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The growth of a lie and the end of “conventional” medicine

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Summary

Throughout its over 200-year history, homeopathy has been proven effective in treating diseases for which conventional medicine has little to offer. However, given its low cost, homeopathy has always represented a serious challenge and a constant threat to the profits of drug companies. Moreover, since drug companies represent the most relevant source of funding for biomedical research worldwide, they are in a privileged position to finance detractive campaigns against homeopathy by manipulating the media as well as academic institutions and the medical establishment. The basic argument against homeopathy is that in some controlled clinical trials (CCTs), comparison with conventional treatments shows that its effects are not superior to those of placebo. Against this thesis we argue that a) CCT methodology cannot be applied to homeopathy, b) misconduct and fraud are common in CCTs, c) adverse drug reactions and side effects show that CCT methodology is deeply flawed, d) an accurate testing of homeopathic remedies requires more sophisticated techniques, e) the placebo effect is no more “plausible” than homeopathy, and its real nature is still unexplained, and f) the placebo effect is nevertheless a “cure” and, as such, worthy of further investigation and analysis. It is concluded that no arguments presently exist against homeopathy and that the recurrent campaigns against it represent the specific interests of the pharmaceutical industry which, in this way, strives to protect its profits from the “threat” of a safer, more effective, and much less expensive treatment modality.

key words:

homeopathy • controlled clinical trials • placebo • homeopathic remedies • clinical research • pharmaceutical industries • law of similars • pharmacogenetics

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BACKGROUND

The August 2005 issue of "The Lancet" contains a coordinated attack of the medical establishment against homeopathy [1] based on a report according to which a meta-analysis of homeopathic clinical trials would show that homeopathy is no more effective than placebo. On the force of this, two other short but triumphant reports emphatically declare the "end of homeopathy" [2] and the final return of the light of "truth" in medicine [3]. As professional physicians and researchers, we would like to distance ourselves from the positions expressed in the above-mentioned papers and show that this new campaign against homeopathy is based on lies rather than truth and represents a step toward the end of "conventional" medicine rather than that of homeopathy.

THE EVER-CHANGING "TRUTHS OF "CONVENTIONAL" MEDICINE

In his "Lectures on Homeopathic Philosophy" [4], James Tayler Kent, one of the founders of homeopathy in the United States, gives us an extraordinary picture of conventional medicine: "...hence we may see, in this century, a medical convention of a thousand physicians who rely entirely upon experience, at which one will arise and relate of his experience, and another will arise and tell his experience, and the talkers of that convention continue to debate, and no two talkers agree. When they have finished they compare their experiences and that which they settle upon they call science, no matter how far they may be from the truth. Next year they come back and they have different ideas and have had different experiences and they then vote out what they voted in before.....This is the wrong direction. The science of medicine must be built on true foundation....Old-fashioned medicine denies principle and law, calls its system the "medicine of experience", and hence its doctrines are kaleidoscopic, changing every year and never appearing twice alike".

How true this last sentence is can be easily appreciated if we consider that in 1994 [5] and 1997 [6] "The Lancet" itself published two important papers in which, using arguments and methods identical to those reported by Shang [1], the authors reached the conclusion that homeopathy is *more effective than placebo*. Given the ever-changing nature of truth in conventional medicine, would it not be wiser to wait for the next Lancet report on this subject before proclaiming the end of homeopathy [3]?

WHAT'S WRONG WITH THE PLACEBO?

Detractors of homeopathy worldwide compare it to placebo to implicate its uselessness. However, for a more accurate evaluation of the placebo effect and its significance in conventional medicine, a few significant facts appear worthy of consideration:

1. the real nature of the placebo effect is unknown;
2. it has never been explained in terms of interactions between molecules and hence must be based on "immaterial" interactions, if any (something like the "vital force" in homeopathy);
3. "immaterial", and hence non-measurable, interactions are commonly discarded as unproven by conventional

medicine. On the other hand, this is the subject of the current dispute between homeopathy and conventional medicine;

4. nevertheless, conventional medicine looks at the placebo effect as something "real". As a matter of fact, controlled clinical trials are commonly planned to include a "control" group of patients to be treated with "sugar pills" and therefore the placebo effect, although mysterious and unexplainable, is still an integral part of the culture of conventional medicine. It would be good to know why homeopathy should not be treated in the same way;
5. in spite of all the above, the placebo still has a curative effect since it refers to people *cured* by the administration of a "sugar pill" instead of an active drug.

Should we still consider the placebo as a sort of unwanted effect of treatment, or would it perhaps be wiser and more advisable to try to better understand its nature and, eventually, exploit it to reduce the incidence of adverse or fatal drug reactions [7]?

"CURE THE INDIVIDUAL, NOT THE DISEASE!" (S.F. HAHNEMANN) (AND RESPECT HIM AS MUCH AS YOU CAN!)

It is a well-known fact that the US Institutes of Health (NIH) long since created the National Center for Complementary and Alternative Medicine (NCCAM) dedicated to exploring complementary and alternative healing practices in the context of rigorous science, training complementary and alternative medicine (CAM) researchers, and disseminating authoritative information to the public and professionals [8]. Although this may not necessarily be an argument in favor of homeopathy, it would appear at least bizarre to the average US citizen that his/her income is being used to finance NCCAM research on placebo or other useless drugs. On the other hand, it is also very well known that the number of people resorting to homeopathy is around 500 million worldwide [9], which is quite a figure to ponder and investigate for a type of medicine which is no more effective than placebo. Overall, Dr. Shang and colleagues, having come to the conclusion that homeopathy is not superior to placebo, do not seem to give much thought to the fact that thousands of medical professionals, hundreds of institutions, and, as already mentioned, hundreds of millions of individuals worldwide believe in homeopathy, use it, and work on it. Should we consider them all foolish, idiots, or visionaries? We prefer to leave the burden of the answer to Dr. Shang and colleagues [1]. It is a fact, however, that with this new paper, conventional medicine attempts once again to confirm its presumed supremacy not by demonstrating it with facts, but rather by dismissing anything else as false or useless.

Since its early days, homeopathy has dealt with sick individuals rather than diseases; the respect of the individual is, therefore, the cornerstone of any homeopathic treatment. Apparently, the same does not apply to conventional medicine, which continues to use its "congenital" arrogance and lack of respect for anyone else's opinions and beliefs. No wonder, therefore, that an ever-increasing number of patients resort to homeopathy as the main treatment for their ailments, and this number continues to increase in spite of the violent campaigns, inspired and largely financed by multinational drug companies, against "complementary" medicines.

THE CONTROLLED CLINICAL TRIAL: THE APOCRYPHAL GOSPEL OF "CONVENTIONAL" MEDICINE

The Lancet campaign against homeopathy was launched by experts on controlled clinical trials and it is therefore based on the unproven assumption that the CCT methodology is reliable, repeatable, accurate, and infallible. This is simply not true. In 1991, Dr. Harris L. Coulter [10], in his book "The Controlled Clinical Trial: An Analysis", reported that "CCT cannot guarantee drug safety and efficacy because the theoretical requirements of CCT are both unrealistic and unscientific". This point of view was more recently confirmed by scientists who reported that there is no evidence for large-scale CCTs other than the vested interests of the pharmaceutical industry to defy sound arguments which demonstrate that the methodology of these studies is deeply flawed [11]. As a matter of fact, CCT methodology is based on the unrealistic and unscientific assumption that any given disease shows the same characteristic features in different individuals and, therefore, can be treated in the same way. In the real world, however, there is no such thing as two identical individuals. Dr. Coulter therefore concludes: "The CCT can never tell a doctor how a given patient will react to a given drug at any given time". The relevance of individual differences in drug treatment is highlighted by pharmacogenetics, a relatively new branch of conventional medicine, confirming that this point of view does not belong to homeopathy only [12,13]. On the other hand, the unpredictability of the individual response to drugs is confirmed by countless reports of deaths from adverse drug reactions, leading US magazines and newspapers to claim that "the FDA approves deadly drugs, and delays life-saving therapies" [14], or prestigious scientific journals to declare that it is time for the creation of a new black box warning and withdrawals for prescription medications [15].

According to Dr. Coulter, the CCT has become popular primarily for political reasons [16]. Given its costs, it is used by pharmaceutical companies to limit competition and raise the costs of medications to the public. But monopolistic objectives are not the only built-in fraud feature of the CCT. Fraud in the safety testing of drugs is a strong likelihood, since investigators may receive more than one million dollars annually (in 1991!) from their testing programs. Among the most frightful examples of dishonesty, fraud, negligence, and other kinds of wrongdoing in clinical trials, the author mentions the trials of a drug designed to prevent kidney transplant rejection which led to 85 deaths among the 650 patients participating, and not one of these deaths was reported to the Food and Drug Administration (FDA). This trend towards fraud in CCTs has not changed very much, but rather increased in recent years: as reported by Nature [17] the attorney-general of New York State sued GlaxoSmithKline (GSK) for allegedly suppressing negative results of trials that tested the safety and efficacy of four different studies on Paxil. Fraud in clinical research and CCTs has been reported by some important scientific and medical journals, such as the British Medical Journal [18], Science [19], the Journal of Internal Medicine [20], and The Lancet itself [21]. With this picture in mind, the reader may now evaluate more objectively the clinical and scientific relevance of the methodology behind CCTs and finally understand why large collections of such investigations, as performed in meta-analyses, would only lead to confusing, uncertain, and misleading conclusions.

HOMEOPATHY AND CCT: INVESTIGATING GALAXIES WITH MICROSCOPES (OR CELLS WITH TELESCOPES)

It is known that pharmaceutical companies look at the CCT as the gold standard ("gold" in this circumstance having apt symbolic value) for drug testing, although, as we have seen, this is an unrealistic and unscientific procedure, heavily compromised by economic interests, dishonesty, fraud, negligence, and many other kinds of wrongdoing. But what is really wrong with CCT methodology and indicates that no comparison can be made between conventional and homeopathic medicine based on it? A practical example will clarify this crucial issue. Let us suppose that a pharmaceutical company has to test the efficacy (and safety) of the new drug "ASA" (acetylsalicylic acid) in the treatment of fever. According to CCT methodology, one would simply select a group of patients with fever, assign them, through the process of "randomization", to either the active drug (ASA) or a placebo treatment, and look for differences in response. Hence: one disease (or symptom) – one treatment.

Homeopathy, in contrast, teaches us that fever may manifest differently in different individuals and it may depend on several diverse causes. Therefore, homeopathy will use *Aconitum* to treat a fever with sudden onset, *Arsenicum Album* for a feverish, anxious, and fidgety child, *Belladonna* for a feverish child who has chills and a flushed and heated face and body, *Bryonia* for fever with strong thirst, *Chamomilla* for fever associated with teething, *Ferrum Phosphoricum* for moderate fever, *Gelsemium* for the child who sustains a fever and whose whole body feels achy and flushed, *Mercurius solubilis* for the feverish child with offensive-smelling breath, body, stool, and/or urine, etc. [22–25], continuing with a list of tens or maybe hundreds of different remedies, each with a single and extremely specific indication. It is easy to see that limiting the homeopathic treatment to one remedy for a single indication, with no further specification, would inevitably end up destroying the essence of homeopathic treatment itself, thus resulting in ineffective treatment. It is also clear that the current CCT methodology is still largely imperfect and cannot be applied to an eminently non-speculative, empirical, and pragmatic science such as homeopathy.

IS THERE ANY PLACEBO EFFECT IN VETERINARY HOMEOPATHY?

Although controversial, homeopathy has gained large popularity in veterinary medicine [26] and, as has been recently reported, its intrinsic efficacy is sometimes so convincing that evidence against it, highly desired by the veterinary medical establishment, is largely disregarded by its routine users [27]. Clinical and laboratory evidence suggests that homeopathy is effective beyond any reasonable doubt, as recently demonstrated, for example, by controlled clinical trials investigating the immunomodulating effect of water extracts of *Calendula Officinalis* in animals [28], but apparently there is no convincing evidence for the supporters of the placebo effect of homeopathic treatment.

However, the presumed or understood existence of a placebo effect in animals still deserves a few words of comment. The placebo effect is considered a psychobiological phenomenon that can be due to different mechanisms, which

include, among others, the expectation of clinical benefits. As recently reported, placebo research underscores the instability of the human mind and its somewhat dangerous tendency to be manipulated not only in a positive (placebo), but also in a negative sense (nocebo), depending on the individual psychological traits and concerns and the ongoing psychosocial context [29]. Have animals the power to reason whether a given treatment is going to work or not? Can any animal be aware of the treatment to be administered to it? Can any animal be skeptical about an alternative medical approach, as a person might? It is evident to us that homeopathy's efficacy in successfully treating animals goes a long way to debunking the claims of those who believe that its effects are "only placebo" [30].

...MORE ABOUT THE "TRUTH" IN MEDICINE

In the article entitled: "Homeopathy: the growth of truth" [3], Dr. Vandenbroucke reminds us that "the ultimate proof" of the efficacy of conventional medicine "is that it makes progress in preventing, alleviating and curing disease ever more efficiently". It is very difficult to share such enthusiasm and trust in conventional medicine if we look, for example, at the yearly tribute paid in human lives to the use (and often misuse) of toxic drugs approved for use in man after fraudulent or misconducted "controlled" clinical trials. Estimates report a death toll from adverse drug reaction of 108,000 in the United States during the year 1996 alone [31], but it is clear that this figure must be much higher [32]. Moreover, since medical research worldwide is in the hands of drug companies, it is very hard to figure out how and why they should become involved in any kind of disease prevention campaign, their business being, as it is, strictly dependent on the perpetuation of human sickness [33]. Finally, while it is clear that conventional medicine can and does alleviate symptoms, it is also evident that very often it cannot go any further than that. Lifelong treatments with corticosteroids, pain killers, antidepressants, antihypertensive, anti-diabetics, antibiotics, and chemotherapeutic agents offered to patients by conventional medicine do not exactly correspond to the idea behind the concept of the curative power of medicines.

...AND MORE ABOUT THE "END" OF HOMEOPATHY

The anonymous author of the article "The End of Homeopathy" recommends: "Now doctors need to be bold and honest about homeopathy's lack of benefit, and with themselves about the failing of modern medicine to address patients' needs for personalised care". As we have shown above, the "failing of modern medicine to address patients' needs for personalised care" largely depends on ignorance, arrogance, and disrespect for others' opinions and beliefs, so typical of conventional medicine and exemplarily represented in the last Lancet paper on homeopathy. As for the "boldness" and "honesty" doctors should adopt in reporting homeopathy's presumed lack of benefit, we would like to remind the reader that the effectiveness (and safety) of homeopathy is demonstrated beyond any reasonable doubt by the number of patients resorting to it and the countless cures reported worldwide for about two hundred years, with no side effects. The same, obviously, does not apply to conventional medicine, and this is the reason why we would rather like to recommend boldness and honesty to all those physicians who:

- a. under the sponsorship of pharmaceutical companies and because of it conceal year after year the hecatomb of deaths, adverse drugs reactions, and similar disasters from the public view by referring and publishing only the positive results of their controlled clinical trials;
- b. by using CCT methodology contribute to the FDA approval of prescription drugs such as Rezulin, Lotronex, Propulsid, Redux, Pondimin, Duract, Seldane, Hismanal, Posicor, Raxar [34], just to mention a few examples, that have had to be withdrawn from the market since 1997 because of harmful and potentially lethal side effects;
- c. in spite of all this information continue (or pretend) to ignore that adverse drug reactions are between the fourth and sixth leading cause of death in the USA [35] and that the real figure is largely underestimated [32], thus implying that the true amount of human lives annually sacrificed for the sake of the business of drug companies **must** be kept concealed from the public.

CONCLUDING REMARKS: "CUI PRODEST" (WHO'S AFRAID OF HOMEOPATHY?)

Any open-minded physician should reasonably welcome new treatments such as homeopathy which show effectiveness and lack of toxicity. The same should apply to patients who, with "unconventional" medicine, can finally fulfil their need for less toxic drugs, individualized treatments, and a closer relationship with their doctors. But what about the drug companies? The growing popularity of homeopathy and complementary medicine represents the most serious challenge and is a constant threat to their multi-billion-dollar business. No wonder, therefore, that they would invest considerable amounts of money in detractive campaigns against homeopathy, even if with poor results.

Given all the above, we believe that no bold and honest person, whether physician, scientist, or researcher, should continue to support the drug industry and its businesses, at least not until it becomes clear to all that medicine is one, and that its only and higher scope is curing of the sick.

REFERENCES:

1. Shang A, Huwiler-Muntener K, Nartey L et al: Are the clinical effects of homoeopathy placebo effects? Comparative study of placebo-controlled trials of homoeopathy and allopathy. *Lancet*, 2005; 366: 726-32
2. No Authors: The end of homeopathy. *Lancet*, 2005; 366: 691-92
3. Vandenbroucke JP: Homeopathy and the growth of truth. *Lancet*, 2005; 366: 691-92
4. Kent JT: Lectures on Homeopathic Philosophy. B. Jain Publishers Ltd, 1999; 41-46
5. Reilly D, Taylor MA, Beattie NGM et al: Is evidence for homoeopathy reproducible? *Lancet*, 1994; 344: 1601-6
6. Klaus L, Clausius N, Ramirez G et al: Are the clinical effects of homoeopathy placebo effects? A meta-analysis of placebo-controlled trials. 1997; 350: 834-43
7. Di Blasi Z, Reilly D: Placebos in medicine: medical paradoxes need disentangling. *BMJ*, 2005; 330(7481):45
8. <http://nccam.nih.gov/about/aboutnccam/index.htm>
9. Trivieri L, Amderson JW eds: Alternative Medicine: The Definitive Guide. Celestial Arts-Berkeley, 2002; 270
10. <http://www.alkalizeforhealth.net/Lfradulentresearch.htm>
11. Penston J: Large-scale randomised trials – a misguided approach to clinical research. *Med Hypotheses*, 2005; 64(3): 651-57

12. Shah RR: Pharmacogenetics in drug regulation: promise, potential and pitfalls. *Philos Trans R Soc Lond B Biol Sci.* 2005; 360(1460): 1617-38
13. Hiratsuka M, Sasaki T, Mizugaki M: Genetic testing for pharmacogenetics and its clinical application in drug therapy. *Clin Chim Acta.* 2005; [Epub ahead of print]
14. http://www.lef.org/magazine/mag2004/may2004_aws1_03.htm
15. Lasser KE, Allen PD, Woolhandler SJ et al: Timing of new black box warnings and withdrawals for prescription medications. *JAMA.* 2002; 287(17): 2215-20
16. Trivieri L, Anderson JW eds: *Alternative Medicine: The Definitive Guide.* Celestial Arts, 2002; 44-59
17. *Nature.* 2004; 429(6992): 589
18. White C: Suspected research fraud: difficulties of getting at the truth. *BMJ.* 2005; 331(7511): 281-88
19. Hangmann N: Scientific misconduct: cancer researchers sacked for alleged fraud. *Science.* 2000; 287(5460): 1901-2
20. Sleight P: Where are clinical trials going? Society and clinical trials. *J Intern Med.* 2004; 255(2): 151-58
21. Hoeksema HL, Troost J, Grobbee DE et al: Fraud in a pharmaceutical trial. *Lancet.* 2000; 356(9243): 1773
22. <http://www.healthy.net/scr/article.asp?ID=1640>
23. <http://www.homeopathyhome.com/reference/organon/organon.html>
24. <http://www.homeoint.org/books/kentrep/>
25. Kent JT: *Repertory of the Homeopathic Materia Medica.* B. Jain Publishers LTD. Reprint edition - 2003
26. Hektoen L: Review of the current involvement of homeopathy in veterinary practice and research. *Vet Rec.* 2005; 157(8): 224-29
27. Hektoen L: Investigations of the motivation underlying Norwegian dairy farmers' use of homeopathy. *Vet Rec.* 2004; 155(22): 701-7
28. Barbour EK, Sagherian V, Talhouk S et al: Evaluation of homeopathy in broiler chickens exposed to live viral vaccines and administered *Calendula officinalis* extract. *Med Sci Monit.* 2004; 10(8): BR281-BR285
29. Coiloca L, Benedetti F: Placebos and painkillers: is mind as real as matter? *Nature Reviews Neurosciences.* 2005; 6: 545-52
30. Trivieri L, Anderson JW eds: *Alternative Medicine: The Definitive Guide.* Celestial Arts, 2002; 274
31. <http://www.heall.com/body/healthupdates/drugs/adversedrugs.html>
32. Chyka PA: How many deaths occur annually from adverse drug reactions in the United States? *Am J Med.* 2000; 109(2): 122-30
33. http://www4.dr-rath-foundation.org/HEALTH_FOR_ALL_BY_THE_YEAR_2020/index.htm
34. <http://www.healingdaily.com/conditions/pharmaceutical-companies-2.htm>
35. Lazarou J, Pomeranz BH, Corey PN: Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-analysis of Prospective Studies. *JAMA.* 1998; 279: 1200-5