The North Texas Skeptic

The Newsletter of The North Texas Skeptics

Volume 15 Number 7 **www.ntskeptics.org** **July 2001**

In this month's issue:

Clinical Research in Homeopathy: A Limited Skeptical Review and Analysis (Part II)

By Daniel R. Barnett

Last month, we reviewed a clinical study evaluating the use of homeopathy to treat childhood diarrhea in Nicaragua. We'll be discussing a study this month dealing with homeopathic treatment of hayfever and the placebo hypothesis, after which we'll discuss meta-analyses of homeopathic clinical trials.

Testing the Placebo Hypothesis with a Homeopathic Hayfever Remedy

Skeptics have often attributed any claims of medical benefit from the use of homeopathy to the placebo effect, especially if a self-limiting illness such as the common cold is alleviated. A team of researchers led by David Taylor Reilly of the Glasgow Homoeopathic Hospital conducted a study to test the placebo hypothesis; the trial was published in the October 18, 1986, issue of The Lancet and is also cited by homeopaths on a frequent basis.

Reilly and his associates randomly allocated patients with seasonal rhinitis to either a homeopathy group or a placebo group, each with 79 patients. The first group received a 30C homeopathic preparation of mixed grass pollens associated with hayfever in Great Britain; the second group received an identical placebo. A 100mm visual analog scale (VAS) of overall symptom intensity was used as the main measure of response. According to the researchers:

> Patients taking a homoeopathic preparation showed a greater improvement in symptoms than those taking a placebo. This difference was reflected in a reduced need for antihistamines, increased in significance when adjusted for pollen count and time of season, and was confirmed by the doctors' assessments.[1]

Stating that aggravation of symptoms is "a well-recognised initial response to a homoeopathic stimulus," Reilly et al mentioned that 21 patients had aggravations in the homeopathy group as opposed to 11 in the placebo group. A repeat

measures analysis of covariance was performed on the weekly scores of 89 patients who lived within 40 kilometers of pollen traps in Glasgow and London in order to rule out the explanation of treatment response by differences in pollen count.[2]

Response to the trial was often critical. One respondent labelled the study as "the first randomised, double-blind trial of one placebo against another." In addition to faulting the trial for subjective assessment of response, he mentioned that symptom aggravation was considered a "response" in the homeopathic group but labelled "natural progression" in the placebo group.[3] M.F. Khan of the Hôpital Bichat in Paris suggested that the placebo should have been a drop of water or saline potentized in the same method as the active medication, due to the possibility of trace contamination. He also stated that no further information about the remedy's final composition was provided.[4]

Reilly et al responded to the charge of inconsistent assessment of symptom aggravation by stating that "Our data demonstrating a greater rate of symptom aggravation in those receiving the potency are rejected without an alternative explanation being advanced…we merely commented on the strikingly dissimilar numbers in the two groups showing this pattern." Referring to Khan's criticisms as "informed but misplaced," the researchers informed Khan how the risk of cross-contamination by air or container was eliminated, and they also stated that the trial examined the clinical effect of homeopathic potencies, not the chemical composition of the medications used in the trial.[5]

As in the Pediatrics study, there appears to be no definitive proof that relief is due to homeopathic intervention. While skeptics have suggested the placebo effect in the past, the responses to the BMJ study demonstrate that the placebo argument is not the only skeptical response to a demonstration of homeopathy's reputed efficacy in clinical studies.

Meta-Analyses and Methodology of Homeopathic Trials

Only two clinical trials of homeopathic therapy have been discussed, but the overall body of homeopathic research is broader than many skeptics might realize. Therefore, it is worth considering how well other similar studies hold up under scrutiny.

After reviewing 89 placebo-controlled trials of homeopathy that were documented in MEDLINE, EMBASE, specialized homeopathic and complementary medicine registries, and conference proceedings and abstract booklets from several homeopathic meetings, a team of medical investigators published a meta-analysis of the trials in the September 20, 1997, issue of The Lancet. The researchers, headed by Klaus Linde, MD, stated that the results of their meta-analysis were not compatible with the hypothesis that homeopathy's clinical effects were completely due to placebo, but found insufficient evidence that homeopathy is clearly efficacious for any single clinical condition. They recommended that further research on homeopathy is warranted provided it is rigorous and systematic.[6]

Linde and associates discussed two issues that complicated the interpretation of their findings: an apparent publication bias against small negative trials and the overall quality of the studies included in the meta-analysis, with two-thirds of the trials deemed as "methodologically poor." According to the researchers, however, this was not deemed to be an adequate explanation of their results:

> Much of this research reflects the lack of infrastructure needed to conduct good studies and develop appropriate research strategies in this area. Many trials were "low-budget" and done by advocates with high enthusiasm. This risks incomplete and selective reporting. In addition, major shortcomings of these trials were evident on the clinical level (definition of the condition, clear and reliable outcome measures, &c). However, an analysis restricted to only the very best subset of these trials reduced, but again did not eliminate, the effect found (odds ratio of high-quality trials, 166).[7]

Another meta-analysis of clinical trials of homeopathy included only randomized trials with a clearly defined primary outcome. Published in the European Journal of Clinical Pharmacology, the meta-analysis examined 16 trials for a total of 17 comparisons (one trial had three treatment groups, therefore analyzing data for two comparisons). As in the Lancet meta-analysis, the researchers found evidence that homeopathy was more effective than placebo. Once again, however, low methodological quality of the trials weakened such evidence, and studies of high methodological quality were more likely to be negative. The authors also stated that further high-quality studies were needed to confirm the previous results.[8]

Apparently, problems with methodology and reproducibility of homeopathic trials can be documented as far back as the experiments performed by Samuel Hahnemann, the founder of homeopathy. In 1790, while examining the effects of cinchona bark on the treatment of marsh fever (now known as malaria)[9], Hahnemann took four drams of cinchona twice a day and experienced fever-like symptoms as a result. This led Hahnemann to conclude that cinchona cures fever by producing the symptoms of fever, hence the birth of the homeopathic maxim simila similibus curentur, or "like cures like."

Although evidence-based medicine was in a very basic and crude form in the late 18th century, physicians still maintained that the validity of any medical treatment depended on whether its alleged benefits could be reproduced. According to researcher Steven Ransom, the cinchona experiment was not exempted:

> When Hahnemann's peers did test cinchona on themselves, they found that no one could reproduce the symptoms of fever Hahnemann claimed he had experienced. Incredibly, to this day no one has been able independently to repeat Hahnemann's cinchona experiment, the experiment that shaped the first principle of homoeopathy.[10]

Homeopaths may have accumulated research data for 200 years, but how reliable is the data? Judging from Hahnemann's original tests and the problems with maintaining a high quality of methodology in recent clinical trials of homeopathy, the results of such investigations are still regarded as being highly questionable at best.

Love the Homeopath, Hate the Homeopathy?

As skeptics, we insist that consistent logic, compelling evidence, and rigorous investigation are indispensable tools of any effective medical discipline. It is imperative that any scientific theory must be examined with rationality, diligence, and the ever-present need to provide the best health care possible for those who need it. The same applies to homeopathy.

Whenever a homeopath confidently informs me that I state that homeopathy does not have any good research because I am not familiar with the scientific literature, I can confidently respond that not only have I perused it, but so far I am still unconvinced. I understand that homeopaths often have strong and sincere feelings concerning the efficacy and scientific validity of their treatments, but my argument is against the homeopathic discipline, not necessarily against the practitioner.

Many homeopaths possess reputable medical degrees, embracing evidence-based biological foundations of disease, and some have made tremendous contributions to the advancement of medical science. For example, the prominent Canadian homeopath Alexander Griffith was willing to use conventional medicine instead of homeopathic preparations to treat a case of diphtheria that plagued his son, Harold.[11] As it turns out, the boy would grow to manhood and assume his own medical practice. Harold R. Griffith, MD, who was no stranger to homeopathy in his own practice,[12] became the first physician to demonstrate the effective use of curare in general anesthesia in 1942.[13]

With all of these factors considered, however, where does the homeopathic movement go from here?

Favorable reports on homeopathic therapy are still making their way into medical journals. Reilly et al have produced another study evaluating homeopathy's value in treating allergic rhinitis.[14] Jacobs and associates have also published a recent study evaluating homeopathy's ability to treat pediatric ear inflammation.[15] In addition, a team of researchers from the Uniformed Services University of the Health Sciences and the Walter Reed Army Institute of Research have presented data to support the claim that pre-exposure of neuronal cells to extremely high dilutions of glutamate (up to 10^{-30} M) can protect against subsequent exposure to toxic levels of glutamate.[16]

In addition to the benefits of academic recognition, the financial stakes in America are also considerable. The National Center for Complementary and Alternative Medicine, funded by the National Institutes of Health, has recently awarded a $250,000 to a team of researchers led by Iris Bell, MD, PhD, of the University of Arizona's Program in Integrative Medicine. The money will be used to fund a trial that studies homeopathy's effectiveness in treating fibromyalgia.[17] It is one of the few modern American studies of homeopathy to receive government funding.

Spurred by controversial reports that seem to indicate a substantial increase in alternative medicine use and expenditures such as the one published by Eisenberg et al in the November 11, 1998, issue of *JAMA*,[18] many homeopaths may also push

for a greater measure of insurance coverage, standardized educational curricula and credentialing, and government approval for homeopathic therapy on a nationwide level.

Still, the central questions of whether homeopathy works and how it works remain unanswered. The Lancet meta-analysis provoked various responses from its readers, some of it questioning whether a rational basis for examining homeopathy is warranted. Jacques Benveniste, whose controversial "memory of water" theory has been cited as a possible mechanism for homeopathy's action, labelled some of the negative commentaries as "a clear-cut example of circularity." He explained:

> Recently, we submitted an article to a reputable journal on transmission of a specific molecular signal via the amplifier…the paper was turned down on the grounds that we could not exhaustively explain the underlying mechanism. This action amounts to turning down a paper on a novel stellar object because science does not have a final and definitive understanding of the universe. And so, the circle is complete; our advance in basic research goes unrecognised because it remains to be elaborated in scientific debate. The clinical data will be dismissed because of the absence of a theoretical explanation. *Ite missa est*.[19]

Is this, however, a fair assessment of the critical response to homeopathic therapy? It is true that some aspects of evidence-based medical practice remain controversial, such as the diagnosis and treatment of attention deficit hyperactivity disorder (ADHD). Although the etiology of ADHD remains unclear and the diagnosis is still largely subjective, there still seems to be enough in the way of reproducible evidence to indicate that ADHD is very probably a legitimate neuropsychiatric syndrome where treatment with stimulants such as methylphenidate seems to have a positive effect. Of course, these assertions are still subject to revision pending further research, but many skeptics are still looking for a similar degree of reliability in the results produced by homeopathic trials.

The clinical evaluation of homeopathy still presents problems due to inconsistent and/or subjective analysis of results, low methodological quality of clinical trials, and the ongoing need to quantify homeopathic concepts of vitalism and "energy medicine" within an evidence-based framework. Homeopathy must resolve these controversies before it can hope to claim a place at the table of modern medical theory and practice.

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[9] *Cinchona* is a genus of trees native to South America. 30 years after Hahnemann's cinchona experiments, Joseph Pelletier isolated the alkaloid quinine from cinchona bark. The efficacy of quinine and other cinchona-based alkaloids in treating malaria has been demonstrated repeatedly in clinical settings.

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FTC Compromises Cancer Quackery in Mesquite

By Daniel R. Barnett

Jaguar Enterprises, a small company that has set up shop in the Texas town of Mesquite, has just been reined in by the Federal Trade Commission (FTC) for making some big claims about some little gadgets.

An ongoing FTC project called "Operation Cure.All" targets distributors of health-related supplements and devices suspected of making unfounded medical and safety claims for health-related products advertised on the Internet.

On June 14, 2001, the FTC announced enforcement actions against six distributors, including Jaguar Enterprises, who were accused of violating the Federal Trade Commission Act by making false or misleading claims about various dietary supplements and medical devices. The announcement marked the fourth group of targeted enforcement actions produced by Operation Cure.All.

Jaguar Enterprises, which is owned and operated by Michael Forrest, sold many devices based on the work of Robert C. Beck, DSc, a physicist who claims that blood electrification is an effective treatment (if not an outright cure) for many serious ailments.

Beck devices sold by Jaguar Enterprises included the Black Box, advertised by Jaguar as being able to "reverse many 'incurable' viral & bacterial conditions, including AIDS, Cancer, Chronic Fatigue Syndrome, Gastritis, Herpes, Hepatitis, Lupus, Gulf War Syndrome (GWS), & Rheumatoid Arthritis." According to Jaguar's on-line literature, the Black Box emits an alternating polarity signal in a user-defined strength of 1/4 Hz, 4 Hz, and 100 Hz. The signal supposedly inhibits viruses from penetrating into cells where they can reproduce, making it easier for the immune system to expel them from the body.

Jaguar also sold a Magnetic Pulser, credited by the company with neutralizing viruses and bacteria with a strong magnetic

pulse produced by the device every 5 seconds. The pulses, when administered as directed by Jaguar, supposedly induced an electric current that allegedly circulated lymph fluid and knocked out microbial nasties plaguing the user. For people with cancer and herpes, Jaguar recommended the Magnetic Multi-Pulser, which emanated a stronger bipolar 5 kHz magnetic field every second.

In addition to the Beck devices, Jaguar sold various instruments based on the work of Royal Raymond Rife (1888-1971), who claimed that cancer was caused by bacteria and that such bacteria could be destroyed by specific radio waves. Jaguar provided testimonials from people who claimed that use of their own version of the Rife Frequency Generator was providing effective relief for patients suffering from multiple sclerosis, stroke, and certain cancers.

Medical science has yet to confirm any of the claims touted by Jaguar Enterprises concerning its devices, and Jaguar has yet to produce a list of competent clinical studies demonstrating the alleged curative properties of these devices. This fact prompted the FTC to take action against Jaguar for using "false and misleading" advertisements to sell their products.

As an aside, Jaguar's mailing address in Mesquite is "1515 N. Town East Blvd., Suite 138-427." The "suite," however, appears to be nothing more than a private PO box at a local branch of Mail Boxes Etc. It's not an uncommon practice for small businesses, but representing a PO box as a suite could be construed by some folks as a bit dubious.

Under the terms of its proposed consent agreement with the FTC, Jaguar Enterprises admits the jurisdictional facts set forth in the FTC complaint but denies violating the Federal Trade Commission Act. However, they have also agreed not to make any false or misleading claims about their products. In addition, Jaguar must offer its customers a full refund for products that were purchased from Jaguar, including the Black Box, the Magnetic Pulser, and the Rife Frequency Generator.

Michael Forrest is currently asking supporters who have purchased devices from Jaguar in the past to write letters to the FTC asking that the proposed consent agreement be retracted, thus eliminating the refund program. The consent agreement will be subject to public comment until July 16, 2001, when the FTC will decide whether to make the agreement final. Stay tuned.

The other five companies targeted in the recent phase of Operation Cure.All are Panda Herbal International, aka Viable Herbal Solutions (Bensalem, Pennsylvania), ForMor International (Conway, Arkansas), MaxCell BioScience, aka Oasis Wellness Network (Broomfield, Colorado), Aaron Company (Palm Bay, Florida), and Western Dietary Products, aka Western Herb & Dietary Products (Blaine, Washington).

These companies have been charged by the FTC with making false and unsubstantiated medical and safety claims for preparations of hypericum (St. John's wort), colloidal silver, ephedra, and other substances. In addition, Western Dietary Products has been cited for selling various herbal compounds and a Hulda Clark-style "zapper" device for curing cancer, Alzheimer's disease, HIV/AIDS, and other maladies. Their "Cancer Cure Organ Package" sold for $997.90, while their "Diabetes Cure" retailed for $1089.95.

All of the companies except for Western Dietary Products agreed to settle their charges against the FTC, which announced the proposed settlements on June 14, 2001, for public comment. As in the case with Jaguar Enterprises, the companies have agreed to cease all false and unsubstantiated claims for their products. Panda Herbal, ForMor, and Aaron Company must supply warning labels for their supplements as directed by the FTC detailing potential drug interactions and/or adverse effects from taking supplements containing St. John's wort or ephedra. MaxCell BioScience has also been ordered to pay $150,000 in consumer redress to the FTC. As for Western Dietary Products, the FTC has filed a complaint in the U.S. District Court for the Western District of Washington against the company.

Further details concerning the charges and settlements can be found on the Federal Trade Commission Web site at this address:

Http://www.ftc.gov/opa/2001/06/cureall.htm

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No Comment

[Urine] is a divine nectar, with supernatural qualities. After all, as the Bible says, "the life (or life-force) of the flesh is in the blood," and as urine comes from the blood, it contains that "life-force." Imbibed fresh and warm, it is a living food, and a nourishing drink, that is also cleansing, as well as medicinal.

— Bob Silverstein, NUT (Naturopathic Urine Therapist)
http://www.possumpages.com.au/bbc/arkive/urinea.htm

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What's new

by Robert Park

[Robert Park publishes the What's New column at http://www.aps.org/WN/. Following are some clippings of interest.]

THE BELIEF GENE: IS CREDULITY ENCODED INTO HUMAN DNA?

[WN — Friday, June 1] It's happened again. A notorious believer in cold fusion has revealed that he knows that magnet therapy works. At a meeting on UFOs, you'll find yourself in a room full of believers in everything from mental telepathy to homeopathy. Did belief confer some survival advantage on our primitive ancestors? Perhaps the Pleistocene forest was too scary to face without a belief in magic. The belief gene may cause more trouble than "fat gene."

FLASH! BUSH IS RUMORED TO HAVE CHOSEN A SCIENCE ADVISOR.

[WN — Friday, June 22] You may recall that back in March the President reactivated PCAST, the President's Council of Advisors on Science and Technology, with Silicon Valley venture capitalist Floyd Kvamme as co-chair. The other co-chair was to be the White House Science Advisor, but there was no Science Advisor, even as the President waded into deep water on global warming and missile defense. But today, it is all over Washington that Jack Marburger, an APS member and the Director of Brookhaven National Laboratory, has accepted the job.

DEFINING SCIENCE: WHY DO CATTLEMEN WEAR HIGH BOOTS?

[WN — Friday, June 22] A bill to define science, HR3344, is under consideration in the Oregon Senate. The definition is taken directly from a statement titled "What is Science?" adopted two years ago by the APS Council. The principal support for the bill is from the Oregon Cattlemen's Association. But why, I can hear you asking, are the cattlemen concerned with how science is defined? You may want to step carefully as we attempt to walk through that barnyard: There is a move in Oregon to clean up its streams, and cows B well, you know what cows do. Anyway, the cattlemen want to counter the peer-reviewed scientific arguments of environmentalists. In the words of a spokesman for the OCA, "Currently, anyone can define what will be called science... The term `peer-reviewed science' could mean a review by a neighbor or friend." Squish!

GLOBAL WARMING: IS THE SCIENTIFIC DEBATE COOLING DOWN?

[WN — Friday, June 8] The National Academy this week delivered a report on global warming, requested by the Bush administration. While emphasizing the need for additional climate research to reduce uncertainties, the report concluded that global warming has taken place in the last 50 years as a result of human activity. According to the report, this conclusion "accurately reflects the current thinking of the scientific community." Indeed, there are hints of a scientific consensus. Rather than scoffing at the idea, critics now seem to argue that if there is warming, it's probably good for us.

EMF: ABC NEWS DISCOVERS CANCER CLUSTERS.

[WN — Friday, June 8] Three older men, working in the same office in Albuquerque, NM, came down with breast cancer. Male breast cancer is a fairly rare disease, suggesting a possible environmental cause. Monday, they appeared on ABC Good Morning America, with their lawyers, to discuss what Diane Sawyer called a "chilling medical mystery." Guess what? They solved the mystery. It had to be the electromagnetic fields from a power vault next to their office. Never mind that other offices have power vaults and no male breast cancer. There was no statistician on the show to discuss clustering, no cancer researcher to discuss the results of epidemiological studies and no scientist to explain why EMF at power line frequencies cannot create mutant strands of DNA.

SEEING STARS: INDIA SEEKS TO RENEW THE "SCIENCE" OF ASTROLOGY.

[WN — Friday, June 29] A couple of weeks ago, WN registered shock when a state agency in Washington authorized a college to issue degrees in Astrological Studies. Several readers pointed out that the situation is far more serious in India, where the University Grants Commission informed universities of the "urgent need to rejuvenate the science of Vedic astrology in India." You will not be surprised to learn that major universities in India are in a fierce bidding war to see which will be selected to start new courses in Vedic astrology. It is not unlike the competition in the US to set up departments of alternative medicine to attract federal funds.

CELL PHONES: A CHURCH STEEPLE CAN BE A "DUAL-USE" TECHNOLOGY.

[WN — Friday, June 29] Claims that cell phone radiation is bad for your health, are often embraced by people whose real objection is to the ugly towers erected in their neighborhoods. Church steeples, by contrast, are generally regarded as picturesque. You can see where this is headed. In Connecticut, and presumably elsewhere, cell phone providers are busy cutting deals with churches. It seems that, concealing an antenna in a church steeple does not interfere with more spiritual forms of communication.

Bob Park can be reached via email at opa@aps.org

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Skeptical ink

By Prasad Golla and John Blanton


I am a pet psychic. I can communicate with live or dead pets.
See that dead dog lying on the side of the road. It's right now in pet heaven chasing a limosine.
Should I bite him now or while he is going home.
Collie Blanton

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