

## Newsletter no 26: July 1997

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## Fat magnets come unstuck

***Eat fat and lose weight.. .can it be possible? HealthWatch Chairman Professor John Garrow reports on an experiment to see whether the latest diet craze to hit the market holds any real hope /or the obese.***

" Fat Binder is a new all-natural concept in weight management that binds with dietary fat, thus resisting absorption by the body. The active ingredient is Absorbitol which 'binds up to twelve times its own weight in fat'." This advertisement resembles others which promote capsules of chitosan, a non-absorbable material made from chitin in the shells of shellfish.

The claim is not altogether implausible; it has been shown in broiler chickens that replacing 3% of the diet with chitosan reduces fat in the small bowel by 26% (1).

An average person in the UK eats about 90g of fat per day, and absorbs 95% of it. If by taking chitosan absorption could be reduced to 69% that would mean a decrease of 23g fat absorbed, with an energy value of 210 kilocalories.

However Fat Binder is quite expensive: £19.99 for 90 capsules, each containing 250mg chitosan. The recommended dose is 4 capsules three times a day, so at a cost of £2.66 per day you could lose up to 36g of fat daily, worth 320 kilocalories! But the problem lies in the fat bound being "up to twelve times its own weight". What if it is only six times, or three times? Then the cost/benefit looks less impressive.

At HealthWatch we believe in controlled trials, so our dedicated volunteer took a typical British diet, with about 90 g fat and 12 g fibre for 7 consecutive days. For the first two days stool samples were collected to establish a baseline (sample A). During day 3 he took 4 chitosan capsules with breakfast, lunch and supper, and with each meal also swallowed a capsule containing 10 small radio-opaque markers of different shapes. Stool samples were collected for days 3 and 4 (sample B), and then for days 5 - 7 (sample C). X-rays of the three stool samples showed that there were no markers in sample A (as expected), 12 of the markers were in sample B, and the remaining 18 markers were in sample C.

If the 3g of chitosan had really performed as advertised there should have been 36g more fat in samples B and C than there was in Sample A. However analysis of the samples showed that there was no increase in fat excretion: the average was 4.1 g/day, indicating that about 95% of the dietary fat had been absorbed, and there was no suggestion that absorption was any less after the chitosan than before it.

Why did the chitosan work so badly in our volunteer, when it worked so well in the broiler chickens? One obvious explanation concerns the dosage: an equivalent dose in a human subject would have been about 45g/day, but that would cost £40 per day. Our volunteer thought it would be preferable just to eat a bit less fat.

In the January 1997 issue of Slimming Magazine there was a critique of chitosan-based slimming products which were not recommended on two grounds: one that the calorie loss was rather trivial, and the other that loss of fat in stool would decrease absorption of fat-soluble vitamins A, D, E and K. Our results suggest that the second problem need not concern customers; if there is no decrease in fat absorption there will be no loss of fat-soluble vitamins. What concerns HealthWatch is that promoters of chitosan-based slimming pills seem to be relying entirely on *in vitro* evidence of fat binding to chitosan, but we have not seen any evidence that the claimed fat binding takes place in the human gut. The effect in the broiler chickens arises because the chitosan in high dosage increases the viscosity of gut contents, and thus decreases the efficiency of nutrient absorption. This has

nothing to do with a "fat-binding" effect.

Reference 1. Razdan A, Pettersson D. Effect of chitin and chitosan on nutrient digestibility and plasma lipid concentrations in broiler chickens. *British Journal of Nutrition*, 1994; 72: 277-288.

We are grateful to Dr John Cummings, Dunn Nutrition Research Centre, Cambridge, who kindly supplied the radio-opaque markers, and to Ms Anna Giles and Dr Dennis Wright, of St Marks and Northwick Park Hospitals, for the radiography and chemical analysis of the stool samples.

John Garrow, HealthWatch Chairman

**See also letter from Dr George Lewith in [Newsletter 27](#)**

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## ASA uphold complaint by HealthWatch

***A magazine advertisement for a treatment named "Chelation Therapy" claimed it is a "safe, non-surgical effective treatment for heart and circulatory problems". The advertisement had been placed by the Arterial Disease Clinic in London.***

HealthWatch wrote to the Advertising Standards Authority questioning the treatment's efficacy, and also questioned whether the advertisement encouraged readers to self-treat serious medical conditions.

Both complaints were upheld. The advertisers maintained that Chelation Therapy, which had been practised for 30 years in the USA and Europe, was a programme of treatments to help with cardiovascular problems which combined the use of drugs, nutrient supplements and lifestyle recommendations. The ASA concluded, however, that the documentation supplied by the clinic did not support their claims and asked them not to repeat them.

The Authority was concerned that the advertisement did not go far enough in encouraging readers to consult a doctor, and that readers with potentially serious conditions could be deterred from seeing a doctor. It therefore asked for the advertisement to be withdrawn.

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## Research misconduct admitted

***An eminent cardiologist has admitted misconduct in a dramatic climbdown five weeks into a £2m libel case he had brought against Channel 4, who claimed he rigged tests and misdiagnosed a terminally ill Aids patient.***

Dr Peter Nixon, 71, previously a consultant at Charing Cross Hospital, claimed that hyperventilation could cause illnesses ranging from heart attacks, Gulf War Syndrome, premenstrual tension and chronic fatigue syndrome. The Channel 4 programme, *Preying on Hope*, (broadcast in February 1994) had secretly filmed and recorded his consultation with an Aids patient who was told that his fatigue was caused by hyperventilation and prescribed an antihistamine and the sedative diazepam.

His case against Channel 4 collapsed when he was compelled to admit that a series of papers published in the *Journal of the Royal Society of Medicine* contained a number of errors that appeared to be, he conceded in the trial, "more than an honest slip of the pen". Dr Nixon agreed to pay £765,520 in costs.

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## New mobile 'phone scare

Mobile telephones really can be hazardous, though possibly not via their electromagnetic fields as suggested in media reports and disputed by HealthWatch committee member Dr Neville Goodman recently (*HealthWatch Newsletter 23*, October 1996. See also [Newsletter no 32](#))

In the *New England Journal of Medicine*, Canadian researchers report an analysis of the call records of 699 drivers with 'phones in their cars who had had accidents causing damage to property. The risk of collision was four times higher during a 'phone call than at other times, regardless of age and level of driving experience.

Reference: *NEJM* 1997; 336: 453-8

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## Patches get the thumbs down

***The patch principle - in which an ingredient is slowly released into the body from. a patch stuck onto the skin***

***-has been so successful in pharmaceuticals that it has caught the imagination of other product manufacturers. Both the Consumer's Association and the Advertising Standards Authority have expressed concern at the latest crop of new products***

A scented blue plaster called Diet Scent makes some rather dubious claims, according to the Consumers Association magazine *HealthWhich?* Manufacturers of the sticky patch, which hit the shops in June, claimed it may help banish cravings for sweet foods, such as chocolate, because 90 per cent of what we taste is based on what we smell.

But whether you can be sure of shedding those extra pounds along with the £30-odd you'll have to shell out for 28 plasters - is another matter, says the Consumer's Association magazine.

"There is a giant step from recognising that smell is connected to taste to claiming that a sweet smell will satisfy all your cravings without you having to eat a morsel," says Rob Ashton, *HealthWhich?* Managing Editor.

According to the Consumer's Association, Diet Scent's inventor, Liz Paul, cites US tests on more than 3,000 people who sniffed inhalers for six months and lost about five pounds a month. Yet even the doctor who conducted the tests admits he's not sure why they worked, says the CA.

In her own tests, the magazine reports, while 11 out of 24 people who wore the patch lost weight, so did ten people out of 25 who wore a dummy patch.

"The tests that have been done on this product are inconclusive to say the least," says Mr Ashton.

"Let's just say the company has got a bit carried away with its marketing."

### **Complaints against impotence patch upheld**

***Advertisements for the "Male Arousal" patch, have also caused concern***

Florida company Health & Life Science sent out a mailshot containing, among other things, a letter from a doctor that stated: "The inability to achieve sexual satisfaction for yourself-and, just as important, your partner. How can you solve this problem? There are two methods I would recommend: The first is to consult a medical specialist such as myself.. the second is to try the special "Male Arousal" scientific skin patch course. This is the method I suggest you try first". The mailing, which also included a leaflet and a letter from a therapist, described the patch as "an effective scientifically-developed product that can stimulate your sexual system-enabling you to enjoy satisfying sexual experiences".

A number of complaints against the mailing were upheld, including one against the use of a fictitious doctor's name coupled with a Harley Street address (the name, the company said, was a pseudonym for a Belgian doctor). A pseudonym had also been used for the therapist.

Claims for the product's efficacy were not supported by the advertisers, they merely said they offered a refund if the product failed to work. The advertisers were asked to withdraw all claims that the patch could improve sexual performance.

Health Which? June 1997

ASA Monthly Report, June 1997

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## **Clinical trials and consumers**

***To take part, or not to take part, in a clinical trial? That is the question that faces many patients. Andrew Herxheimer emeritus fellow of the UK Cochrane Centre and a member of the HealthWatch Committee, explains the whys and wherefores of clinical trials and argues for consumers to have more say in the process***

Clinical trials are essentially planned experiments that involve patients or healthy volunteers. They aim to find out how effective medicines and other treatments or interventions are, how different treatments available for the same problem compare with each other, what unwanted effects they have, and how particular treatments are best used.

Conclusions from other kinds of research or from casual observations are often wrong and always unreliable, for example because the course of illnesses is so variable and because of biases in favour of one or other treatment.

### **Control of trials**

Many illnesses get better even when no treatment is given. A treatment is of value only if the patients receiving it do better than those not receiving it. We therefore need a comparison group, called the control group, to control our conclusions. To make sure that any differences in outcome between the test group and the control group can be attributed to the test treatment, everything else about the groups should be as nearly as possible the same. For example, the severity and duration of the illness should be similar, and both groups should be treated in the

same place and by the same staff

The most reliable way of making sure that the participants in the treatment and control groups are as similar as possible is to randomise them - that is, to determine by chance which group they will be in.

But randomisation is not always enough to eliminate bias. If the patient strongly believes that his or her treatment works, then that belief will reinforce and magnify any biological effect of the treatment by adding a powerful "placebo" effect (1).

In a double-blind trial neither the staff nor the patients know which treatment a patient is getting, and the design of the trial must also make it impossible or difficult for them to find out-even though many very much want to know

The size of a trial also matters: small trials more often give unrepresentative or even freak results than large ones.

### **Why trials are done**

Most clinical trials are performed to investigate new drugs, as part of the development of new treatments by pharmaceutical companies. To obtain a licence to market a new product, a company has to satisfy the licensing authority (in Britain the Medicines Control Agency or the European Medicines Evaluation Agency) that it is effective and safe.

There are two fundamentally different types of question that a clinical trial can ask. One aims to find out what is the best that the treatment under test is capable of achieving in the most favourable circumstances. In this type of trial, often called an 'efficacy trial', the patients are carefully selected to make the treatment effects clearly visible, and to keep other influences on the outcomes to a minimum. For example, patients with a complicated illness or with poorly functioning kidneys are usually excluded. In such patients the drug tested will work less reliably and may be more likely to cause unwanted effects.

But such trials tell us little or nothing about how the drug will perform in all the patients who might be given it in everyday life. The other type of trial, often called a 'pragmatic trial', does that: it aims to show what the drug can achieve in the whole range of patients with the relevant problem in the general population. Efficacy trials are done early in a drug's career, and if the drug looks sufficiently promising, pragmatic trials follow.

### **Quality of life**

Until fairly recently the design and planning of clinical trials focused especially on changes that could be measured objectively and reliably, such as biochemical changes that can be picked up in a blood test, body temperature and so on. They were not, however, concerned with what the illness does to patients' lives-their ability to work or to go out, how they feel, their enjoyment of food, and so on. Such 'quality of life' (QoL) indicators differ greatly between individuals and are harder to measure. Clinical trials now increasingly try to assess QoL (2), and as they get better at doing this the results will mean more to patients. Progress in this direction requires active participation by consumers and their representatives in the commissioning and planning of trials (3).

### **For and against taking part**

Participation offers advantages to individual patients as well as to collective future patients with the same problem. When the trial is of a new drug or other treatment, there is the opportunity of being given it before it is generally available and that may be especially important when current and previous treatments have been disappointing. Secondly, in a clinical trial patients tend to get more and better attention than they usually do in routine practice, since the quality of data is important for the success of the trial. Third, the patient is likely to learn more about her or his health problem and its treatment, and can become a more effective partner in its management.

These advantages can sometimes become disadvantages. To be among the first to try a new treatment exposes patients not only to potential new benefits but also to unknown risks and harm. The closer attention may become onerous and a nuisance rather than reassuring. It can even do harm by causing anxiety or by leading to over-treatment (4).

### **Informing patients about trials**

It seems obvious that when patients are invited to take part in a trial they should be given all the information about it that they need to make a balanced decision on whether or not to accept.

But this is not always the case. The World Medical Association (WMA)'s Declaration of Helsinki for the ethical guidance of investigators states that, "If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee." The UK Breast Cancer Coalition has recently petitioned the WMA to delete this clause from the Declaration.

It is essential that patients understand:

- what their rights are (5);
- the purpose of the trial-what questions it is seeking to answer, and how;
- what it will involve for them personally in terms of medicine taking, tests, follow-up, attendances, etc;
- what are the possible/likely benefits, disadvantages and risks for themselves;
- how the trial is being paid for and managed/supervised;
- what arrangements exist for compensation if anything goes wrong as a result of the trial;
- whether the outcome of the trial will be published.

### Ethical aspects

In order to find out whether a drug is effective, it is necessary to compare it with an inactive treatment or no treatment. This means that the 'control' patients will be denied the 'active' treatment. If the active treatment is beneficial, they will not benefit; if it does harm they will not be harmed by it. This seems reasonable and fair if no effective treatment for the condition is known, but may not seem so to those patients or doctors who strongly believe that the new treatment works.

Because the zeal of investigators and sponsors of trials may bias them in favour of ethically debatable studies, such questions are decided by a research ethics committee (REC) in the institution or district where the trial is proposed. The work of RECs is of uneven quality. Many still endorse research which is unnecessary, and acquiesce in under-reporting of research which they have approved (6).

Another issue is whether a proposed trial is scientifically justified and sound: is it asking an important question and is it capable of answering it? If not, then the trial would be a waste of resources.

Patients should be told that they will be free to withdraw from the trial at any time if they wish, without having to give a reason. But investigators do not want participants to withdraw 'unnecessarily', since this would jeopardise the success of the trial.

If people are to understand the implications of taking part in a trial, the information given to prospective participants should be drafted and tested with the active help of consumers / patients.

### Patients' preferences

A trial compares two or more treatments or a treatment and placebo, to find out which is more favourable, usually when this is not known. Patients therefore often prefer one or other of them, and do not wish to be randomised. There is so far no clear view how best to proceed when randomisation is either impossible or unacceptable to most patients (7).

### Independent auditing needed

Every organisation connected with health research should include consumers who can represent the interests of patients and the community. Their participation should be funded from the research budgets, audited independently and publicly. This might be done by or in collaboration with the NHS Research and Development Programme.

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### Acknowledgments:

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Andrew Herxheimer ,Consultant clinical pharmacologist

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## Homoeopathic arnica "not effective"

**A paper in the *Journal of the Royal Society of Medicine* recently concluded that the homeopathic remedy arnica "had no effect on postoperative recovery".**

Arnica has traditionally been used by homeopaths to prevent bruising and to treat trauma. It is widely used just before and immediately after major operations to speed recovery and reduce pain and bruising. But there have been few high quality clinical trials of homeopathy, say the researchers, and a total of nine published trials on arnica, of which four were inconclusive.

This trial, by researchers at the University of Southampton, examined the effects of arnica C30 on pain and post-operative recovery in 73 women following total abdominal hysterectomy at Southampton's Princess Anne Hospital. The trial was double-blind, placebo-controlled and randomized.

Women were given two doses of arnica C30 tablets or identical-looking placebo tablets during the 24 hours before the operation, then three doses a day for five days starting on the morning after the operation.

The paper concluded, "In terms of pain, analgesia, infection and operative severity, this study revealed no significant differences between the arnica and placebo groups."

Reference: Hart O, Mullee MA, Lewith G, Miller J. Double-blind, placebo-controlled, randomized clinical trial of homeopathic arnica C30 for pain and infection after total abdominal hysterectomy. *Journal of the Royal Society of Medicine* 1997; 90: 73-78.

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## Importance of bedside manner

High satisfaction rates for complementary treatments could owe as much to the time spent and information given by the practitioner as to the efficacy of the treatment. Professor Edzard Ernst and colleagues from Exeter University's Department of Complementary Medicine surveyed 333 women who had consulted both their GP and a complementary practitioner for arthritis symptoms. They found the patient-therapist encounter is perceived to be more satisfying with complementary practitioners than GPs.

Particularly when there is no prospect of a cure, as with 'arthritis', we ought to remember how much a good bedside manner may achieve," they write.

Reference: Ernst E, Resch KL, Hill S. Do complementary practitioners have a better bedside manner than physicians? *Journal of the Royal Society of Medicine* 1997; 90: 118-9.

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## Spotting junk science

### How can the layperson know how to sort the facts in the news from the hype?

The US Food and Nutrition. Science Alliance (FANSA- Institute of Food Technology, American Dietetic Association, American Institute of Nutrition and American Society of Clinical Nutrition) recently issued 10 red flags to help consumers to spot "junk" science.

- Recommendations that promise a quick fix.
- Dire warnings of danger from a single product or regimen.
- Claims that sound too good to be true.
- Simplistic conclusions drawn from a complex study.
- Recommendations based on a single study.
- Dramatic statements that are refuted by reputable scientific organisations.
- Lists of "good" and "bad" foods.
- Recommendations made to help sell a product.
- Recommendations based on studies published without peer review.
- Recommendations from studies that ignore differences among individuals or groups.

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## CA Aiming for "even-handed" assessment of therapies

**Dr David Dickinson, editor of the magazine "HealthWhich?" speaks for the Consumer's Association. Are the CA, wondered HealthWatch Chairman Professor John Garrow, truly objective when assessing complementary and alternative medicine?**

Professor Garrow opened the discussion. "The Consumers' Association is famous for its willingness to apply objective tests to goods and services offered to the public. My impression is that it does not apply similar tests to alternative and complementary medicine. Is that true?"

*Dickinson:* It is not true: we do a lot of testing of healthcare products and complementary therapies. What we do not do, because we do not have the resources, is conduct clinical trials.

*Garrow:* But concerning the efficacy of a treatment you tend to quote the opinion of unnamed "experts" rather than giving the results of trials which have been done.

*Dickinson:* That is a good point, but our experts are not always unnamed, and in the February issue of *Which?* about chiropractic we do quote lots of research including the trials done by Meade *et al.* We try to present a balance of good quality evidence, and are often criticised as being negative about complementary medicine, because although in some therapies like chiropractic there is quite a lot of good quality evidence, in acupuncture there is some but not a lot, and in homeopathy very little.

We have also just published the "Which? guide to complementary medicine" which is careful to draw distinctions between those treatments backed by strong evidence, and the more outlandish therapies.

*Garrow:* Do you see any scope for cooperation between CA and HealthWatch in situations where a simple clinical trial might be done? For example there are products being marketed which are alleged to prevent you from absorbing fat in food. The validity of this claim could be checked very easily by measuring faecal fat.

*Dickinson:* CA does not want to be aloof or separate: we are committed to empowering people to make informed decisions about healthcare, just as HealthWatch is, and we already have teamed up with the National Asthma Campaign, for example, to investigate extraordinary claims for asthma remedies.

However we want to be even-handed - it would be invidious to show that many complementary therapies have no good evidence of efficacy, and ignore the fact that the same is true of many therapies in conventional medicine.

*Garrow:* I agree. Let us move to another question. CA, like the BMA and HEA, want a "single register of competent practitioners" of complementary medicine, so "consumers should be able to trust a practitioner's registration as proof that they are up to scratch." Is it not necessary to have evidence of efficacy of a therapy before you can compile such a register?

*Dickinson:* Evidence of efficacy would make it easier to assess the competence of practitioners, but even without that a register has value. It is important that practitioners should recognise the limitations of their own competence, so they avoid situations in which they might do harm, such as manipulation of a back damaged by malignant disease. The really dangerous people are those who see no limitations to their therapy, and encourage their patients to abandon all conventional medicine and "walk free". However our surveys suggest that there are fewer patients who have complaints about complementary therapy (about 3%) than about conventional therapy (about 7%): in part this may be because people know how to complain about treatment from their GP.

Probably the main reason for registration is the question of safety and redress. Practitioners will come to realise that it is their interests to have professional registration and indemnity, and this will tend to drive the ill-equipped practitioner out of practice. Osteopaths and chiropractors have found it possible to set up a single professional register, and I am sure it is not coincidence that these are the therapies with best evidence of effectiveness.

*Garrow:* CA also campaigns for changes in the law to improve consumer protection. I am worried about highly misleading health claims which are made by publishers advertising books available by mail order. It seems that there is a weakness in the law controlling this form of abuse.

*Dickinson:* I think that is true: we report such cases to the Advertising Standards Authority, but in some cases they seem to have no effective sanction. I agree that in some ways selling a book which provides bogus healthcare information is more dangerous than selling a specific gadget which is ineffective.

We are at the moment overhauling our campaigning aims, so I will make sure that the point you raise is one that goes on the list. We would certainly like to see a more vigorous reaction from the ASA on the material we send them. Sometimes they do not seem to be as wholeheartedly on the side of the consumer as they should be.

John Garrow, Chairman of Healthwatch

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**Letter: Complementary cures - taking time to work?**

**Gus Plaut, retired General Practitioner of Halstead, Essex, writes:**

Dear Sir,

Dr Andrew Herxheimer in his review of the book by Professor Edzard Ernst (HealthWatch [Newsletter 24](#), page 5) states that we have hardly begun to ask how we can identify and optimise the context effects of non-specific factors such as a good bedside manner, or a healer's optimistic attitude.

I suggest our ancestors knew about these effects. The eminent 18th Century physician Dr John Fothergill was popular and so successful, patients came to see him in London from far and wide, even America. This may have been partly because he avoided such drastic measures as excessive bleeding and purging, but undoubtedly mainly because he was sympathetic and caring, and also had a good knowledge of diseases. Unlike many of his contemporaries he always dressed neatly, never swore and never drank excessively. He was a Quaker and his habits were known to be above reproach.

A sympathetic attitude of this kind is as helpful now as it was in those days. Half an hour's consultation is usually the minimum for a consultation with a practitioner of Complementary Medicine; it is unusual in NHS general practice. A caring attitude is especially important if effective medication is not available.

A comparison may be made with modern private consultations and general practice of earlier days. In both, a single-handed doctor consults for a fairly long time with the patient. The practitioners of complementary medicine have similar arrangements. The complementary medications may be ineffective, but the practitioner's empathy with the problems of the patient will be felt to be valuable and thus often beneficial.

It could be said that scientific research into the benefits of complementary medicine is in its infancy. I suggest the infancy of mainstream medicine is being continued by the practitioners of complementary medicine.

Yours faithfully

Gus Plaut

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