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

By Daniel R. Barnett

For a successful technology, reality must take precedence over public relations, for nature cannot be fooled. – Richard Feynman

Here's a bold statement from Frank King, DC, a North Carolina chiropractor who advocates the use of homeopathic medications:

Whenever critics may say that homeopathy does not have any good research, we can confidently inform them that they are not familiar with the scientific literature. Homeopathy has an impressive accumulation of statistics that has been acquired over the last 200 years...In an age when medicines have a rapid turnover due to harmful side effects or ineffectiveness, homeopathy has stood the test of time. As basic truths will always exist, so have the remedies of homeopathy.¹

This sentiment is apparently shared by a growing number of people who have embraced the use of homeopathy, some of whom can be found in the American and British entertainment industries. On the advice of her chiropractor, actress Mariel Hemingway started using Zicam, a homeopathic nasal gel-spray that supposedly shortens the duration of the common cold; she now calls it her family's "secret weapon" against colds.² Jane Seymour, who played the title character in *Dr. Quinn, Medicine Woman*, frequently administers homeopathic medications to herself, her children, and fellow actors; her sister, Annie Gould, is a homeopathic doctor.³ Also, Suzanne Somers of *Three's Company* fame recently told Larry King that, against her doctors' advice, she has been taking a homeopathic preparation of mistletoe instead of a more traditional regimen of chemotherapy to fight breast cancer.⁴

It has been approximately 200 years since German-born physician Samuel Hahnemann codified the methods and basic theories of homeopathy. Unfortunately, attempts to explain the mechanism of homeopathy in scientific terms still remain few and far between – partially because homeopaths have yet to reach a definite consensus on how homeopathy works or even if it's that important to know how it works.

Dana Ullman, MPH, states in his booklet *A Beginner's Guide to Homeopathy* that "Although there are various theories about how and why the small doses act effectively, most people are more interested in knowing that these doses are effective, rather than technical or theoretical explanations that try to describe why they work."⁵ Judyth Reichenberg-Ullman, ND, MSW, and Robert Ullman, ND, authors of *Ritalin-Free Kids: Safe and Effective Homeopathic Medicine for ADD and Other Behavioral and Learning Problems*, offer this statement concerning criticisms of homeopathy:

Homeopathy admittedly does not work on a biochemical level. Nor does acupuncture. These types of medicine are effective because they are forms of energy medicine. We do not yet fully understand how to measure, analyze, or evaluate energy medicine. But, just as acupuncture has been used very effectively for centuries, homeopathy has also shown clinical success for the past 200 years and is widely accepted in many parts of the world.⁶

To bolster such claims of clinical success, homeopaths often call attention to various randomized double-blind clinical trials that have been published in prestigious medical and scientific journals in the recent past. These trials apparently show promising results stemming from the use of homeopathic remedies for specific ailments.

A fairly comprehensive account of such trials can be found in *Mosby's Complementary and Alternative Medicine: A Research-Based Approach*. This textbook, which just hit bookshelves a few months ago, is designed to give medical professionals complete and clinically relevant coverage of alternative therapies used in modern practice. When discussing clinical trials of homeopathy, co-author Lyn W. Freeman, PhD, presents case studies demonstrating the purported efficacy of homeopathic medications in treating conditions such as hay fever, dust-mite sensitivity in asthmatics, childhood diarrhea, hepatitis B, rheumatoid arthritis, and fibromyalgia.⁷

This series seeks to conduct a brief examination of two clinical studies of homeopathic therapy, discussing the methods used and the results obtained as well as commentary in response to these trials. Two meta-analyses of clinical trials of homeopathy will also be reviewed.

Homeopathic Treatment of Childhood Diarrhea in Nicaragua

One recent clinical trial that has proved to be popular among homeopaths was published in *Pediatrics*, the journal of the American Pediatric Association, in 1994. Spearheaded by Jennifer Jacobs, MD, MPH, of the University of Washington School of Public Health and Community Medicine, the study details the methodology and results of a randomized double-blind clinical trial conducted on 81 children (aged 6 months to 5 years) with acute diarrhea in León, Nicaragua, in July 1991.⁸

All of the children were given physical examinations, assessed for dehydration using "a standardized World Health Organization scheme of signs and symptoms," administered corresponding oral rehydration therapy, and assigned diarrhea index scores as indicators of the severity of illness. An American homeopathic practitioner then gave each child a homeopathic interview and examination; the data from such interviews was subjected to computer analysis to determine the most appropriate homeopathic remedy for each child. Afterwards, all children were randomly assigned to either a treatment group, who received sucrose/lactose pellets impregnated with a homeopathic medication from Boiron USA⁹ such as *Arsenicum album* or *Chamomilla* of 30C potency, or a control group who received an identical placebo.

The abstract for the clinical trial detailed the following results:

The treatment group had a statistically significant ($P < .05$) decrease in duration of diarrhea, defined as the number of days until there were less than three unformed stools daily for 2 consecutive days. There was also a significant difference ($P < .05$) in the number of stools per day between the two groups after 72 hours of treatment...

The statistically significant decrease in the duration of diarrhea in the treatment group suggests that homeopathic treatment might be useful in acute childhood diarrhea.¹⁰

Commenting on the results of the clinical trial, Jacobs and her associates stated, "No scientific explanation for the mechanism of action of homeopathy currently exists. However, the numerous anecdotal reports of its efficacy and its use by millions of people worldwide suggest the need for a thorough scientific examination of this modality."¹¹

Chamomilla vs. the River Jordan: Response to the Jacobs Study

Not everyone was so quick to agree with Jacobs et al. For example, two physicians from Massachusetts General Hospital responded by asking whether the change in stool output was due to homeopathic therapy or due to a dietary factor that hadn't been taken into account.¹² Another respondent mentioned reports that emphasized how the effects of rice-based or cereal-based oral rehydration solutions varied depending on the quality of a child's previous nutritional status.¹³ Jacobs et al responded by claiming that the outpatient setting of the trial did not allow for more precise measurements of stool output or nutritional management.¹⁴

It was not until Wallace Sampson, MD, and William London, EdD, wrote an analysis of the Jacobs study that Pediatrics presented a thorough critique of the clinical trial's objectives, method, diagnosis, treatment selection, and interpretation of results.¹⁵ Concerning the study's outcomes, Wallace and Sampson stated that the treatment and control numbers were "unbalanced by a difference of 50% or more" for seven of the eight compounds expressly listed in the study. For example, eight children in the treatment group were given Chamomilla 30C, but only five children in the control group were given the corresponding placebo. In addition, all diagnostic and treatment groups were lumped together for analysis, making it impossible to determine the efficacy of one particular homeopathic remedy.

As for the commentary from the study's authors, Wallace and Sampson indicated that the statement "No scientific explanation for the mechanism of action of homeopathy currently exists" assumes that homeopathy has an action in the first place, despite what the critique described as poor evidence for homeopathy's efficacy. The use of a 30C potency – the dilution of a mother tincture at 10-60 concentration – led Wallace and Sampson to state that "it is more likely that there would be a molecule of the River Jordan water rather than a molecule of the material in the original solution."¹⁶

Jacobs and the other authors of the study responded to these comments (and others) from Wallace and Sampson shortly afterwards. The researchers agreed that pooling the results made it difficult to determine which individualized treatments were effective, but stated that "if effectiveness was uneven between treatments, this pooling would tend to dilute the strength of any positive treatment association, making it more difficult to show a significant difference."¹⁷ When the topic changed came to the question of whether homeopathy has a mechanism of action or reliable scientific evidence, the researchers stated:

We acknowledge that the lack of biologic plausibility makes homeopathy difficult to accept. However, does this mean that scientific inquiry should be restricted to phenomena comfortably inside the paradigm of modern, Western medicine? Should we not carry out studies on phenomena for which the mechanism of action is not understood? There are many examples in medicine and public health in which effects were accepted empirically before their mechanisms were understood.¹⁸

The apparent lack of a resolution to the debate did not deter Boiron USA, the manufacturers of the disputed remedies, from proclaiming that the Pediatrics trial marked a significant step "in the application and effectiveness of infinitesimal doses to human biology" in their pocket guide, *The Smart Guide To Homeopathy*.¹⁹ Nor did the abstract's relatively mild assertion that homeopathic therapy "might be useful in acute childhood diarrhea" prevent the authors of *Ritalin-Free Kids* from proclaiming that the study "demonstrated homeopathy's effectiveness in pediatric diarrhea in Nicaragua."²⁰ The study and its results have also been cited in *Mosby's Complementary and Alternative Medicine* as well as numerous homeopathic pamphlets, books, and on-line articles.

Next month: A study in the BMJ testing the placebo hypothesis with a homeopathic hayfever remedy, plus a look at

meta-analyses of homeopathic studies and the methodology used by such trials.

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The Weakest Skeptic Debuts at NTS

Laura Ainsworth Hosts a Game Show that's not for the Faint of Intellect

By Daniel R. Barnett

For our May 2001 meeting on Saturday the 12th, the North Texas Skeptics decided to shift gears. Instead of a skeptical lecture or a guest speaker, we decided to try our hand at a game show called The Weakest Skeptic.

Patterned after the television program The Weakest Link, a British import hosted by Anne Robinson on NBC, our show featured five contestants who were peppered with various questions dealing with rational thought, pseudoscience, urban legends, and alternative medicine. We had the questions and the rules of play ready to go, but all we needed was a capable host with a sharp wit and a decent repertoire of insults, which Ms. Robinson makes frequent use of on her program.

Fortunately, we had someone who was up for the task. Laura Ainsworth, a member of the NTS Board of Directors, also works with husband Pat Reeder on a comedy subscription service for radio stations called The Comedy Wire. When she walked up to the podium in an all-black ensemble and wire-rimmed spectacles, she explained the rules to the

contestants, stating that winning The Weakest Skeptic would give the lucky individual "the right to declare yourself 'the smartest person in the room' after I leave it."

The rules for TWS are pretty straightforward. The game is divided into five rounds in which each player is asked five questions per round in rotating order, winning a point for each question answered correctly. Unlike The Weakest Link, where contestants are expected to work as a team to build up the jackpot and then vote each other off the team, in TWS it's every player for himself or herself. "There is too great a temptation to remove the smartest competitor," Laura explains, "and at skeptic meetings, we do not punish people for being intelligent."

At the end of each round, the player with the lowest score was given an imperious stare by the host, who then declared, "You are the Weakest Skeptic. Goodbye!" That was my cue to chase the player back into the audience with a blast of hardcore free-form jazz from my Naked City collection. (Hey, just because I'm not the host doesn't mean that I have to be nice...)

We played two sessions of the game with five players each, their names being drawn at random before each session. Questions concerning Uri Geller, Scientology, and extraterrestrials proved to be popular, but Laura kept the contestants on their toes with a broad variety of queries. Those who fell short on correct answers found themselves on the business end of a skeptical insult from Laura, such as "Your intelligence is as real as the N-ray" or "Were you having a near-death experience when that question was being asked?" When it came time to tally the scores at the end of a round, Laura would ask a question like "Whose brain was lost in the Bermuda Triangle?" or "Which contestant is possessed by a demon – a demon with a very low IQ?"

It isn't very often that you have a room full of people who are being insulted and enjoying every minute of it. Laura pulled off her duties with polish and finesse, earning a standing ovation for her at the end of our meeting.

Congratulations go out to our two winners, Michael Binder (a high school chemistry teacher) and Virginia Barnett (my wife and fellow NTS Director). Both of them received a vintage NTS T-shirt and a \$10 gift certificate to either Half-Price Books or Paperbacks Plus. Michael also won a copy of *Scientific Creationism* by Henry Miller and the Institute for Creation Research, while Virginia won a copy of *Possessed: True Tales of Demonic Possession* by Brian McConnell.

If you missed The Weakest Skeptic this time around, please check your newsletter and our Web site to learn when we'll be playing the game again. Judging by the response that we've received so far, this won't be a one-time event. In fact, TWS may be popping up at a few venues outside the realm of the North Texas Skeptics in the not-too-distant future. We'll try to keep you posted.

Until next time – "Goodbye!"



Laura Ainsworth says "Goodbye."

Note from DRB: In addition to Anne Robinson and the executive producers of The Weakest Link, respect is due to the Georgia Skeptics, the Reality Examination Association of Lincoln Land (REALL), the Philadelphia Association for Critical Thinking (PhACT), and the New England Skeptical Society (NESS), whose skeptical quiz shows in the past contributed greatly towards inspiring the creation of this game.

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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.]

Cell phones and cancer: So what does the GAO know?

In an orgy of budget cutting, Congress abolished its Office of Technology Assessment in 1995 (WN 29 Sep 95). So where does Congress go to get answers to technical questions? Sen. Joseph Lieberman (D-CN) and Rep. Edward Markey (D-MA) turned to the General Accounting Office, the investigative arm of Congress, for a report on possible health risks associated with cell phone use. In its report, released on Tuesday, the GAO finds no evidence of adverse health effects, BUT they conclude there is not yet enough data to conclude cell phones pose no risk at all. Of course not! And there never will be. You can't prove anything is risk free. A problem may yet show up only at higher exposure, or after longer incubation, or when cell phone radiation is combined with caffeine, or... Physicists ask to see a plausible mechanism.

Placebo effect: It won't shrink tumors or cure baldness.

A Danish study challenges the widely accepted claim that just about any disorder that afflicts people will show a positive response to a sham treatment. This so-called "placebo effect" has been widely hailed by proponents of mind-body medicine as evidence of the mind's power to heal. It's more likely to be evidence of self-deception. For any disorder that could be measured, such as excess weight, the Danish study found the use of a placebo to be no more effective than no treatment at all. The placebo myth may result from a reduction in stress hormones in people who are

convinced the treatment will work. Stress hormones can make you feel lousy. The release of the Danish study comes as the sale of herbal medications is falling, following several negative trials.

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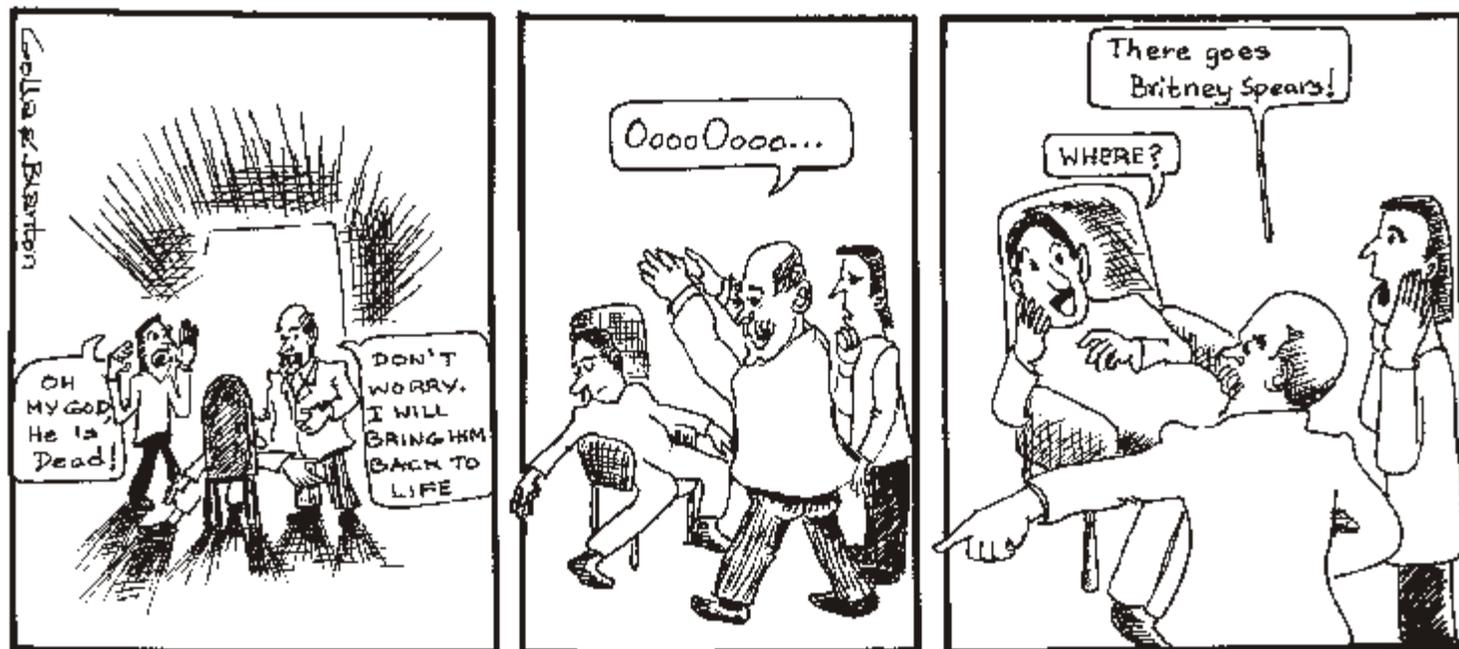
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Skeptical ink

By Prasad Golla and John Blanton

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