

## HealthWatch Newsletter no 5: August 1990

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**Our name was changed from *Campaign Against Health Fraud* to *HealthWatch* by a vote passed at the AGm**

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## POSITION PAPER: Confiance and Magnesium-OK

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*HealthWatch, The Campaign Against Health Fraud, is concerned over the promotion to the public of the vitamin/mineral supplements Confiance and Magnesium-OK, both manufactured by Wassen International Ltd.*

### Confiance

On the pack the claim is made that Confiance is "The major breakthrough once-a-day nutritional supplement for women going through the menopause". No other specific therapeutic claims are made on the packaging, nor in the package insert, but the reader is left in no doubt that Confiance is designed to alleviate menopausal symptoms. Further, a Press Release dated November 1989 states that:

"Confiance has been specifically formulated to reduce menopausal symptoms such as hot flushes, depression, insomnia and dizziness by providing the specific nutritional requirements that a woman needs during this time of life. The vitamins and minerals can help regularise hormone levels and supplement dietary deficiencies which may result from stress resulting from the way so many people have to live today, quite apart from alcohol and smoking."

If it was known to the Medicines Control Agency of the Department of Health that these health claims were made by the manufacturer (as they would be if they were printed on the package or product information), the product would be subject to the Medicines Act and require licensing for these indications. A licence would only be issued when proof of efficacy was produced. There is the risk that statements in the Press Release might encourage journalists to make claims not permitted to the manufacturer. In turn, this might encourage assistants in health food shops to repeat them at the time of sale. Thus the purchaser might be given the impression that Confiance can do more for them than can legally be claimed.

HealthWatch has studied the product literature, including the references cited in it, and can find no evidence to show that Confiance does have any effect upon the symptoms associated with the menopause. Until such evidence becomes available for Confiance, HealthWatch cannot advise women to use this unproven product.

### Magnesium-OK

Magnesium-OK is directed at women suffering from pre-menstrual tension. As with Confiance, no specific therapeutic claims are made on the package or in the package insert, but the prominent boxed heading "PMT (Pre-Menstrual Time)", though isolated from any specific claim, makes its intended use obvious.

A News Release dated June 1989 again goes much beyond the carefully restrained package statements with:

"...can help up to 70% of British women between the ages of 15 and 45 (around 10 million) who suffer from the symptoms of pre-menstrual tension according to the results of recent trials."

In support of this claim, the News Release refers to one uncontrolled study in which 71.8% of 103 participants are said to have benefited from taking Magnesium-OK for a one to three month period.

This trial has not been published in the medical literature; HealthWatch has not been able to obtain details of the criteria used for defining pre-menstrual tension on entry to the trial, nor find out what scientific measurements

were used to assess the results of treatment.

Many medical conditions show a marked response to any treatment, including placebo, and review of the scientific literature shows this is definitely true for pre-menstrual tension. An uncontrolled clinical study cannot provide serious evidence for the effectiveness of a product in pre-menstrual tension.

Another statement in the Company's News Release is worrying:

"Our decision to launch Magnesium-OK meant that we were able to offer consumers a product which is affordable, and which gave a fast return to the retailer".

Again, it concerns HealthWatch that there may be a financial incentive for health food stores, whose sales assistants have limited medical or scientific background (and certainly do not understand the Medicines Act as well as do Wassen International Ltd), to make claims for the product which the manufacturer is prohibited by law from making.

*It is the position of HealthWatch that products (medicinal or not) offered to the public for the treatment of medical conditions should have been properly tested in adequate clinical trials to demonstrate their safety and effectiveness.*

### **What Constitutes an adequate trial?**

***An adequate trial of a treatment must have:***

- **measurement of the baseline condition of all participants entering the study;**
- **the group randomly divided into two so that half can receive the treatment under test and the other half can receive an established treatment or placebo;**
- **measurements repeated after an appropriate treatment period;**
- **statistical tests applied to see if the differences could have occurred by chance**

It is the position of HealthWatch that promotion of products, licensed or unlicensed, should always be within the limits of the claims that the law permits the manufacturer to place in the product literature, and that no encouragement should be given to sales assistants to make additional and uncontrolled statements at the time of sale, nor should journalists be encouraged to make such statements in the media.

HealthWatch challenges the manufacturer of Confiance and Magnesium-OK to show their faith in these products by subjecting them to adequate testing. HealthWatch will provide a scientific peer group which will assist Wassen International Ltd with the design of the study and will publicly endorse the value of the products if their benefit is established in this way.

***Until such evidence can be produced, HealthWatch advises women considering the purchase of these products that they have not been adequately tested and that there is no evidence that they have any effect on the symptoms of menopause or pre-menstrual tension.***

Prepared by: Walli Bounds SCM

Member, Executive Committee, HealthWatch

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## **POSITION PAPER: Registration of homeopathic remedies for sale in the UK**

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***From the time the Medicines Act came into force in 1968, licensing has been required for products used for a medicinal purpose and prepared in a form suitable for administration as a medicine or for use as an ingredient in dispensing a medicine. A doctor or dentist does not require a product licence for a product prepared to his prescription for administration to a particular patient; it follows that a traditionally prescribed homeopathic product, made up for a specific patient on the basis of a medically qualified homeopathic practitioner's evaluation of the whole range of symptoms exhibited by that individual, would be exempt from control by definition, and there would not be the need to obtain a product licence for such a product.***

This exemption applies both to homeopathic and orthodox products; it permits great latitude for the individual doctor to prescribe, and by extension to import, products which have not been subject to objective scrutiny by the Medicines Control Agency. While it seems on the face of it a casual method of control and liable to abuse, it works well in practice. The more formal approach taken in America, where the Food and Drug Administration has devoted a great deal of time to the examination of appeals for the compassionate use of unregistered drugs (most notably in cases of cancer and AIDS, where the slow process of trial assessment conflicts with the perceived need of dying patients), does not seem to provide significantly better protection for the public.

It is the position of HealthWatch that the UK process on balance does not work to the detriment of patients and that the control of homeopathic remedies prescribed after detailed examination of an individual patient is a matter for the homeopaths' professional body, but that:

1. qualified medical assessment must first be made to exclude the possibility that the patient has a disease for which there is available a well-proven treatment
2. the patient should be informed about any established treatment;
3. the patient should routinely be informed that the homeopathic remedy has not been subjected to scrutiny by the Medicines Control Agency.

HealthWatch understands that the European Commission has proposed a Directive on Homeopathic Products and that the provisions of the Directive, when approved, will be incorporated into British Law. The Directive requires that a simplified registration procedure be established for manufactured homeopathic products which will concentrate upon pharmaceutical aspects of the *quality* and *safety* of these products. These requirements will not involve animal testing; safety in this context refers to procedures for ensuring minimal risk in the dilution of potentially toxic starting materials. No review of *efficacy* of these products is proposed in the Directive.

HealthWatch supports this initiative, which should ensure that manufactured products are cleanly and correctly made, while not interfering with a long-established tradition of medicine. HealthWatch also urges homeopathic practitioners to initiate trials to show the efficacy of their treatments.

**The position of so-called homeopathic remedies made up by manufacturers and sold over the counter to the public through pharmacy and other retail outlets is very different.** These products appear to contradict the fundamental principles of homeopathy, that a specific remedy should be determined for a specific patient on the basis of careful analysis of all, rather than a few disease-specific symptoms, by their purchase on the basis of a patient's self-diagnosis without the intervention of a trained practitioner. Indications for use are not given on the product packaging, but lists are provided at the point of sale which inform the purchaser (aided by an unskilled shop assistant) regarding the claimed actions of the products.

Such products are clearly covered by the Medicines Act 1968 definition of medicines. As such, licensing has always been required, but it would seem that there are a large number of products on the market on the market which do not have product licences.

The Medicines Control Agency of the Department of Health, which is responsible for the control of such products, has not to date shown interest in them, presumably because the indications for use do not appear on the pack.

HealthWatch notes that the European Commission proposed Directive also draws a distinction between traditional homeopathic products and those promoted directly to the public. The Directive proposes that the latter should be registered with a similar simplified scheme to that intended to be applied to traditional homeopathic products, but that proof of *efficacy* should also be provided.

***It is the position of HealthWatch that no product of this type should remain on the market without a product licence.***

***HealthWatch strongly supports the aims of the proposed Directive and urges that these products should be subject to review without delay to ensure they meet the requirements of quality, safety and efficacy applied to orthodox remedies.***

Prepared by: Michael E Allen BPharm MRPharmS MBIRA,

Member, Executive Committee, HealthWatch Revised text: 21st May 1990

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## Who needs vitamin and mineral supplements?

### 1) The vitamin industry's view

Vitamin Forum, which represent the interests of the nutritional supplement industry, have given the Ministry of Agriculture, Fisheries and Food a ticking off for their new guidebook, *Eight guidelines for a healthy diet*. They particularly object to the statement that "supplementing your diet with vitamin and mineral pills is rarely necessary." According to spokesman Maurice Hanssen, "we are not suggesting that supplements are an alternative to a good, healthy, balanced diet. We are simply pointing out that they make an increasingly valid contribution to the nation's health and well being."

They also make, though he omitted to mention it, an increasing contribution to his own and his industry's wealth and well being.

### 2) The nutritionist's view

Can ordinary people expect any benefit from taking vitamin and mineral supplements? Expert Committees, such

as the American Institute of Nutrition, and the Society for Clinical Nutrition do not think so, and nor does the Ministry of Agriculture, Fisheries and Food, who recently reported that vitamin intakes for all age groups were well above current recommendations. However, the public continues to believe that they do.

Yet, according to Professor Stewart Truswell, in a *BMJ* leader on 21 July 1990, the US National Research Council could find "no documented report that daily multiple vitamin-mineral supplements, equalling no more than the recommended dietary allowances ... are either beneficial or harmful for the general population."

Three things go wrong when people choose to treat themselves with supplements. Firstly, it is the people who eat good diets, rather than those who eat poor diets, who take supplements.

Secondly, the supplements that people choose are often not the ones lacking in their diets. Thirdly, few preparations make it clear whether the doses they contain are around the recommended daily amounts or many times greater. In Professor Truswell's words, "*all too often the wrong people are taking the wrong doses of the wrong vitamins.*"

A good multivitamin is hard to find. The ideal preparation would contain the RDA of all 13 vitamins and none of the non-vitamins; such a preparation is not listed in the British National Formulary. Those listed contain up to 10 vitamins, but most have 4-10, and they rarely include folic acid.

Who might need supplements? Newborn babies may need vitamin K; pregnant women may need iron, calcium and folic acid. The housebound, pregnant Asian women, and children in the north of England and Scotland, may need vitamin D in winter. Vegans and their infants need B12; alcoholics need thiamin.

Though one widely-publicised trial showed that a multiple supplement produced a tiny improvement in non-verbal performance, two attempts to confirm the result - the second of which removed certain design flaws in the original trial - failed. Though the public believes that vitamin C relieves or prevents colds, a meta-analysis of 27 controlled trials shows that it has no worthwhile effect.

Multivitamins may be needed by those with a low calorie intake, either slimmers or those with poor appetites, the elderly and frail, food faddists, the emotionally disturbed, and the socially disadvantaged.

We are still waiting to hear whether supplements will prevent cancer, or neural tube defects in the children of women who have previously had an affected baby. None of the present evidence is more than suggestive.

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## THE CHIROPRACTIC DEBATE

***HealthWatch's recent support for State Registration for accredited chiropractors has brought howls of protest from some members, whose letters are printed here.***

We asked Dr Tom Meade, head of the MRC Epidemiology and Medical Care Unit, to write about the background to the clinical trial he conducted comparing chiropractic with hospital outpatient treatment for low back pain of mechanical origin.

We also asked Graham Heale, secretary of the British Chiropractic Association, to outline what chiropractic is about, and to answer accusations sent in by members, and illustrated by pictures from turn-of-the-century, that chiropractic is quackery. (We noted that no member sent any quack illustrations from turn-of-the-century orthodox medical texts, though there is plenty of available material.)

### Chiropractic and hospital out-patient management for low back pain

#### Tom Meade

MRC Epidemiology and Medical Care Unit, Northwick Park Hospital, Harrow HA1 3UJ

***The results of a recently reported 'pragmatic' trial of two policies for the management of low back pain of non-specific origin clearly showed that chiropractic is substantially more effective than conventional hospital outpatient management (Meade TW et al, BMJ 1990;300:1431-7). The benefit lasts for up to three years and is mainly seen in those with chronic, severe symptoms.***

Two contrasting aspects of the trial are worth special comment.

In 1981 and at the suggestion of the MRC and the Department of Health, the MRC Epidemiology and Medical Care Unit at Northwick Park Hospital, who carried out the trial, were consulted by several heterodox or 'alternative' groups about the evaluation of their methods. Alone among these groups, the British Chiropractic Association readily and unreservedly accepted the advice they were given about the need for a randomised comparison and allowed the Unit to plan and conduct the trial quite independently. The Association's conduct was exemplary, particularly bearing in mind that at the outset they did not of course know what the results would be, and it is to be hoped that other groups will follow their lead.

Much less impressive have been some of the reactions of other groups involved in the

management of back pain. It is understandable that they may feel threatened by the trial's results but if the interests of patients are to be paramount, fair and balanced consideration of the implications of the findings is essential even if difficult in what has always been a very controversial field.

An authoritative review in 1986 concluded that manipulation has little if anything to offer in managing chronic or severe back pain (Jayson MIV, *BMJ* 1986,293:1454-5). Nothing had changed much between then and the time we completed our trial. So endorsement of manipulation as an effective treatment in a letter to the *Times* on 13th June 1990 from the Chairman of the Chartered Society of Physiotherapy was in itself a remarkable U-turn in general thinking.

But as well as wrongly implying that the trial had been one of different manipulative methods and that there is not much to choose between chiropractors and physiotherapists in this respect, the Society's chairman omitted to point out that the technique often used by chiropractors is very different from that used by most hospital physiotherapists. Other physiotherapists have claimed that it was the larger number of treatments given by chiropractors or the longer time period over which they were

spread that were responsible and that hospital treatment would have been equally effective if it had not been given under the less than ideal conditions some of the hospitals were certainly faced with. But the trial was not designed to answer these questions - though there is now a strong incentive for further trials to do this. In another letter to the *Times* on 7th June the Secretary of the General Council and Register of Osteopaths, welcoming the results of the trial, implied that they would also apply to osteopathy. Again, this may or may not be true but the trial was not a comparison of chiropractic and osteopathic techniques.

These reactions are disturbing for two reasons. First, without an appreciation of the background against which they have taken place, they may detract from the strong case properly trained chiropractors now have for appropriate recognition and registration. Having done what many have advocated but few have so far practised in letting their methods be independently evaluated in a randomised comparison, chiropractors could now be forgiven for suspecting that other groups are trying to slip-stream in on the findings and implications of the trial at the expense of the credit properly due to them.

Secondly - and far more important - many back pain patients may be unnecessarily confused and misled. Whether to go to a chiropractor or to a hospital (regardless of the specific treatment components in each case) is a real-life question facing many hundreds of patients each week, and it is this question that the trial answered and answered quite clearly. It did not investigate any particular technique or form any basis for the several other interpretations of the results that I have referred to. To suggest otherwise is to obscure one of the very few facts in a field hitherto largely dominated by conjecture and mystique and (at any rate while the trials that may answer these other questions are being conducted and quite possibly subsequently) this is not in the interests of the many thousands of patients who stand to benefit from chiropractic.

## Chiropractic - what it is and is not

### Graham Heale.

Secretary, British Chiropractic Association, Premier House, Greycoat Place, London SW1P 1SB

***Chiropractic began in 1895 when one Daniel David Palmer, A 'healer', of Ohio decided that a supposed spinal misalignment could be rectified by a direct forceful movement. After doing this, he reported, there were considerable changes to his patients' symptoms.***

Early chiropractors also thought that nerve impingement ('subluxations') could cause disease. They drew up detailed diagrams based on the nerve supply to various organs; this was a guide to which vertebrae needed to be realigned to remedy a plethora of conditions. This simplistic model of spinal function took no account of the many causes now known to produce symptoms.

Chiropractic has come a long way since then. We now know that bones do not pop out of place and pinch nerves.

Instead, chiropractors now study, as well as anatomy and physiology, biomechanics - the study of joint and muscle interaction, applying engineering principles to the musculoskeletal system. They combine the case history, orthodox orthopaedic and neurological testing and x-rays to make a diagnosis, and they apply these biomechanical principles to assess and treat patients who show signs of altered joint and muscle function.

There is little doubt that patients who show abnormal or restricted joint motion are more vulnerable to injury to associated muscles, nerves and joints.

Chiropractic treatment aims to restore normal movement to those joints, reduce associated muscle spasm, and relieve any possible nerve irritation. To do this, chiropractors make precise adjustments to specific joints in an attempt to improve their flexibility. These adjustments are brisk and forceful, but of little depth. They are not usually painful but must be applied skilfully if the restricted joint is to be moved without excess stress on associated structures.

The chiropractic training course is an accredited degree (BSc chiropractic) conferred after four years' full time study. Graduates must then undergo a further one year postgraduate programme before receiving their Diploma in Chiropractic (DC).

Chiropractors are not bone setters, nor are they plying quackery on a vulnerable and desperate section of the population. They are properly trained, skilful diagnosticians who apply biomechanical engineering principles clinically in order to restore normal muscle, joint and nerve function, enabling patients to maintain an active life-style free from, or with reduced, pain and discomfort.

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## Physiotherapy - the orthodox alternative

Dear HealthWatch

The Chairman's reply to Mike Hutchinson is ill informed. She should not compare the training and work of the Chartered and State Registered physiotherapist with that of chiropractors and she should not state that "the work of State Registered Physiotherapists is subject to little scrutiny."

Unlike chiropractors, State Registered physiotherapists are trained in the same medical institutions and hospitals as doctors. Their knowledge of anatomy and physiology is on a par with that of doctors and is basic to physiotherapeutic technique including manipulative techniques and they are well aware of *contraindications* to such treatment (Grieve GI, *Physiotherapy* 1989,75: 445-53). They are trained to make an informed diagnosis and have first class hospital orientated patient handling experience.

The training and work of State Registered physiotherapists is under constant scrutiny by medical colleagues, university researchers, writers of medical dissertations and epidemiologists looking at specific treatment modalities such as ultrasound (Partridge CJ. *Physiotherapy* 1987; 73:166-8). The limitations of treatment, combinations of treatment modalities and success rate are well documented and no comparison should be made with other alternative medical forms.

Manipulative treatment available to the general public is well catered for by Chartered Physiotherapists within the NHS and independently by the Organisation of Chartered Physiotherapists in Private Practice.

Physiotherapists adjust, mobilise and manipulate in an informed and well substantiated way using 'hands on' treatment HealthWatch should encourage the public to use the orthodox alternative supplied by physiotherapists when seeking manipulative techniques rather than seeking to denigrate this therapy by comparing it with an alternative treatment yet to achieve the standard of training and patient care acceptable to the statutory body.

Jenny Archer MCSP SRP

Hon PR Officer, Northern Ireland Organisation of Chartered Physiotherapists in Private Practice, Bangor, Co Down.

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## Demarcation of the absurd

Dear HealthWatch

In the last Newsletter our chairman dismisses the complaint by Mike Hutchinson and Lewis Jones about HealthWatch's support for chiropractors, as if chiropractic was about helping people with backache. I recommend our chairman to read Crelin's chapter on chiropractic in the book you advertise on the last page of the Newsletter (*Examining holistic medicine* ed. by Stalker and Glymour) before making these naive pronouncements.

In the same issue you wonder whether 'fraud' is not a bit strong to have in the title. What about Campaign for the Protection of Quackery? Or Campaign for the Protection of Alternativists Who Agree to an Occasional Controlled Trial?

Iain Chalmers has got carried away with his advocacy of controlled trials and suggests Campaign for the Assessment of Health Care. Since when has alternative medicine been health care? Since when has alternative 'medicine' been medicine? We should not fool ourselves that controlled trials will settle the matter: after all, the value of homeopathy was 'proved' by a randomised controlled trial in the *Lancet* [for hay fever only - ed]. Are HealthWatch members to give homeopathy the benefit of the doubt? Extraordinary claims require extraordinary evidence, and randomised controlled trials, applied to absurd claims, are more likely to mislead than illuminate.

Iain confuses two separate issues:

1. many medical procedures have not been properly evaluated by controlled trials and thus it is possible that some of them are ineffective or doing more harm than good;
2. 'alternative' practices should not be called ineffective before they are properly evaluated by controlled trials.



The first issue is uncontroversial and, thanks to people like Iain, medicine has inbuilt correcting mechanisms, such as controlled trials, which gradually separate useless from useful treatments. The second issue of one of demarcation of the absurd.

What purpose would it serve to have a controlled trial of, say, the effect of prayer on the outcome of Alzheimer's dementia? The fundamental problem is that alternative medicine is both an umbrella for various competing systems of 'healthcare' and a welter of metaphysical, irrational and pseudoscientific ideologies offering 'alternative' world views. Medicine is not quite a science yet but at least is underpinned by science and it gradually throws away ballast and slowly ascends. 'Alternative medicine', on the other hand, is represented by petrified systems, all-knowing and all-explaining, dogmatic, arrogant, untestable.

I agree with Iain that the objectives of the Campaign are unlikely to be achieved, but this failure is not due to 'fraud' in the title but to the innate inability of most humans to see reality through the haze of wishful thinking. Things are bad enough, but without the Campaign Against Health Fraud, provided you keep the title and keep up the spirit, they would be even worse.

Petr Skrabanek, Community Health Department, Dublin University.

## Chiropractic qualifications

Dear HealthWatch

Mike Hutchinson and Lewis Jones have criticised HealthWatch for supporting the British Chiropractic Association. I understand that the reason for this support is based on the grounds that there is a CNA first degree in chiropractic. I do not believe that this is an acceptable criterion by which HealthWatch endorses a system of treatment and I am disappointed by the loose and arbitrary nature of the reasons given by the Chairman to justify this decision.

Michael Heap, Hon Sec, British Society of Experimental and Clinical Hypnosis.

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## Which? Way to Health slates a premenstrual tension supplement

### Expensive advice and a potentially dangerous supplement

***Which? Way To Health, published by the Consumers' Association, have voiced concern in their August issue about the value of a course of treatment and a supplement recommended by the Women's Nutritional Advisory Service, based in Hove.***

They asked four women to write to WNAS. Though all gave different sets of symptoms on the WNAS questionnaire, they each got back similar folders containing

- good dietary advice that would apply to anyone;
- a personal diet programme that was basically the same but with paragraphs added or removed according to the symptoms listed;
- the promise of a 4-month follow-up;
- a ready completed order form for nutritional supplements, to accompany each personal diet programme.

The form had a space for the practitioner's name, and in the space was stamped the name of Maryon Stewart, wife of WNAS medical adviser Dr Alan Stewart.

Top of the list of supplements on each order form was a supplement called Optivite. WNAS say that Optivite, because of many clinical trials, "is the most tried and tested supplement for PMS on the market." But *Which? Way to Health* says "the trials to date have not convinced us."

Optivite tablets contains 50 mg of vitamin B6; at the highest recommended dose - six tablets a day a person would take 300 mg daily. There is no British recommended daily dose of B6; the US recommended daily allowance for women is 1.6 mg. Three hundred milligrams a day of vitamin B6 can affect the nerves and lead people to lose feeling in their extremities. A WWH expert said "the risk of side effects in this instance certainly outweighs any evidence in favour of prescription."

They add: the WNAS 'course of treatment' is not good value. For £66 its recommendations were good and sensible but nothing out of the ordinary."

*Which? Way To Health* are worried about the way WNAS repeatedly recommend Optivite, which they also do in their video, their book, and in press reports. They say that WNAS is paid "a small royalty or commission" by Optivite's distributor when it recommends Optivite; WNAS say this money is put back into WNAS research.

WWTH conclude "nobody we consulted would recommend Optivite; some saw potential risks in using high doses. Because of the money WNAS gets from Optivite's distributors, their impartiality as an advisory service is

compromised."

Since then, WWITH have told us that WNAS, who disliked the pre-publication copy they were given of the report, have induced some of their patients to ring the Consumers' Association and complain.

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