remarkable biological properties. *Mater Res Innovation* 2007; 1(1): 3–18.

[29] Demangeat J-L, Gries P, Poitevin B et al. Low-field NMR water proton longitudinal relaxation in ultrahighly diluted aqueous solutions of silica-lactose prepared in glass material for pharmaceutical use. *Appl Magn Reson* **26** (2004) 465-481.

[30] Demangeat J.-L. NMR water proton relaxation in unheated and heated ultrahigh aqueous dilutions of histamine: Evidence for an air-dependent supramolecular organization of water. *Mol. Liquids* 144 (2009) 32-39.

dilutions.[31, 32] Dissipative structures are complex, self-organising systems, far from thermodynamic equilibrium. Within a dissipative structure there is long-range interaction between particles, and they exchange energy and matter with their environment. Examples of dissipative structures include cyclones, lasers and living organisms.

22. Turning to the clinical research literature, two reviews of the clinical research literature in homeopathy, conducted by different authors and using different methodologies have examined the clinical areas in which homeopathy is effective. The two reviews yielded similar results, both concluded that homeopathy is effective for the treatment of influenza.[33, 34] A systematic review of homeopathy for upper respiratory tract infections reached a positive conclusion.[35] A Health Technology Assessment commissioned by the Swiss Federal government, found that 24 of 29 trials were positive and showed significance or a trend in favour of homeopathy in the course of treatment when compared with placebo, or significance, a trend or equivalence when compared with conventional standard treatment.' The conclusion was '...the trial results showed probable effectiveness of

[31] Elia V, Napoli E. Dissipative structures in extremely diluted solutions of homeopathic medicines: A molecular model based on physico-chemical and gravimetric evidences. *Int. J. Design Nature Ecodynam* (2010) 5:39–48.
[32] Elia V, Napoli E, Niccoli M Thermodynamic parameters for the binding process of the OH^- ion with the dissipative structures. Calorimetric and conductometric titrations. *J Therm Anal Calorim* (2010) DOI 10.1007/s10973-010-0757-1.
[33] Mathie RT (2003). The research evidence base for homeopathy: a fresh assessment of the literature. *Homeopathy*, 92:84–91.
[34] Jonas WB, Kaptchuk TJ, Linde K (2003). A critical overview of homeopathy. *Annals of Internal Medicine,* 138:393–399.
[35] Bellavite P, Marzotto M, Chirumbolo S, Conforti A. Advances in homeopathy and immunology: a review of clinical research. *Front Biosci* (2011) 3:1363-1389 .

homeopathy for allergies and infectious diseases of the upper respiratory tract.'[36] As a result of this report homeopathy is now reimbursed by compulsory health insurance in Switzerland.

23. There have been four systematic review/meta-analyses of homeopathy as a whole (i.e. for all conditions) have been published. Of these three have reached positive conclusions; that there is evidence that homeopathy is clinically effective. The one exception is the review by Shang at al.[37] This meta-analysis was controversial, not least because its conclusions concerning homeopathy were based on only eight clinical trials whose identity was not revealed until several months after the publication of the paper, precluding informed examination of its results. The only undisputed conclusion of this paper is that clinical trials of homeopathy tend to be of higher quality than matched trials of conventional medicine: of 110 clinical trials each of homeopathy and conventional medicine, 21 of homeopathy and 14 of conventional medicine were judged to be of higher quality. 'Higher quality' equates to less risk of bias.

24. Based on the literature regarding the effectiveness of homeopathic remedies, as well as clinical experience with those remedies used by patients worldwide it is, in my opinion, improper to reach any scientific conclusions regarding the efficacy or effectiveness of any (or all) of the products named in Plaintiff's Second Amended Complaint solely by looking at whether homeopathic remedies are effective in general. In order to determine whether, for example, Hyland's Calms Forté has been falsely or misleadingly represented to provide

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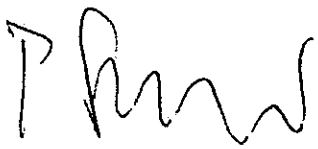
[36] Bergemann SM, Bornhöft , Bloch D, Vogt-Frank C, Righetti M, Thurneysen A, Clinical Studies on the Effectiveness of Homeopathy for URTI/A (Upper Respiratory Tract Infections and Allergic Reactions). In Bornhöft G, Matthiessen PF (eds), Homeopathy in Healthcare – Effectiveness, Appropriateness, Safety, Costs. Springer, Berlin 2011. DOI 10.1007/978-3-642-20638-2_10.

[37] Shang A, Huwiler-Muntener K, Nartey L, et al. (2005). Are the clinical effects of homoeopathy placebo effects? Comparative study of placebo-controlled trials of homoeopathy and allopathy. *Lancet*, 366:726–732.

temporary relief of simple nervous tension and sleeplessness, one needs to evaluate the ingredients in that product, and whether there is evidence to demonstrate that the ingredients do not provide such relief.

I declare under penalty of perjury under the laws of the United States and the State of California that the foregoing is true and correct. Executed this 14th day of June, 2012, at London, England.



Peter A. G. Fisher