# Dr Harris A Steinman

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Email: xxx


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The Registrar/CEO: Advocate Boyce Mkhize
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Dear Sir,

Re: Dr Paul Abrahams – Substantiation of Homemark products

It is with no pleasure that I am laying a complaint with the HPCSA against Dr Paul Abrahams.

Homemark is a direct marketing company that has developed a reputation for selling products to consumers that are either unsubstantiated and/or were banned in the USA for being regarded as scams (Peel Away the Pounds, Slim Coffee). I have laid a number of complaints against these products, in particular those making health related claims, with the Advertising Standards Authority of South Africa (ASA).

Clause 4.1 of Section II of the ASA's Code states "*Before advertising is published, advertisers shall hold in their possession documentary evidence as set out in Clause 4.1, to support all claims, whether direct or implied, that are capable of objective substantiation.*"

and

"*Documentary evidence, other than survey data, shall emanate from or be evaluated by a person/entity, which is independent, credible, and an expert in the particular field to which the claims relate and be acceptable to the ASA*".

As Homemark had no evidence of efficacy for a number of their products, they have sought out "credible experts" who are prepared to substantiate their products. Dr Abrahams has substantiated two products and I argue that the evidence for the substantiation was either not robust enough, or non-existent, and therefore that Dr Paul Abrahams was directly responsible for the continued marketing of therapeutic substances, or "complementary medicines", without scientifically acceptable levels of proof, to scientifically naïve consumers and to the potential detriment of those consumers. I brought to Dr Abraham's attention at the time of his substantiation for the second product, that if he was prepared to substantiate the particular product with inadequate scientific support for a product with no known scientific validity or proof of

efficacy, this would be tantamount to a resultant complaint being laid with the HPCSA. This was not in order to threaten Dr Abrahams, but primarily for the protection of the consumer and secondarily to indicate that his evidence needs to be robust and sound, and that these had to be properly addressed and in my research had found no evidence to support efficacy for the product. As Dr Abrahams has ignored my concerns and substantiated a product which I argue cannot fulfil the claims being made for it, I have no option but to now proceed with my complaint.

Product 1: Proxygen – magnesium peroxide / magnesium oxide

On 25 July 2004, I laid a complaint with the ASA for this product, which claimed "Proxygen aids in the proper function of immune system, detoxification and enables the ideal metabolic function of the body". I argued that not only is there not a single study on humans or animals to support these claims for the principle constituent, magnesium peroxide, but can they prove that the constituents present in their products, namely, magnesium oxide, bioflavonoids, and Vitamin C (ascorbic acid) are completely bioavailable?

Homemark approached Dr Abrahams in January 2006 following a number of complaints of breach against Homemark, to substantiate this product.

Dr Paul Abrahams pointed out that the product should have stated that the term "Magnesium Oxide" should have read "Magnesium Peroxide" and substantiated that the claims being made for the product has sufficient scientific proof to back up the claims. He claimed that the claim "Oxygen in a capsule" was true and that Proxygen, "through introducing oxygen into the system, supports the normal function of the immune system. It aids in the detoxification of the body and futher in the body's metabolic function. It helps to boost the immune system". See accompanying document: Proxygen substantiation.pdf

I argued that the claims of introducing oxygen into the system were completely counter to physiological principals, and that an evaluation of one of the major tools for evaluating peer-reviewed published medical research, Pubmed, (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?), with the search term "Magnesium Peroxide", listed 289 articles dating as far back to 1963 and related to this compound, and not one listed this compound for therapeutic use in humans. In further correspondence with the ASA (see accompanying selection of documents), I made it absolutely clear that the claims were impossible, implausible, and not based on scientific evidence. However Dr Abrahams would not retract his substantiation.

I pointed out that the evidence that Dr Abrahams supplied does not emanate from a scientist but from an individual convicted for fraud. See attached document: Donsbach Summary.doc. However Dr Abrahams would still not retract his substantiation.

I also argued that 9 professors of pharmacy or pharmacology were consulted and all felt that there was no evidence for the claims, and one went as far as stating that the product must be a scam. See accompanying document: Proxygen Verbal submission.doc. However Dr Abrahams would not retract his substantiation.

I also submitted a deconstruction of the product, and Dr Abrahams arguments by Prof. Roy Jobson, Associate Professor of Pharmacology at Rhodes University (see

accompanying document: Proxygen2006-09-23 Roy Jobson support.doc), but this did nothing to change Dr Abrahams's stance. I subsequently had to request arbitration.

This incident should be sufficient evidence that Dr Paul Abrahams was instrumental in the continued marketing of a probably scam product to unwitting consumers.

However, recently Homemark was reported to the ASA as marketing a product, Remedy Blue Spray, which claimed that spraying this compound onto the skin would have the following effects:
"Pain relief spray for quick symptomatic relief"
"Pain relief spray for quick symptomatic relief from sport injuries, muscle pain, joint pain, degenerative diseases, menstrual cramps and more."
"Qiuck (sic) symptomatic relief from pain, helps build up joint resilience, easy to apply, just spray. Anti-Inflammatory pain reducing properties."
"Will work for pain associated with:
Degenerative deseaces (sic)
Joint Pains
Muscle pains
Sport injuries
Menstrual pains
Head aches
Sinuses"

I argued that there is no evidence that this product is effectively absorbed through the skin resulting in pain relief, in particular for the conditions listed. Common sense will point out that any skin spray that can relieve headaches, sinus headaches, menstrual pains, etc, would be a miracle spray.

The product contains among other, Methyl Sulphonyl Methane (MSM), Emu Oil, Aloe Vera concentrate, and herbal extracts. In Dr Abrahams letter of substantiation, he states: "[I]n my opinion, based on the research performed, it is reasonable to conclude that, given the properties and functions played by the key ingredients of Remedy Blue Spray and its ability to be absorbed through the skin, the claims listed above are adequately and reasonably substantiated and are not misleading." (See accompany document: 20091103 substantiation.pdf) To support his contention, Dr Abrahams lists four studies, and included copies of the studies. (See accompany document: 20091210 Abrahams's substantiation.pdf)

In an earlier document (See accompany document: 041109 Homemark Remedy Blue Spray Dr Abrahams.doc), I wrote among other

> The dose that is delivered through this spray is infinitesimally small compared to the oral dose that is usually prescribed for the same ingredient. Furthermore, the efficacy of the oral dose for which this product claims to be effective for certain conditions has not been demonstrated in clinical studies for all the conditions listed. Indeed, some of the studies cited have demonstrated no effect. Therefore, if there is no proof that large oral dosages have efficacy, then how is it that miniscule dosages through the spray will have any benefit? (Without proof).

Abrahams has given no evidence that the product is absorbed through the skin -- he relies on an assumption that the spray (and gel) is absorbed without evidence for that and states "it is reasonable to conclude that". In fact, without revealing the sources of his research (no references) it is not "reasonable to conclude" anything about the product. Where is the evidence that the “spray” or "gel" is in fact absorbed through the skin?

Section i Clause 4.25 of the Advertising Standards Authority’s Code of Advertising Practice states: “Scientific substantiation” means substantiation based on statistically valid data, employing a validated, proven scientific method and applicable to the claim being made."

Dr Abrahams has not shown that his substantiation is based on statistically valid data which employ a validated proven scientific method and which are applicable to the claim being made. All he has said is that because the gel is absorbed, the spray will be absorbed.

What validated proven scientific method was described in the research he consulted to show that the product or its ingredients are absorbed through the skin? He needs to supply the documentary evidence with proper and suitable references. The question remains unanswered.

Evaluating the “evidence” that Dr Abrahams supplied in support of the claims for this product, I have to conclude:
The studies that Dr Abrahams included in his substantiation confirmed MSM’s role to act as an adjuvant for the absorption of a secondary ingredient and not for MSM. The studies in support of his claims for skin absorption were done in animals and are proof of concept but not proof of efficacy.

The primary study that Dr Abrahams supplies, a review of MSM published in the 1960’s, states in the summary: “[F]rom a review of the clinical evidence presently available, it appears that DMSO may have a limited role in the treatment of some musculoskeletal diseases” and “[T]here is nothing in any of the clinical literature to date which indicates that the indiscriminate use of DMSO can be expected to improve even those conditions in which it has been reported to be most effective; for example, acute trauma and bursitis.” It also states “There is little pharmacological evidence that DMSO has any reliable primary activity as either a local anaesthetic or analgesic.” Significantly, the article examines mostly oral administration of DMSO and Dr Abrahams appears to equate oral ingestion with topical application, clearly not acceptable. It furthermore states “[S]ome care should be exercised in the treatment of cases of these conditions in which large areas are involved both because systemic effects are readily produced by topical application and also because of the different sensitivities of various parts of the body”, and in the body of the article states, “topical application of small quantities to some patients can produce local irritation as well as systemic effects.” “systemic effects due to absorption following topical application include lethargy (6), reduction of circulating platelets, increases of indirect bilirubin, alkaline phosphatase, blood urea nitrogen, SGOT and SGPT levels” and therefore, the question arises whether this product, may pose a risk to consumers in particular when sold through Homemark stores?

Of course, an essential problem with the substantiation is that Dr Abrahams does not supply any proof that the product indeed contains any active ingredients at all but simply takes Homemark on trust.

In particular, this product claims to have efficacy in “degenerative disease, joint pains, muscle pains, sport injuries, menstrual pains, headaches, sinuses” when applied topically. Dr Abrahams has substantiated that this product with have efficacy for ALL of these conditions, although the evidence for these claims were not supplied to the ASA. A search of PubMed for “Sinus AND (Methyl Sulphonyl Methane OR MSM OR DMSO OR Dimethyl Sulfoxide)” did not produce a single study confirming use of MSM in sinus conditions. Similarly, a search for “menst* AND (Methyl Sulphonyl Methane OR MSM OR DMSO OR Dimethyl Sulfoxide)” found no articles reporting the use of MSM for any menstrual conditions.

A search of Natural Medicines Comprehensive Database, the “Scientific Gold Standard for Evidence-Based, Clinical Information on Natural Medicines” (http://www.naturaldatabase.com/) for data on MSM, states unequivocally that there is insufficient proof of efficacy for the claims being made for MSM, and does not even mention sinus or menstrual problems as a potential condition for use of this ingredient.

I am not in principle against Dr Paul Abrahams substantiating products making therapeutic claims, but insist that acceptable robust evidence of efficacy should be required. I have pointed out above that in the case of Proxygen, it is completely absent, and in the case of Remedy Blue Spray, is either absent, insufficient, or not applicable for the topical spray.

Apart from this, neither of these products have been registered by the Medicines Control Council in terms of the Medicines and Related Substances Act (Act 101 of 1965). The Medicines Act prohibits the sale and advertising of medicinal products which are not registered and which have been called up for registration.

I am reluctantly submitting this complaint for I am gravely concerned that Dr Abrahams will continue to substantiate products with health claims for Homemark, products that in actual fact have insufficient or no evidence to support the claims, and he is therefore directly responsible for taking advantage of scientifically naïve consumers.

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Sincerely,
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Dr. Harris Steinman