

# **HOMOEOPATHY: A CRITIQUE**

**(IN FOUR PARTS) (MAY 1999)**

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**As presented in person to the full council of the Medicines Control Council, Pretoria, 23 July 1999.**

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**PART 1. - ARE YOU PAYING GOOD MONEY FOR NOTHING?**

**PART 2. - EVAPORATING EVIDENCE FOR EFFICACY OF HOMOEOPATHIC MEDICINE**

**PART 3. - HOMOEOPATHIC MEDICINE VS SPONTANEOUS REMISSION / PLACEBO**

**PART 4. - SAFETY PROFILE OF HOMOEOPATHY REFUTED!**

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## **PART 1.**

### **INTRODUCTION – POLITICS AND POWER IN MEDICAL FRAUD**

In published form titled:

**“ARE YOU PAYING GOOD MONEY FOR NOTHING?”**

(The title and original concept for this paper is credited to my colleague Dr Anthony Rees.)

#### **Commercial Indication Homoeopathic Products: State Sanctioned & Taxpayer Sponsored Health Fraud!**

**PSEUDO-SCIENTIFIC HOMOEOPATHIC PRODUCT MANUFACTURING COMPANIES ARE HIDING BEHIND FALSE ADVERTISING AND PREJUDICING THE ESTABLISHED SCIENTIFIC HEALTH AND THERAPEUTIC POTENTIAL OF NUTRITIONAL AND HERBAL PRODUCTS, TO FRAUDULENTLY PEDDLE THEIR PLACEBO PRODUCTS AS MEDICINES, WITH SERIOUS UNSUBSTANTIATED INDICATIONS AND EFFICACY CLAIMS, WITH STATE SANCTION, AND AT TAXPAYER'S EXPENSE.**

The proposed “listings system” (Expedited registration procedure- ERP), initiated, dominated and driven principally by the “big three” natural pharmaceutical homoeopathic pseudo-medicine companies, is a natural health suppressive and monopolistic GMP-based regulatory initiative, inappropriately favouring financial might and impractical quality rather than safety / efficacy criteria.

#### **THE POLITICS**

The Dukes Review Report, whose two external experts, not coincidentally hailed from the only countries currently enforcing the listing system, strategically endorsed what was initiated by disgraced former MCC chairman Folb, in line with a developing WHO pharmaceuticalisation / harmonisation policy. This will prejudice nutrition and herbalism via a self-favouring homoeopathy-driven compromise whereby the least scientific modality benefits disproportionately by the regressive policy position that “the criteria of demonstrated efficacy will be replaced by ‘evidence’ that the medicine is used within a particular philosophy or tradition for particular purposes”, thereby missing the central objectives of medicines regulation. Ironically, o-t-c homoeopathic indication, and especially the combination products, do not strictly qualify as homoeopathy. A concomitant compromise is that “the criteria for reliable information will be modified so that claims can be accepted which do not transcend certain specified limits”, and specifically “no reference should be made to resistant conditions, major infectious diseases, asthma, cancer and epilepsy”.

Whilst it is obvious (based on the scientific evaluations presented) that these latter limitations are entirely appropriate for over-the-counter combination homeopathic products, they are inappropriate, indeed devastatingly prejudicial to both nutritional and herbal products. Whereas considerable real scientific validation exists for nutritional and herbal substances, and this expands chrono-exponentially, the opposite pertains to homeopathic medicines, which are still struggling with hypothetical therapeutic rationale, and have yet to convincingly establish significant therapeutic efficacy for a single clinical condition.

During the apartheid era, homeopathic remedies enjoyed a unique status in the health market-place, being largely unregulated until the mid-80's, and for the next decade illegally enjoying pseudo-registration status whereby product application numbers were allocated, but registrations never processed further, since no efficacy data existed, but yet these applications were never cancelled, and these products fraudulently remain on the market with totally unsubstantiated serious indication claims, putting consumers at considerable risk. Subsequent to the democratic elections, the post-sanctions era heralded a flood of nutritional and herbal products onto the local market in competition with the local homeopathic companies, who reluctant to relinquish their apartheid-gained monopolies, increased familiarities with the now disgraced former MCC hierarchy and via the HPA executive, despite financial vested interests, negotiated the terms of reference for the listing system to preferentially suit their own local circumstances and pharmaceutical company status.

In South Africa today, only homeopathy enjoys the benefits of taxpayer's money by means of grants to its training faculties, in spite of it being the least scientific of all the complementary modalities. In the mid-70's, the Allied Professions Board closed all courses teaching self-reliant homeopathy, naturopathy, and herbalism. A decade later two Technikons opened faculties exclusively teaching non-classical pseudo-homeopathy, with syllabi essentially teaching biomedical homeopathy, a soulless hybrid in conflict with the Hahnemannian tradition. Recent graduates, no longer making their own remedies, now resort to purchasing commercial stock from the big companies. After 25 years, herbalism nearly became extinct, since with the exception of personal favours and admissions of previously disadvantaged unqualified students for political expedience, not even internationally qualified herbalists were granted registration by the new Interim Allied Professions Council, still openly exercising ideological bias in favour of homeopathy and against herbalism.

## **THE REALITY**

Homeopathy dates back to the late 1700s when Dr Samuel Hahnemann began formulating its basic principles, based on provings which have been in use for about 175 years without substantial revision. Even recent provings are of highly questionable quality, not to mention value. The doctrine is not and can never be a theory of physiology or of the effects of drugs on the organism and pathological processes. Homeopathy's elaborate symptomatic descriptions require an extreme degree of individualised case-taking. The homoeopath has little leeway in the remedy selection and must at all times be guided by the (totality of) the symptoms (1).

Whatever is not compatible with Hahnemann's three rules is excluded from homeopathy, which advocates the single remedy since the provings are never of mixtures (1). Indication products cannot qualify as homeopathy. Homeopathic success is attributable primarily to spontaneous remission, the healing power of the compassionate and reassuring consultation (1-3 hours), plus the power of placebo (belief), which are collectively estimated to contribute some 70-100% of observed benefits in controlled trials, and all of which are negated with the use of such products. This author believes that the practitioner's desire to relieve suffering has a synergistic effect, according to the maxim: "energy follows thought". The author is utterly convinced, on the basis of the latest scientific research, that the homeopathic remedy itself has no intrinsic effect. This conviction is confirmed by negative results in the most rigorous trials.

The author's position on the mere ritualistic value of homeopathic remedies are borne out by the results of placebo statistics and meta-analysis of randomised placebo-controlled trials of homeopathy which show that placebo (nothing) works better than the remedy. The most recent and comprehensive 1997 meta-analysis of 89 strict-criteria randomised placebo control trials by a German university Centre for Complementary Medicine Research concluded that there was "insufficient evidence that homeopathy is clearly efficacious for any single clinical condition" (2), the complex homeopathic remedy epitomised.

The laws of chemistry state that there is a limit to the dilution that can be made without losing the original substance altogether, (Avogadro's number), which corresponds to homeopathic potencies of 12C or 24D(X). A 30X dilution means that the original substance has been diluted 1,000,000,000,000,000,000,000,000,000,000,000,000,000,000 times. To get even one molecule of the substance in the most common 30X pills, would necessitate taking two billion of them, about a thousand tons of lactose tablets (or one hundred tons of drops). Even under the most scrupulously clean conditions, airborne dust in the manufacturing facility carry thousands of different extraneous molecules of terrestrial and even extraterrestrial origin. Similarly, the "inert" diluents used in the process have their

own vast variety of micro-contaminants. How does the emerging preparation differentiate as to which of the molecules present are intended to be potentised?

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## PART 2.

### EVAPORATING EVIDENCE FOR EFFICACY OF HOMOEOPATHIC MEDICINE COMMERCIAL O-T-C HOMOEOPATHY: SCIENCE FACT, OR SCIENCE FICTION?

After evaluating all scientific reviews of homoeopathic trials to date, even though the remedy 'appears' in many cases to perform beyond mere placebo, one has to conclude that the spontaneous remission / placebo complex, commonly and hereafter simply termed placebo (nothing), in the final analysis, is at work rather than the actual remedy itself. This is based logically on the scientifically indisputable (measurable and reproducible) existence of a reliably powerful placebo effect. (1), (2),(3),(4),(5)&(6), whereas conservative elimination of the confounding trial factors comprising considerable methodological flaws and significant publication bias (7-19), reduces any supposed favourable evidence to mere false-positives, also confirmed by subsequent rigorous trials.

I shall substantiate my taking care to choose only publications and authors known to be objective in the evaluation of complementary medicine. Data searches encompassed all published reports of controlled clinical trials, including journals, books and conference proceedings, as well as reviews and meta-analysis, covering all countries and all homoeopathic types and potencies. Overall, there were considerable positive results, especially in earlier studies, but progressively controlling for confounding factors by correctly making trials more rigorous has resulted in the scientific conclusion by homoeopathic advocate scientists, that there is insufficient evidence for the efficacy of homoeopathic medicines for even a single clinical condition (13) (which is the application of complex remedies bearing disease indications / claims). Observe the steady evaporation of presumed evidence.

Investigation started with the earliest comprehensive 1984 review by Scofield, "Experimental research in homoeopathy - a critical review" (7), which concluded that, *"It is obvious that despite much experimental and clinical work, there is only little evidence to suggest that homoeopathy is effective. This is because of bad design, execution, reporting, analysis and particularly failure to repeat promising experimental work and not necessarily because of the inefficiency of the system which has yet to be properly tested on a large enough scale. There is sufficient evidence to warrant the execution of well-designed, carefully controlled experiments. Homoeopathy has most certainly not been disproved."* Before advocates celebrate this tit-bit, they are reminded that there is more to come and that it is the absence of proof, rather than the absence of disproof that matters.

As Scofield concluded: *"It is hardly surprising in view of the quality of much of the experimental work as well as its philosophical framework, that this system of medicine is not accepted by the medical and scientific community at large."* A 1990 "Review of randomised trials of homoeopathy" by Hill and Doyon (8), covering published European studies and a wide range of pathologies, did *"not provide acceptable evidence that homoeopathic treatments are effective."* Out of 40 randomised trials, all but three had major design flaws and only one of these had reported a positive result. (8) Published in a French journal, this review received little attention outside France, especially since the conclusion was that *"proof for efficacy is inadequate"* (9)

A contemporary English review by Kleijnen et al (10) disagreed, including two trials considered to be non-randomised and seven negative by Hill and Doyon as randomised and positive (9), and concluding that *"on the basis of the existing evidence, they would be ready to accept that homoeopathy can be efficacious if only the mechanism of action would be more plausible."* (10) The Kleijnen review *"became the paper of reference, even though it was criticised for two shortcomings, in particular: 1) In the quality assessment, a crucial issue of methodological quality - handling of drop-outs/withdrawals - was not included; 2) The method of categorising results into 'positive' and 'negative' is open to bias and leading statisticians do not recommend this."* (9) Kleijnen, an authority on alternative medicine, as principal author, himself admitted several shortcomings. (10)

Kleijnen et al in their 1991 BMJ review (10) "Clinical trials in homoeopathy" commented as follows: *"The results of all studies may be seriously biased because of several methodological shortcomings. In 42 of 107 trials, there was insufficient data to check the often over-optimistic interpretation of the outcome(s). Overall, the quality was disappointing. Sometimes only some of several interventions, measurements of outcome, or data presentations met the criteria. Only 23 scored greater, and 84 less than 55 for the maximum of 100 for quality. With limited participants (often not mentioned) (less than half had over 25 patients per group), one cannot be confident that randomisation will equally divide known and unknown confounders"*. (10)

*"Publication bias is an important problem. Only 17 described the method of randomisation. Whilst 75 were double blind trials, placebo was 'described' as indistinguishable in only 31. Patients have many ways to break the code, which might explain any differences in favour of homoeopathy. Double blinding was not checked in any trial of homoeopathy. The process of producing preparations and their composition, especially herbs, differs greatly among manufacturers and hence preparations may still have pharmacological effects since it is sometimes difficult to demarcate phytotherapy (Prob.>1C/2D-2C/4D)(ST) from modern homoeopathy"*. (10)

*"A trial of very high quality by the Groupe de Recherches et d' Essais Cliniques en Home'opathie initiated by the French Ministry to retest (apparently positive) results in a new rigorous trial, found no positive evidence for homoeopathy"* (11). *"Will more such trials refute the existing 'evidence' ?"*, asked Prof. Kleijnen.(10) Boissel et al of the 1996 Homoeopathic Medicine Research Group, in report titled "Critical literature review on the effectiveness of homoeopathy: overview of data from homoeopathic medicine trials" reflected this dismal state of affairs when they stated that *"after examining 184 reports of controlled trials, they considered only 17 to be worth considering"* and concluded: *"the number of participants was too small to draw any conclusions about the effectiveness of homoeopathic remedies for any specific condition."*(12)

Dr. Klaus Linde, principal author of the comprehensive 1997 Lancet meta-analysis, "Are the clinical effects of homoeopathy placebo effects? A meta-analysis of placebo controlled trials", (13) (Centre for Complementary Medicine Research, Munich, FRG), authored a rave BMJ review of research on St. John's Wort for depression. The final author (13) was Dr. Wayne Jonas (Director, Office of Alternative Medicine, National Institutes of Health, USA). Funding included the pro-homoeopathic Carl and Veronia Carstens Foundation, Essen, FRG. (13) Acknowledged were the contributions of the documentational centres of Boiron, Dolisos and Heel. To placate sponsors, the results were interpreted as "not compatible with the hypothesis that the clinical effects of homoeopathy are 'completely' due to placebo", with an honest bottom line: *"We found insufficient evidence ( in 185 trials) that homoeopathy is clearly efficacious for any single clinical condition"*. (13)

Elation at the placatory result was further deflated by an under-reported analysis in Prescrire International announcing that: *"A thorough examination of this meta-analysis reveals design errors that make the results untrustworthy. There is nothing to suggest that homoeopathic drugs are any more effective than placebo"*. (14) What Linde et al found and why. *"The combined odds ratio for the 89 studies entered into the main meta-analysis was 2.45 in favor of homoeopathy, (reduced to) 1.66 for the 26 best-quality studies. The ratios were computed such that a result greater than 1 indicated greater effectiveness of homoeopathy. A combination of publication bias and poor-quality trials and/or other factors unaccounted for might have led to erroneous results. The evidence in our overall analysis would be more compelling if there were independently replicated, large-scale rigorous trials of defined homoeopathic approaches in at least a few specific disorders"*. (13)

To put this into perspective, a review in the journal Bandolier: Evidence-based health care, which favourably reviewed Kleijnen's ginkgo and Linde's St John's wort papers, described the results thus: *"This will be interpreted by some as signifying that homoeopathy works, but in 60% of trials, homoeopathy could not be shown to have any benefit over placebo. If this were a new treatment, we would look at it with a very cold and fishy eye. A skeptic might say, if this is the best they can do, why bother ?"*. (15) Bandolier provided a comparative quantitative analysis of the clinical categories: Overall, placebo alone beat placebo plus homoeopathy in 6 out of 10 (58%) of the trials. Where homoeopathy minimally added to placebo (allergy, neurology, rheumatology and miscellaneous), the ratio was only 4 to 3, but where placebo beat homoeopathy, the ratios significantly favoured placebo: dermatology 6/3, gastroenterology 6/3, musculoskeletal 4/2, chest infection, asthma, ENT 11/4, and surgery and anaesthesia, 8/4, all in favour of placebo. (15) (100% superiority)

*"Quality of evidence is a major problem, the mean quality score being 52%. About 2/3 were poor, 1/10 good. Many trials by advocates with high enthusiasm risks incomplete and selective reporting. Major shortcomings were evident on the clinical level. Inadequate peer-review allows other undetected 'fatal flaws'. Overall quality-assessments can mix and obscure confounding, eg. unequal distribution of prognostic factors might explain positive results; knowledge and expectations about receiving 'active' treatment can bias judgements during reporting or measurement of outcomes; dropouts, withdrawals, or inadequate follow-up can result in unequal distribution of results between groups not due to treatment effect; and multiple outcome-measures or post-hoc selection of*

*outcomes can lead to reporting false-positives. No trials met our criteria for reproducibility". Of only three qualifying industry inclusions, the combined quality scores were 48.5, 31.5 and 24 out of 100. (13)*

*"Patients, physicians, and purchasers need valid and reliable information (unencumbered by opinion) on which to make decisions. Whilst randomised placebo-controlled trials hold an important place in such decisions, it is likely that higher quality trials in homoeopathy will show less significant results. We found little evidence of effectiveness for a single homoeopathic approach on any single clinical condition. In the end homoeopathy may be found to have no value". (13) In subsequent correspondence, Linde and Jonas respond to three letters to the editor enthusing the data: "We do not share the enthusiasm. The evidence is not overwhelming". (16) Responding to prior data of this nature, a London health authority recently stopped paying for homoeopathic purchases after a decision to support only evidence based medicine led to a review of recent research, including that by the Royal Homoeopathic Hospital, which produced no evidence of clinical benefit. (17)*

In the Lancet, Prof. M Langman, (Univ Birmingham) commented: *"Only 34 trials showed adequate evidence of concealment of treatment allocation and 28 sufficient handling of drop-outs". (13) In a subsequent Lancet, Dr. A Koch, (Univ Heidelberg) wrote: "Where there is no concealment, two placebos might well differ with respect to efficacy if there is one in which one can believe more". (16) In the BMJ, Dr. M Francis-Kahn (Me'decin de l'Hospital Bichat, Paris) wrote: "One can challenge results obtained with dilutions retaining some active molecules and high dilutions in which no active molecule is present and results presented by a homoeopathic drug company. A negative report by Kleijnen is in Linde's meta-analysis positive (yet) Andrade's overall conclusion is negative. The report by Fisher (Research Director, Royal London Homoeopathic Hospital) was so poor that a critical study was published in the Lancet showing the inappropriate use of statistics. With respect to the negative best controlled study by French health authorities to confirm or contradict two previous quite poor reports, it is unfair to write that the pooled effect was in favour." (17)*

*"Publication bias is a significant problem and occurs when the chance that a trial is reported depends to some extent on the outcome of the trial. We cannot completely rule out bias as an explanation for positive results. Funnel plot of log odds ratios versus their standard errors has been widely used to detect potential publication bias. The asymmetry indicates missing negative trials. The general non-parametric selection model applied to the 89 studies confirmed that there was statistically significant publication bias and suggested this was due primarily to under-reporting of studies with statistically insignificant effects and with negative effects". (13) In the Lancet, Prof. J Vandenbroucke (Univ. Leiden) commented: "A randomised trial of 'solvent only' versus 'infinite dilutions' is a game of chance between two placebos. The authors used a funnel plot to look at the results. If there is publication bias, there should be a gap on the negative side of the plot. Linde et al find a bunch of outliers among the positives". (13) See next paragraph / page for funnel plot.*

In this regard, Vandenbroucke in the BMJ petitioned for experts' views, pointing out that *"Egger et al's funnel plot test predicts that there might be a problem because the funnel plot is asymmetrical and that the cause of the asymmetry can be anything from publication bias, willingness to please during data collection, data massage in the analysis, downright fraud or a mix of these". Matthias Egger (Univ Berne, Switzerland) responded: "Results of meta-analysis will depend on how many small or large studies are included (more positive results in smaller trials). Vandenbroucke could have benefited from a formal analysis of funnel plot asymmetry when he discussed a recent meta-analysis on homoeopathy (13), since the significant funnel plot asymmetry lent support to his assertion that bias had produced a body of false positive evidence". (18) The article's accompanying figure of the asymmetrical funnel plot signifying bias, is provided below.*

BMJ No 7129 Volume 316, Letters, Saturday 7 February 1998

Bias in meta-analysis detected by a simple, graphical test.

Bias in meta-analysis is often reflected in asymmetrical funnel plots. Vandenbroucke could have benefited from a formal analysis of funnel plot asymmetry when he discussed a recent meta-analysis of homoeopathy. (1) Significant funnel plot asymmetry (P0.001) (would have) lent support to his assertion that bias had produced a body of false positive evidence (fig). (2)

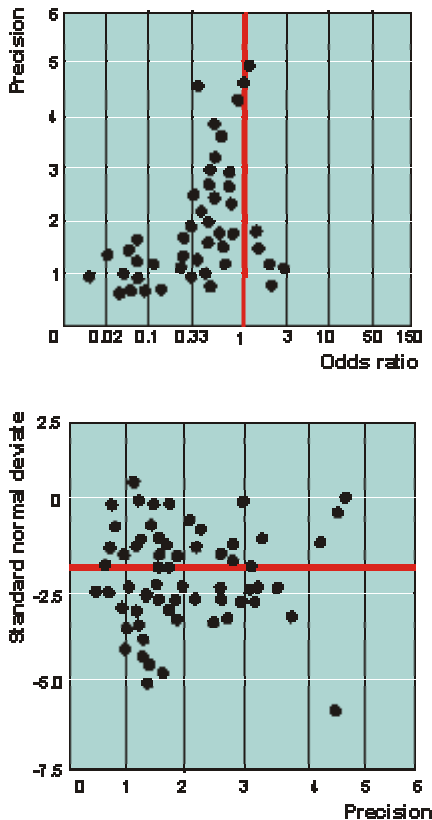


Fig 2.

Asymmetrical funnel plot of clinical trials of homoeopathy (upper panel) indicating presence of bias. The linear regression of the standard normal deviate against precision (defined as the inverse of the standard error) shows a significant ( $P < 0.001$ ) deviation of the intercept from zero (arrow). In the absence of bias, trials would scatter about a line running through the origin at standard normal deviate zero.

Matthias Egger, George Davey Smith, University of Bristol.  
 Christoph Minder Head, University of Berne.

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Prof. E Ernst, holds the world's first permanent Chair in Complementary Medicine, (Dept. Compl. Med. Univ. Exeter, UK). Prof. Ernst has published positively in medical journals on eg. garlic, St John's wort and yohimbe; extensively on placebo and on safety and efficacy of complementary medicines, and has authored textbooks on complementary medicine, garlic and homoeopathy. (19) In the *Lancet* he responded as follows: "*We compiled data from trials of homoeopathy published after Linde and colleagues' searches were completed. Linde mentions two, both of which were negative. We found four further reports and the only common factor is that none of them show any superiority of homoeopathy over placebo. Furthermore, a recent systematic review of seven controlled trials of homoeopathy for a condition judged non-clinical by Linde, included three randomised controlled trials, all of which reported negative results for homoeopathy. The picture painted by Linde may well be slightly more positive for homoeopathy than recent published evidence implies.*" (16)

The most commonly quoted allegedly positive homoeopathic trials are those of Reilly D (*Lancet* 1994; Dec) and Jacobs J (*Pediatrics*, 1994; May). Both have been methodologically criticised, yet are still widely quoted. Reilly's paper was criticised by Plasek and Zvarova. The treatment was not homoeopathic, but isopathic and the reliability of the trials analysed called into question. (20) Jacob's study was criticised by Sampson and London: 1) it used an unreliable and unproved diagnostic and therapeutic scheme, 2) there was no safeguard against adulteration, 3) treatment selection was arbitrary, 4) the data were oddly grouped and contained errors and inconsistencies, 5) the results had questionable clinical significance, and 6) there was no public health significance because the only remedy needed for childhood diarrhoea is adequate fluid intake/ rehydration. (21) Just because an article appears in a scientific journal does not mean that it should be accepted and incorporated into therapeutic regimens. It is only published initially for critique and review for possible further research.

Kleijnen, Boissel, Linde, and Ernst are all researchers who have in common an interest in complementary medicine taking its rightful place in health care, which is only possible if evidence-based. They are recognised authorities in their respective fields and are key members of the Cochrane Complementary Medicine Field. Cochrane Centres world-wide are evaluating both paradigms according to the available evidence. Dr. Ian Chalmers, Director of the UK Centre, a vociferous proponent of systematic reviews, illustrated their objectivity when he told a conference on integrated medicine in London recently that "Critics of complementary medicine often seem to operate a double standard" and that "the aim should not be to indulge in data-free arguments, but to assess the effectiveness and safety of any healthcare intervention, be it orthodox or complementary". (22)

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## PART 3.

### HOMOEOPATHIC MEDICINE VS SPONTANEOUS REMISSION / PLACEBO

Previous articles in this series proved quite conclusively that homoeopathic remedies are worthless beyond their singular ritualistic value. The local homoeopathic fraternity were invited to present any evidence to the contrary, but either declined or subsequently withdrew their efforts as the strength of this thesis became evident. Similarly, the threats of legal action evaporated as the truth of this position set in.

It was originally the intention to expose only the monopolistic and fraudulent acts being perpetrated by the big homoeopathic companies from behind a sickening charade of public beneficence, but subsequent denial by homoeopaths themselves and refusal to consider evidence led to the publication of proof of their delusion. This led to even deeper denial as their peculiar cultic faith, and or ego's (besides considerations of financial concern) stood in the way of honest reappraisal and acceptance of the facts of solid wholistic science, presented in the main by actual proponents of homoeopathy and complementary medicine.

John Davidson, a highly respected modern esoteric author noted: "It is one of the most important, yet most neglected discoveries of medicine that 'nothing' will actually cure, regularly and frequently". (1) In a British homoeopathic journal he wrote that "In homoeopathy, the issue may be even more complex: Homoeopathy it is often claimed, works through enhancing the self-healing processes; this could mean that homoeopathy simply maximises the placebo response". (2) Davidson has further written that "Even pathological and physiological symptoms can disappear when the individual's mind is convinced. If the mind is convinced ill-health will continue, then all the drug-molecules in the world will not help". (1)

Prof. Dr. W. Gaus and Dr Hogel (Univ. Ulm), developed a homoeopathic trial design which takes into account the individual selection of classical homoeopathic medicines. In a double-blind trial in patients with chronic headache,

after two months of such treatment, patients suffered from headache on fewer days, duration of headache was less severe, and intake of analgesics had been reduced. Not bad for homoeopathy, generally not very successful with headache. However, therapy was equally successful in the placebo group. (3) Is it really so wrong to expose how much of healing, (incl. orthodox), is placebo?

A recent example of blind enthusiasm is a feature in the local publication, 'Health Independent' (Sept 98), which ran a propaganda piece titled "Homoeopathy gaining acceptance throughout the world: AMA journal publishes positive study of homoeopathic medication for vertigo". The text implied that finally being featured in medical journals, attributed scientific credibility to homoeopathy, whereas anyone remotely honest would have to reach the opposite conclusion. The cited Lancet and BMJ (isopathy) and Pediatrics studies have been subsequently refuted due to flawed methodologies, and the Lancet meta-analysis failed homoeopathy on the same criteria, plus established no efficacy for any single application.

Significantly the obscure AMA Archives of Otolaryngology paper was a comparison of Vertigoheel with betahistidine as an equivalence control, rather than with placebo. Furthermore the study was unorthodox in that it was conducted by the manufacturers: Heel Inc, and this story lifted off their commercial web-site. Most telling however, is that betahistine is described as "standard conventional therapy" and Vertigoheel as being "as effective", yet the spokesperson, also the principal author, goes on to reveal the illusion of efficacy by stating that "because of the lack of effective conventional treatments, Vertigoheel fills a serious void", but thereby logically admitting that the homoeopathic treatment was as effective as a non-effective conventional treatment. Enter spontaneous remission and placebo and hey presto: efficacy!

Vertigoheel, a combination clinical so-called homoeopathic medication, interestingly does not strictly qualify as such, since in the manufacturer's own words "unlike classical homoeopathic drugs, the active ingredients in Vertigoheel are not ultra-highly diluted and the pharmacological and clinical profiles can be defined within the conventional medical paradigm, a bridge between homoeopathy and conventional pharmacology". Furthermore, I note that the most concentrated active (D3)(Conium) is a potent toxin and is within a range where it admittedly functions pharmacologically. The 70% improvement attributed to both 'active' treatments is however also well within the same range of that expected from a good placebo.

Over and above the refuted evidence from homoeopathic clinical trials, really weak arguments include 'evidence' from case studies, materia medica 'provings' (observations), and healing with animals, which simply do not constitute an iota of scientific evidence, since the circumstances and numbers are not only inadequate, they are a joke, and spontaneous remission (we are all self-healing organisms) and placebo effects easily cover the observations. Animals also respond to care and concern and professor Ernst, Chair of Complementary Medicine at the University of Exeter has described the animal argument as "weak". (4)

Science has not embraced homoeopathy, and for good reason. New Scientist Magazine commented on the recent Linde et al homeopathic meta-analysis as follows: "A few teams failing to publish a negative trial; a few claiming they tested the remedy blind when in fact they were aware which patients were getting the remedy and which the placebo, and hey presto, homeopathy nudges ahead in the pooled analysis" (5). In a recent Scientific American article, Walter Brown (psychiatrist) of Brown University School of Medicine commented that: "Although alternative medicine healers and their patients believe fervently in their effectiveness, many of these popular remedies probably derive their benefit from the placebo effect". (6)

## **75 - 90% OF ALL MEDICINE IS PLACEBO**

Most people who think that they do, don't truly understand what the placebo effect is. Spontaneous remission and the placebo effect, known as nonspecific effects, are significant phenomena that have veiled impact. The major logical error in plotting disease progress is: *post hoc, ergo propter hoc* ("after and therefore because of"). This common fallacy credits improvement to a specific treatment merely because the improvement followed the treatment. Placebo is best understood in terms of the common factors associated with various types of therapy, such as expectancy, contact with a therapist, and therapeutic alliance. Not only medication, but also other features of the physician-patient encounter may recruit the healing response. Careful analysis may be far more comforting than immediate diagnosis. (6)

The use of a placebo group is now widely considered by scientists to be crucial in demonstrating that the observed improvement is not the result of the incidental aspects of treatment. The adoption of the randomized, placebo-controlled trial (provided that statistical significance is not falsely P-valued, but is rather analysed using Bayesian methodology) ensures an elegant control, since experimenter or patient bias or a confound of patient differences with treatment method may be respectively countered by double-blinding and randomization. Although orthodoxy



controls for placebo, almost no one evaluates them, yet significantly, more placebos have been administered and confirmed than for any experimental drug. (ST) Some perceptive scholars believe that the history of medicine is the history of the placebo response. (7)

The standard textbook 30% for placebo is unrealistic low. Strauss and Cavanaugh showed placebo response rates for some psychiatric disorders: major panic disorder 51%; depression 67%; & generalized anxiety disorder 82%. (8) A recent conference reported that 50-72% of the children in a Ritalin- Placebo evaluation, were rated as being improved while on placebo in both the home and school environment regarding the severity of problems, and the number of problems demonstrated. (9) Verdugo and Ochoa, noted that after diagnostic intervention, pain/hypoaesthesia was relieved in 66,6% of patients. (10) In its most general sense, "placebo" includes spontaneous remission, the patients belief, the healer's 'energy follows thought' contribution and other incidental factors. Medicinal efficacy are exclusive effects, if any.

Kirsh and Sapirstein, Ph.D's at Univ. Connecticut and Westwood Lodge Hospital, MA, respectively, using meta-analysis to evaluate the magnitude of the placebo response against 16 antidepressant medications (including Prozac) in 19 strict criteria double-blind clinical trials with 2,318 patients, determined that the inactive placebos produced improvement of 75% of the effect of the active drug. They concluded that "experiencing more side-effects, patients in active drug conditions concluded that they were in the drug group; and this can be expected to produce an enhanced placebo effect in drug conditions and thus, the apparent (additional) drug effect may in fact be an active placebo effect". (11)

Larry Beutler, University of California, added: "translating the mean placebo response effect size reveals that 88% of patients who received only placebos experienced improvement (12% stayed the same or got worse) and only 15% gained benefit by antidepressants over placebo alone. To some it might appear obvious that the front line treatment of choice is placebo, not antidepressants". He also commented: "Collectively, the poor showing of antidepressants in this and other meta-analytic studies raise an interesting question about why and how public enthusiasm and faith is maintained in these treatments, a research question whose importance may even exceed that of the effects of the drugs themselves". (12)

Beutler opined that "One may wonder whether the increase in the number of drug patients improved is worth the cost. These results challenge certain widely held beliefs about the effectiveness of medication and have direct relevance for questions about the adequacy of contemporary methodologies to control for the effects of expectation, hope, and nonspecific treatments". (12) Kirsh stated that "Although our data do not prove antidepressants to be ineffective, it does indicate that effectiveness still needs to be established". (13) The same for homeopathic medicines, which to date have not achieved any proven success. Any statistical significance is negated by Bayesian analysis to standard arbitrary P-value results.

Dr Andrew Weil M.D. points out that "in 1842 Oliver Wendell Holmes (*echoing Voltaire*) wrote that the fact of homeopathic cures should not be admitted as evidence, because 90% of cases commonly seen by a physician would recover sooner or later, with more or less difficulty, provided that nothing were done to interfere seriously with the efforts of nature". Weil adds: "In other words, most sick people will get better no matter what you do, as long as you do not actively make them worse, a strong argument, consistent with the experience of most observers of illness, (and concludes that) we may quibble over the percentage of cases that will recover anyway, but it is certainly high, and may well be as high as 90%". (7)

## **THE ETHICAL SOLUTION**

Dr Robert Becker M.D. writes: "The minimal techniques of energy medicine are quite different from the placebo effect as depicted and condemned by orthodox medicine. The body's internal energetic systems may be accessed by the conscious mind through the use of several techniques that do not involve the addition of any external energy into the body. Standing in the shadows beyond the light of present day science, is the placebo effect which is capable of producing the desired medical effect in 60% of clinical cases overall". In line with my own conviction as a consumer, Dr Becker has suggested that "ethical practitioners of minimal-energy techniques not deceive their patients (but) tell them from the start that they are going to cure themselves by means of control over their own bodies / destinies" (14).

Such an approach would empower and ethically serve both patient and practitioner, yet most homeopaths apparently feel intimidated. Dr Weil relates a personal favourable encounter with homeopathic treatment and concludes: "I feel comfortable with the conclusion that the homeopathic remedy functioned as a placebo". (7) A key concept at a recent conference was that complementary therapies construct the consultation to give non-specific factors prominence, where especially symptom relevance and congruence between health beliefs of the practitioner and the client may be particularly significant. (15)

Although placebo may be defined as a treatment that does not have a specific effect on the illness for which it is being used, or as an intervention for which there is no scientific theory explaining its mechanism of action, placebo can be an effective therapeutic intervention. Placebo can be administered as a drug or as a procedural intervention. Multiple factors affect the ultimate intensity of the placebo response. One of these factors is the approach taken by the health care provider in administering an intervention. The medical literature is replete with clinical studies showing beneficial results of placebo administration. Physicians should attempt to better understand placebo to harness its beneficial effects, avoid nocebo or negative effects, and maximize the placebo response. (16)

Physicians throughout medical history knew three possible ways to explain the association between treatment and cure: 1. the beneficial effect of the treatment itself, 2. the healing power of nature, and 3. the placebo effect. In the modern definition by Grunbaum, a treatment is a placebo when the effect cannot be explained by the theory that describes its activity. In clinical practice the placebo phenomenon is commonly misunderstood. Most clinical pain can be reduced to at least half of its intensity by placebos. Also cough, headaches, asthma and other ailments can thus be relieved. (17) Explanatory theories are often much narrower in focus than the phenomenon they seek to explain.

There can be no final verdict on the efficacy of any, (including all orthodox) treatment until researchers start to take the placebo effect seriously. This means evaluating instead of controlling it. Patients might not mind being given dummy pills engineered to produce a convincing but harmless array of side effects. (18) The mere act of treatment, independent of its content, can elicit cures by means of the placebo response (7). Deliberate use of the placebo response will maximise patient satisfaction and treatment efficacy. If the placebo effect could be patented and bottled, it would be worth a fortune.

The placebo effect is an unpopular topic. In complementary medicine the 'aura of quackery', linked to any discussion of the placebo effect is for many, too close for comfort. At a recent conference titled "Placebo: Probing the Self-Healing Brain" Lawrence Sullivan, a historian of religion at Harvard Divinity School noted: "Nobody wants to own it. Even shamans and witch doctors would be offended by the idea that their healing powers depended on the placebo effect". Harvard Medical School anthropologist Arthur Kleinman asked: "Why is the placebo regarded as pejorative? Is it threatening to medicine?" (19) The author of this and associated reports has no gripe with homoeopathic practitioners using the homoeopathic placebo to good effect for self-limiting conditions and minor conditions under their supervision. It is however considered criminal to treat serious conditions thus, and to sell otc's to this end.

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## PART 4.

### SAFETY PROFILE FOR HOMOEOPATHY REFUTED

“A common fallacy” within homoeopathic advocacy is that “homoeopathy is both safe and effective”. Director of the Office of Complementary Medicine, US National Institutes of Health, Dr Wayne Jonas, author of a popular treatise on homoeopathy (1), reluctantly increasingly a sceptic in the light of developing research, in an article titled “Safety in homoeopathy” explains that *“The conventional reaction is that they are all placebo, can have no specific effects at all; that is, either therapeutic or toxic, and therefore are at least harmless. This attitude is reflected in the approach taken by the US Food and Drug Administration, that generally classifies homoeopathic preparations as over-the-counter drugs approved for sale without claims of effectiveness, and exempt from the standard toxicity and safety testing required of other medications”*. (2)

Jonas: *“If recent evidence indicating that homoeopathic medications may not work in identical fashion to placebo, are substantiated, and they produce specific effects, then the possibility exists that they also may produce specific adverse effects and their evaluation will require the same assessment of risk benefit ratio as any other intervention”*. (2) My thesis is that homoeopathic treatment bears definite risk that a patient with a serious non self-limiting condition will actually be receiving no effective extraneous treatment, and is also at iatrogenic risk. Jonas, corroborates: *“treatment with ineffective therapy, will result in unnecessary progression of disease and adverse effects. Some homoeopaths claim that there is a duration of action from certain potencies, even up to a year after a single dose. The author has seen cases in which individuals with chronic illness, such as gingivitis and gall bladder disease, have been told to wait for the full duration of action of the remedy, resulting in continued suffering”*. (2) Similar records exist involving children, eg treated for atopic dermatitis, pneumonia, cervical strep-lymphadenitis, and acute lymphatic leukaemia. (3)

Avogadro's law states that above a dilution of 12C/24D(X), there is unlikely to be a single molecule of the original substance. As a general rule, low potencies could, according to the “pharmaco-logical” or “immuno-logical” potential of the starting substance, produce a measurable effect, but with the exception of toxic agents, allergens and disease organisms or inoculants (nosodes/isopathy), higher potencies are unlikely to exert other than allergenic, let alone claimed beneficial effects. Loscher concurs: *“Homoeopathic drugs may exert pharmacodynamic, including toxic effects at low dilutions of D0-D6. There is no scientific effect of higher dilution except for substances with high toxic potential”*. (4) Low potencies and especially the complexes with indications, respectively violate 1, 2 and 3 of Hahnemann's Three Laws of Homoeopathy.

Definitive study of the adverse effects of homoeopathic remedies have not been conducted but even if they are merely placebos, adverse reactions (known as “nocebo effects”) can clearly still ensue from their use. (5) Professor Edzard Ernst, Chair of Complementay Medicine at Exeter University (UK), believes that *“The assumption that homoeopathy, even though ineffective, is free of risks, is questionable, since side-effects and complications associated with homoeopathy have been reported in the literature, and on the basis of which data the notion of totally risk-free homoeopathy is untenable”*. (6) Loscher and Richter, Institute of Pharmacology, Toxicology and Pharmacy in Hannover, Germany, conducting a critical evaluation of the most important homoeopathic drugs concluded: *“Several of the marketed homoeopathic drugs for treatment of animals represent a risk for both the animals and the consumer of food produced from animals”*. (7)

Aulas conducted an extensive literature search, reported and recommended: *“Little progress has been made in documenting the side-effects of homeopathic preparations. Serious adverse effects have been reported with low dilutions <4C/8D(X) given parenterally or orally. Homeopathic preparations should not be used to treat serious diseases when other drugs are known to be both effective and safe. Regardless of the condition treated, homoeopathic dilution below 5C/10D(X) and especially low decimal dilutions must not only be considered as having no proven efficacy but also as having potential dangers”*. (8)

Products misbranded as homoeopathics may also work only because of adulteration with therapeutic levels of eg steroidal drugs. (9) Because it is not mandatory, yet is actionable, homoeopathic side-effects are rarely sought and/or reported. Homoeopathy employs numerous extremely toxic substances supposedly in infinitesimal amounts. However, commercial remedies have been found to contain toxic doses. By way of one example: *“In order to test the widely held assumption that homeopathic medicines contain negligible quantities of their major ingredients, six such medicines labelled in Latin as containing arsenic were purchased over the counter and by mail order and their arsenic contents measured. Values determined were similar to those expected from label information in only two of six and were markedly at variance in the remaining four. Arsenic was present in notable quantities in two preparations. No warnings appeared on the labels”*. (10) *“Acute pancreatitis following administration of a complex homoeopathic remedy”* has been reliably reported. (11)

Montoya-Cabrera reported: *“an infant with diaper dermatitis and mild respiratory and enteral infections, treated with a homeopathic mercurial medicine: Mercurius 6a (cinnabar dilute 1 x 1000000), thereafter became seriously ill with exacerbation and dissemination of the dermatitis as well as irritability and albuminuria. Mercury urine levels were 60 micrograms/L (reference less than 10 micrograms/L)”*. An antidote chelating agent was administered. The clinical conditions improved and urinary levels of mercury decreased to normal values. The researchers concluded that *“homeopathic medicaments should be recognised as potentially harmful substances”*. (12) Stevens reported: *“a case of human thallotoxicosis, confirmed by faeces analysis, caused by the taking of a homoeopathic preparation”*. The patient rapidly developed symptoms of thallium poisoning. Antidote treatment with Prussian blue resulted in recovery. (13)

Prescrire International reported that Austrian authors (14) recorded adverse reactions in three patients. *“The first, recovering from a ‘flu like’ syndrome, took a homeopathy preparation containing compounds in 4 D(X). After three days he developed pruritis with palmar and plantar oedema followed by erythroderma. The second developed a measles-like skin rash after taking a complex botanical homeopathic mixture. The third developed anaphylactic shock requiring intensive care after taking homeopathic preparations of pollens. Re-challenge with the associated remedy was positive in all cases, and show that homeopathic preparations can induce immuno-allergic reactions without having to be injected”*. (8) Others report similarly, confirming that homoeopathy can produce dangerous side-effects as seen with orthodox drugs. (15)(16) Also Apis (crushed bee)(source Hahnemann Homoeopathy Clinic), has resulted in worsening episodes of back-pain, spreading to other parts of the complainant’s body; and both Hepar sulph (source unstated) and Silicea, (source Dolisos), has resulted in anorexia, paresthesia, psychological and systemic symptoms. (17)

Homoeopathic philosophy raises interesting questions, eg *“Tinctures possess a number of undesired side effects. Why would only the beneficial effects be amplified (“potentiated”), while all other side-effects would be attenuated?”* (18) This logically leads us to the possibility that all high potency effects might be adverse effects. Ivons has warned: *“Homoeopaths eagerly anticipate homoeopathic aggravations which are not always benign. Severe, even life threatening physical or emotional symptomology is possible in the guise of aggravation. We do a disservice to the public to tout homoeopathy as absolutely safe”*. (19) Dantas and Fisher, in a recent review of UK proving trials expressed surprise at finding that *“most provings were done because of known properties of medicinal plants“* and concluded: *“on the negative side, some recent homoeopathic pathogenetic trials are unreliable and may be positively damaging to patients”*. (20)

Dr Fredric Motz, Chairman of the Homoeopathic Association of SA, in a 17 September 1997 submission to Parliament, clearly stated: *“the public is unable to practice homoeopathy, and this goes for health shops and other health professionals. It is dangerous to practice homoeopathy without requisite knowledge and much harm can be done in this way. Arnica can cause fatal haemorrhage in certain individuals that take blood thinning agents (like Warfarin). Silica can open up old TB glands with deleterious effects. Phosphorus given to a bronchial carcinoma can easily lead to death. Caulophyllum may produce abortion at any stage of pregnancy etc. Much harm comes also from unqualified people treating or giving advice to sick people because due to lack of knowledge and diagnostic skill, this could lead to very dangerous consequences. It is wrong to assume a public right to self-medicate or buy via OTC, medicine used in homoeopathic practice”*. So even the homoeopaths themselves, or at the more honest individuals amongst them, agree with my thesis.

Jonas: *“Assessment of safety in homoeopathy is even worse. Even minimal approaches are usually not found. When done objectively, it has not indicated an innocuous nature, even with high dilutions. The author has seen a sudden severe aggravation of asthma necessitating hospitalisation. Homoeopathic literature teaches suppression or symptom shifting in which superficial treatment or symptom control results in deeper and more serious symptoms arising. Classical literature describes serious suppression arising from treatment in the hands of incompetent practitioners. Homoeopaths often see the return of old symptoms as a good sign rather than an adverse effect. Important issues arise about the interpretation of return of old pathological conditions, eg whether old pathologies might also return in serious conditions eg cancer, asthma or other diseases”*. (2) Benmeir et al report how *“a patient with a melanoma, subsequent to exclusive postoperative treatment with homoeopathic remedies, developed a recurrent tumour weighing 1.8 kg.”* (21)

German researchers report: *“Severe adverse reactions observed in association with homoeopathic remedies, including need for treatment in an intensive care unit”*. Hentschel et al recently analysed emergency room /intensive care unit admissions to the Medical Dept at the University of Erlangen to detect causal relationships between homoeopathic treatment and emergency hospitalisation. *Homoeopathic treatment had been applied for an average of 18.6 days prior to admission. (In a 1-year period) 63 patients themselves attributed their complaints to the homoeopathic treatment they had received. With one exception, all were ‘above’ X 23.”* The shocking conclusion: *“The rate of adverse reactions, 39.7 %, is (relatively) high”*. (22)

The public naively associate homoeopathy with wholesome herbs, but in addition to the above-mentioned serious safety considerations, common remedies often include highly objectionable, toxic and even disease-sourced causative organisms including cockroach, bedbug, snake, spider and insect and animal venoms, dog's milk, rabid dog's saliva, cancerous tissue, diphtheria virus, syphilitic virus, tubercular abscess pus with bacilli, and hundreds of other agents, including their inevitable combination with their vehicular milk-sugar tablets and alcohol drops, creating ethical problems for unsuspecting Jews, Muslims, Sikhs, Hindus and strict vegetarians and vegans. These products should accordingly carry mandatory explicit ingredient and warning labels, and in accordance with the lack of evidence of efficacy, bear no indications / false therapeutic claims.

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