Complementary medicine has become one of the fastest growing consumer healthcare sectors, say market analysts MINTEL in a new report.


The alternative therapy business has been boosted by rising prescription charges, greater dietary awareness and demand for products which are "natural", says the report, Complementary Medicines, published July 1995.

The largest sectors are herbal remedies, which account for 56% of the total market, and homeopathic remedies with 28%. Aromatherapy oils showed the fastest growth of the three sectors covered, with sales increasing by 67% to £10 million in 1994.

Complementary medicines are popularly used for common problems such as back pain, colds, 'flu and migraine. The biggest growth areas are in treatments for mental problems, such as stress and tension, but alternative remedies are now considered for an increasing range of ailments as well as for treating conditions where traditional drugs may not have been effective. In 1992 the BMA accepted that there was growing consumer demand for complementary medicine and that more GP's wanted to be trained in their use.

The most sceptical consumers are the elderly. Twenty-three per cent of over 65s believe alternative medicine does not work, against an all adult average of 15%.

Acupuncture - elusive and exciting?

In the October 1994 HealthWatch Newsletter no 16 we published an article in which Dr Ian Johnson explained his disappointment with acupuncture. The Summer 1995 issue of Holistic Health includes a reply by Dr James Hawkins (MB BChir Dip Ac Nanjing). We have agreed to share his views with HealthWatch members.

"Traditional Chinese medicine, like many other things, is not at all perfect, consisting naturally of both pearls and rubbish."

Ian Johnson's experience of acupuncture and his subsequent doubts in many ways mirror my own.

I too have been involved with this field for about twenty years. I too started with a short introductory course and later went on to a more prolonged training—in my case at the College of Traditional Chinese Medicine in Nanjing. I too became fairly disillusioned and considered throwing up the whole subject. Unlike Ian Johnson, however, I have persisted in exploring the possible usefulness of acupuncture and related techniques. I am glad I have.

Like Ian Johnson and just about all other health workers, we are continuously engaged in a struggle to find more effective ways of helping those who come to us in distress. It seems to me that the honest, caring response is to
ask which of these possible therapies is backed by the best evidence - evidence both of possessing beneficial
effects for this particular sufferer’s problems and evidence of minimising side-effects and costs.

Before judging acupuncture too severely, it is worth glancing at the research underpinning conventional medicine.
The use of anti-depressants, for example, has been perceptively challenged in a recent meta-analysis.

A further meta-analysis on physiotherapy in the treatment of musculoskeletal disorders concluded that:

“In general the methodological quality of the studies appeared to be low, and the efficacy of
physiotherapy was shown to be convincing for only a few indications and treatments. On the other
hand, because of the prevalence of serious methodological flaws, it cannot be concluded that
physiotherapy has no effect.” These reviews highlight the fact that conventional forms of therapy may
well also lack adequately strong research backing.

Randomised clinical trials are the basic data from which meta-analyses draw their conclusions. Ideally such
randomised trials will form the bulk of research efforts. A review of research designs in three leading medical
journals, however, found that only 16% of published articles over a ten year period were randomised controlled
trials. Certain fields such as surgery (and acupuncture) do not lend themselves so easily to double blind
randomised methodology and so will have an even lower percentage of their research trials of this type. In many
ways it is impressive that the now somewhat dated meta-analysis on acupuncture and chronic pain quoted at
length by Ian Johnson should have been able to find so many controlled clinical trials to review.

Loss of important detail?

Meta-analyses of research on approaches such as acupuncture may also be more difficult than on, for example, a
therapy such as antibiotics. In the longer version of this paper* I explain concerns about the type of acupuncture
stimulation involved, the mismatching of what was thought to be comparable treatment and control groups and
possibly over-harsh restrictions on what constitutes an adequate placebo treatment group.

Other research not looked at in the meta-analysis

Research has of course continued since the important meta-analysis quoted at length by Dr Johnson. Probably
the most impressive body of work has been the series of studies on the treatment of nausea initiated by John
Dundee, Professor of Anaesthetics at Queen's University, Belfast. Fourteen papers cover the treatment of nausea
due to opioid analgesics, cancer chemotherapy and pregnancy using manual acupuncture, electrical acupuncture,
transcutaneous electrical nerve stimulation (TENS), finger pressure and the use of pressure bands on the wrists.
Stimulation of the P6 acupuncture point at the wrist by any of these methods produces relief of nausea which is
better than that achieved by stimulation at a control point. The findings have been supported by at least four
other research teams.

This work highlights two further issues. Firstly, needling acupuncture points is simply one method of producing
effective stimulation. Pressure and electricity are other useful hyperstimulatory techniques and may well at times
be more convenient.

Secondly, the work demonstrates that acupuncture is not just a treatment for pain. It has other important uses,
including its effects on viscera. A recent review published in the American Journal of Gastroenterology states
“there is strong evidence to support the regulatory effect of acupuncture on several gastrointestinal functions,
including motility, electrical activity, and secretion. These effects are mediated through neural opioid peptide
pathways. The review describes ninety or so studies on both animals and humans.

Other organ systems can be treated using hyperstimulatory techniques. A prospective randomised trial on renal
colic showed acupuncture to be as effective in relieving pain as an intramuscular injection of analgesic.
Acupuncture however acted more rapidly and produced fewer side-effects. Both acupuncture and TENS are
effective for dysmenorrhoea. Labour too can be induced using such methods.

Stimulatory techniques can also be extremely helpful for the treatment of anginal pain. Clas Mannheimer and
colleagues from Goteborg in Sweden have published at least half a dozen papers on this subject (their 1990
study includes references to past research).

Dr Birger Kaada from Norway has spent over a decade studying the hyperstimulatory techniques on blood flow.
TENS can be used to produce vasodilation with potentially useful applications for peripheral vascular disorders. A
more recent paper has looked at the helpfulness of TENS for high blood pressure, and provides an introduction to
acupuncture's mechanisms in this area as well.

A paper from the Karolinska Institutet in Stockholm follows up the possible link from acupuncture to the
autonomic nervous system and on to the immune system, showing that acupuncture can modulate the immune
response at least in laboratory animals.

Another impressive paper from the Karolinska Institutet reported on acupuncture, low energy laser, pulsed
ultrasound, elbow band, splintage and steroids for the treatment of tennis elbow in 337 patients over a 5 year
period, and concluded “The ‘deep’ acupuncture technique applied to acupuncture points related to the elbow is
the method of choice in treating lateral epicondylalgia.”

A Danish team looked at the long-term effects of acupuncture in the treatment of osteo-arthritis sufferers waiting for knee replacement surgery. The response was encouraging with significant reductions in pain and medication, and over 20% of the patients improved so much that they said they no longer wanted surgery.

Scandinavian researchers have also done further work on migraine treatment. A randomised double blind trial found acupuncture to be as effective as beta blockers in reducing the frequency of migraine attacks.

This quick scan suggests a field ripe continues with very considerable promise. The data does not support a tradition-bound adherence to historical Chinese principles. A major challenge for at least the next decade will be to learn from the growing body of laboratory work on underlying mechanisms of action so that we can develop increasingly effective forms of hyperstimulatory treatment in the clinic.

Lack of cross-fertilisation between research on mechanisms and research on therapeutic benefits

Vincent and Tsutani attended the 3rd World Conference on Acupuncture in Kyoto at the end of 1993. They comment on how many reports on acupuncture are so anecdotal as to be virtually worthless. The positive side to this is that it is not hard to keep abreast of important emerging research in the field. Vincent and Tsutani also remark that research on mechanisms is seldom linked to research on clinical efficacy. There are, however, a surprising number of mechanisms triggered by hyperstimulatory techniques. Examples include increased local blood flow at the needle site for two or three days after treatment, more widespread humorally mediated vasodilation, local release of opioid peptides, activation of local and descending inhibitory pain pathways in the spine, release of both opioid and non-opioid transmitters in spine and brain, modulation of autonomic nervous system activity, immune modulation and possible disruption of memory-like pain processes in the brain.

In conclusion

Many traditional concepts were major steps forward historically, but now are very dated and in danger of limiting development of the field. As a steady trickle of good research studies continues to emerge amongst the flood of more anecdotal reports, so the patchwork of improved understanding continues to build. Hyperstimulatory techniques are clearly of potential use in many clinical situations. Informed innovative practice is going to help many patients whose present suffering is not adequately eased either by other forms of medicine or by our current more limited use of acupuncture and TENS. Acupuncture is certainly elusive. On closer inspection though it is found to be not so much illusory as exciting and full of promise.

*For reasons of space, the paper above has been edited by HealthWatch in consultation with the author. A copy of the full paper, along with a complete reference list is available on request. Please send an SAE to the author at the following address: Dr James Hawkins, 78 Polwarth Terrace, Edinburgh EH11 1NJ

Dr James Hawkins has 20 years experience in complementary medicine and is a founding doctor trustee of the British Holistic Medicine Association. He is a member of the International Association for the Study of Pain, a founder member of the North British Pain Association, and is on the editorial board of the Journal of Orthopaedic Medicine. He gained a Chinese acupuncture diploma in 1981 and is a regular lecturer on Postgraduate Courses in Edinburgh and elsewhere.

Dr Hawkins works through the small charity Good Medicine, as a consultant in pain and stress management.

Consumers in the dark over 'light' foods

Misleading food claims and poorly presented nutrition information could be confusing customers who want to follow a healthy diet, says the August issue of the Consumers Association magazine, Which?.

A Consumers Association survey of 1,454 adults found that over 60% want to eat healthily, but half of those interviewed find it difficult to use nutrition panels to choose a healthier product.

Claims on labels can be misleading, and consumers often take claims with a pinch of salt. The magazine gives as an example the use of the word 'light' on food labels, and highlights some anomalies from the supermarket shelves:

- two cheese spreads, both calling themselves 'light' yet, weight for weight, one had three times as much fat as the other;
- an oil whose 'light' claim referred to its colour-its calorie content was as high as other oils;
- a butter alternative labelled as being 'light' and 'low-cholesterol', but containing more fat and calories by weight than butter.

While welcoming the fact that more and more manufacturers are including clear nutritional information on their packs, Which? found that there is still widespread confusion. "The law governing nutritional claims is inadequate,"
says Which?. They urge the European Union, who begin reviewing the Nutrition Labelling Directive later this year, to look at ways to make labels easier to understand.

Allergy tests "could lead to wrong treatment"

Allergy testing is often a waste of time, warns the Drugs and Therapeutics Bulletin.

Around one person in six has an allergy, and the use of skin prick tests and antibody screening for reaction against a wide range of common allergens is often used as a means of pinpointing the source of the problem. But, according to the Bulletin, test results can often fail to identify the cause of allergy symptoms or to allow doctors to choose the best treatment.

"Allergy testing can only act as a guide," says editor Dr Joe Collier. Used unselectively, such tests are wasteful, increase risk, and may lead to inappropriate management.

Complaints upheld against arthritis ads

Two companies advertising remedies for arthritis have had complaints upheld against them by the Advertising Standards Authority this month.

One, Maple Marketing (UK) Ltd of Southall, Middlesex was asked to rewrite a national press mail-order advertisement which claimed, "Did You Know that it is possible to obtain quick and lasting relief from the pain of Arthritis? A brand new book... explains what researchers now know about arthritis, and reveals a wide range of methods that can bring long-term relief for all sufferers today." The same company was asked to remove claims from an advertisement for a book that offered a fast-working method of flattening the stomach with "No dieting! No weights!"

The Margaret Hills Clinic of Kenilworth, Warwickshire was asked to withdraw a brochure entitled "Natural relief of arthritis" promoting a diet-based treatment.

MS sufferers resort to illegal drugs

Many multiple sclerosis sufferers are risking their health and breaking the law to relieve their symptoms, by using cannabis from back-street dealers, a researcher claims in a report in Which? Way to Health.

Cannabis reduces pain, muscle spasms and bladder problems, according to about 60 MS patients who have spoken to Dr Roger Pertwee at Aberdeen University. Cannabis from illegal dealers varies in strength and may not be pure. There are worries that patients are using it without medical support.

According to Roger Ashton, Assistant Editor of "Which? way to Health", the healthy brain naturally produces compounds similar to that found in cannabis, which seem to be linked with muscle movement and pain perception.

Chiropractic "more beneficial than hospital treatment" concludes trial

Patients with low back pain derived more benefit from treatment by a chiropracter than from a hospital, says a paper published in the BMJ in August.

The three year study, carried out by a team based at St Bartholemew's and Northwick Park Hospitals, randomly allocated 741 male and female patients to either a chiropractic clinic or a hospital outpatient department.

Outcome was measured using the Oswestry questionnaire on back pain, in which patients give ratings for factors such as intensity of pain.
According to total Oswestry scores the patients treated by chiropractic manipulation improved by 29% more than did those who received conventional treatment. The beneficial effect on pain was particularly clear, says the report, which recommends further trials to identify the effective components of chiropractic.


Editorial

When an organisation with a reputation for being "antidrugs industry" writes to HealthWatch suggesting friendly links, 'since it would seem that we have a lot in common", we can be grateful that at least not everyone has succumbed to the fanciful idea that HealthWatch is in some way tied to the drug industry.

The organisation concerned is called the Medical Lobby for Appropriate Marketing (MaLAM for short). This rather awkward name disguises a worthy cause, which slots in well with the ideals of HealthWatch.

MaLAM is international, with branches in many countries - Australia, the Americas, Europe and Asia - and when John Appleby, the Coordinator for MaLAM UK (address 13 Springfield Road, Thornton, Bradford, BD15 3DA) wrote to us and sent us literature the HealthWatch committee unanimously accepted the invitation for reciprocal relations.

We like the way in which MaLAM politely but persistently challenges the big drug companies to justify some of their marketing methods in developing countries.

It is sometimes tempting for firms to promote drugs in these countries in a less careful and less stringent way than they might do in the developed world. MaLAM, which roundly declares that "in the developing world misleading drug advertising is common" sets out to monitor and check this. One of the names on its headed paper, as you might expect, is that of Andrew Herxheimer, one of the HealthWatch committee re-elected at our last Annual General Meeting.

Our present century, now with little more than four years to go, has-rather surprisingly, but fairly clearly-shown that competition, capitalism and profits, with all their disadvantages and imperfections, generally give the consumer a better deal than does a more idealistic society that forbids or drastically restricts such things. And there don't seem to be any very good grounds to think that this is not as true in the health field as in any other.

But there is a constant danger that the drive for commercial success (sometimes not so much for success as for survival against fierce competition) will overstep the boundaries of acceptable ethical standards. This, of course, applies just as much to the burgeoning multi-million pound "alternative" health industry ("natural" remedies, "ancient" remedies, and so on) as it does to the generally more effective and sometimes life saving mainstream drug industry. The idea, popular in some fringe medicine circles, that different commercial criteria apply, doesn't stand up to serious consideration. But both industries have to be watched and we applaud MaLAM for watching them, as in our small way we try to do ourselves.

Thurstan Brewin, Chairman of Healthwatch

Identifying randomised trials in titles and references

Assessing the weight of evidence supporting the effectiveness of healthcare interventions could be easier if randomised controlled trials (RCTs) are made to stand out from other data.

"In practice the best evidence comes from randomised controlled trials comparing two or more 'treatments', because correctly performed randomisation is the most certain way to minimise bias," says Andrew Herxheimer in his paper, "Identifying randomised trials in titles and references: why and how", published in the October issue of European Science Editing.

The number of RCT's cited by a paper roughly indicates the weight of the evidence. It would help readers if they could identify reports of randomised trials as such, and see quickly to what extent conclusions and recommendations in review articles are based on findings from RCTs.

A solution is for reports of randomised trials to have "(RCT)" added to the end of the title, and references to RCTs cited at the end of an article to be prefixed with "R" or "RCT" before the number of the reference.

The suffix RCT was introduced in Medline in 1991 as a publication-type term, and is now being applied retrospectively with the aim of identifying all RCTs included in the Medline database. The first publication to use the prefix "R" for references to RCTs is Drug and Therapeutics Bulletin, which introduced it this year.

HealthWatch plans also to adopt the practice. Reference lists in future issues of the HealthWatch newsletter will
Value judgment

HealthWatch committee member Andrew Herxheimer wonders whether treatments that prove ineffective should be subjected not to VAT but to value-subtracted-tax! Readers' comments welcome.

Trading standards: Food Source One - Nutra Health U.K. Ltd

Committee member and former Health Watch chairman Professor John Garrow reports on the successful prosecution of a food supplement company who distributed a leaflet making unrealistic claims for the product's slimming properties.

The enforcement of the Trade Descriptions Act 1968 falls to the Trading Standards departments of local authorities. Prosecution of offenders involves considerable costs which are often not fully recovered from the defendants, even after a successful prosecution, so in times of financial stringency there is a strong disincentive for these departments to prosecute. It is therefore encouraging that four authorities (Coventry; Essex, Hampshire and Croydon) joined together to prosecute Nutra Health UK Ltd, of Handforth, Cheshire, who distributed tablets called Food Source One.

The case was brought at Coventry Magistrates Court by Coventry Trading Standards on 15.2.95: Mrs Vicki Buckley was the Prosecuting Solicitor and Nutra Health was not represented. The charge involved a total of 25 offences in three different areas: misleading advertising claims; differences between the analysis as stated and as determined by Public Analysts for the prosecuting authorities; and minor breaches of the Food Labelling Regulations 1984.

An interesting feature of the promotion for this preparation was that the local newspaper carried an advertisement (and headed as such) formatted as if it were a news item, datelined "WASHINGTON", with the headline "Weight loss baffles scientist", which recounted that an American scientist "was baffled at how successful a natural food tablet and plan had become at helping overweight people to lose weight". The explanation was said to be "still something of a mystery". There followed testimonials from a woman in New York and another in Louisiana who had lost 70 lb within a year. The paragraph ended: "Ask your pharmacists - Food Source One is available at: " and give the address and telephone number of a local stockist.

The specific claims on which the prosecution was based were in a leaflet or a letter from the supplier to the pharmacist. The leaflet entitled "Natural nutritional weight loss with food source one" said "Food Source One is a wholesome and pleasant tasting dietary supplement with the proper balance of essential vitamins, minerals, protein, carbohydrates, fatty acids and fibre that would be contained in a well-balanced meal". The packaging indicated that 3 tablets should be taken with 8 oz water three times a day 30 minutes before meals, and that 3 tablets provided 13.4 kcal, 0.89 g protein, 2.60 g carbohydrate, a trace of fat, 0.77 g fibre and 30% of the daily requirements of vitamins. The Birmingham Public Analyst reported that the protein content of the tablets was overstated, and that the daily fibre intake of only 2.5 g provided by the tablets was unlikely to produce the appetite suppression as claimed.

The Magistrates found all 25 offences proven and imposed a fine of £1000 for each of 12 offences under the Trade Descriptions Act 1968, £500 for each of a further two for applying and supplying false descriptions to goods (protein claims; again under Trades Descriptions Act 1968), and £500 for each of 11 for breaches of the Food Labelling Regulations 1984, making a total fine of £18,500. The Court also ordered the defendant company to pay £2,785 prosecution costs.

This case shows that, with suitable cooperation between Trading Standards Officers of different Authorities, successful prosecutions can be brought for misleading claims for diet tablets, even when the claim is made by a distributor via the pharmacist who sells the product, rather than directly to the public.

John Garrow, Professor of Human Nutrition, St Bartholomew's Hospital Medical College

Skeptics discuss increase in fringe medicine in Europe

Meeting in Rossdorf in Germany in May, more than 120 delegates to the 7th European Skeptics Conference discussed the alarming and meteoric rise in fringe medicine. Many felt that the devious tactics, political manipulation, and financial clout of the proponents of quackery are a source of serious concern.

Professor Ernst Habermann of Germany in his talk "Poisoned without poison" examined the way drugs or chemicals, whether prescribed by a practitioner or emitted in the environment, are perceived as somehow "bad". "Hysterical" or psychosomatic illnesses were also covered, along with phenomena such as Gulf War syndrome or...
Sick Building syndrome.

M. A. Wagner discussed the history of chiropractic and the split between those of its practitioners who still believe that almost all illness can be treated by spinal manipulation and those who have given up this idea. Despite flaws which should prove fatal to the movement it flourishes.

Sir John Maddox, the retiring editor of the science journal, Nature, talked about how and why top scientists, like Nobel prize winner Linus Pauling, occasionally latch on to an unshakable belief in some sweeping theory or claim and cling to it, no matter how much the evidence piles up against it.

Other speakers included James Randi, noted conjurer and exposer of psychic fraud and Paul Kurtz, chairman of the 20-year-old American organisation CSICOP (the Committee for the Scientific Investigation of Claims of the Paranormal).

Further information is available from ECSO (European Council of Skeptical Organizations) Postbus 2657, 3500 GR Utrecht, The Netherlands.

Harriett Moore, 17 Ballynaris Hill, Dromore, County Down BT25 1JB

Opinion: Homeopathy - It may be popular, but does it work?

**Dr Neville Goodman has heard plenty of anecdotes about the effectiveness of homeopathy in clinical practice. But, he asks here, where is the hard evidence?**

The great strength of orthodox science is its scepticism. It is a weakness of scientists, not of science, that puts undue stress or credence on attractive but flawed ideas. Sir Peter Medawar pointed out that strength of belief in an idea has no bearing whatever on whether the idea be true. A corollary is that the number of people who hold a belief has no bearing on its validity. Truth is not democratic.

Homeopathy is becoming more popular. We are told that more and more people in Britain want homeopathic medicines, and we are also told that one of the reasons we should make homeopathy more available on the NHS is its widespread use on the Continent. Medawar permits us to ignore this, but how well do the homeopathists themselves state their case? I will first state mine: the idea that dilute solutions have effect is not a problem, but it depends what you mean by dilute. Homeopathic dilutions are such that even the homeopathists admit their solutions contain nothing except water. These solutions cannot have any effect on disease unless we rethink entirely the physicochemical basis of physiology and pharmacology, and I paraphrase Professor Michael Baum when I write that however many trials there are (and there are not many) that have shown some possible effect of homeopathy, the results are not impressive enough to warrant this radical rethink.

Homeopathy is useless, but homeopathists can do much good. In Bristol we have a homeopathic hospital and a number of excellent GP's who practise homeopathy alongside their orthodox medicine. They do not claim homeopathy can cure cancer, but they do believe that homeopathy can help in a number of diseases. In common with many alternative therapies, the claims are strongest for conditions for which orthodox medicine has few answers: back pain, eczema, asthma, and similar chronic but varying conditions. One of the medical societies in Bristol invited one of these GP's to give a talk. I went along. I took with me my file cards on the subject and sat cautiously about two-thirds of the way back in the audience.

As a presentation to confirm the views of the converted, or to capture the views of the innocent and ignorant (a term I use without insult), the talk was brilliant. The speaker was an obviously sympathetic doctor who cared greatly for his patients. In the course of 45 minutes he presented not a single scientific fact in support of homeopathy as a specific use of influencing the course of disease. He started with the basic idea of homeopathy: like cures like; a substance that causes the problem will in infinite dilution relieve it. He suggested this was not so different from orthodox medicine, which cured diarrhoea by giving fluid. The audience nodded sagely, and I knew I was on a loser. Further "proof" of the efficacy of homeopathic medicines was his prescribing costs, only 30% of the average. He kept mentioning the scepticism of orthodox medicine and how clinical trials were now showing that homeopathy works. We saw no results of these trials, but heard repeated assertions of their worth. The quasi-science lasted for quarter of an hour or so and then we had an endless succession of successes. With suggestions that we really should tryaconite or pulsatilla or lycopodium, but with no suggestion why, we saw many before-and-after photographs of (mainly) children with sore or unhappy faces.

After the last smiling child had been shown, the questions started. They were all how or what; no-one asked why. I raised my hand. I complimented him on his prescribing costs, pointed out gently that perhaps this was the result of general over-prescribing, and then gave what I imagined would be my deadly thrust. He had kept speaking of favourable clinical trials but I had read some meta-analyses of homeopathy (I mentioned the authors' names and the journals) and they were lukewarm at best. He parried; and to the satisfaction of the audience, by now tangibly hostile to me, asked me if I had read the more recent study by so-and-so. I hadn't. Well you should, he said. And we went back to questions about what we should do with a child with earache.
Recently I picked up a leaflet in Boots on homeopathy. Aconite is used for earache that comes on in cold, dry winds; belladonna for sudden earache that throbs; pulsatilla for earache that is worse at night and occurs with a swollen ear. Why? Much is made of a recent trial that does suggest homeopathic treatment is effective in eczema but, typically of proponents of complementary medicine, that single suggestion is taken as firm evidence that all homeopathic medicines are effective. Has there been an objective test of gelsemium in 'flu or arnica in bruising?

Boots tells us that 80% of people receiving homeopathy in the UK were satisfied with their treatment. I'm glad for them. But I remain unconvinced, and in matters of medicine scepticism is more useful than faith until the evidence is admissible.

Dr Neville W Goodman is Consultant Senior Lecturer in Anaesthesia at the University of Bristol and Southmead Hospital, Bristol BS10 5NB

---

**Position paper: Functional foods**

**Designer foods: dubious benefits?**

The United Kingdom Food Labelling Regulations (1994) make it an offence to claim that a food can prevent, treat or cure a human disease. For the food manufacturer the only way around this would be to present evidence thought to justify calling a particular food a medicine; and then apply for a product licence under the Medicines Act (1968).

However, articles in magazines and editorials are the opinion of the writer and do not constitute a claim. This is how a number of so-called health foods are promoted at present.

So-called Functional Foods (also known as designer foods, pharmaceutics or nutraceuticals) are processed foods, developed in Japan in the 1980's. Some are enriched versions of familiar foods. Others are specially formulated foods, containing specific ingredients.

Occupying a position midway between food and over the counter medicines (and marketed in Japan by both food companies and pharmaceutical companies) it is claimed for them that they can neutralise harmful substances, prevent disease, promote recovery and delay the effects of aging.

In 1984 the Japanese government decided that, subject to official scrutiny, such a food could be designated as "Functional Food". This term was later changed to "Food with a Specific Health Claim."

Despite a vast literature claiming health virtues for some 100 naturally-occurring substances the supporting evidence is of doubtful validity. There always seems to be at least one study showing benefit, but the majority of reports (often not cited by proponents) fail to confirm the claims.

Dietary fibre, for example, reduced cholesterol, but only in those with abnormally high levels and the overall benefit is still controversial. Though the antioxidants in fruits and vegetables seem to have a general protective effect against cancer, recent trials of individual antioxidants in specific cancers have shown no benefit.

There are also potential risks with functional foods. There are toxins present in many natural substances which pose potential problems if the intake is unusually high.

In clinical trials of drugs the expected benefit may justify any potential risk but in trials of the active compounds of functional foods that are claimed to benefit apparently healthy, well-fed people the risk may outweigh any potential benefit. For example:

- Some nutrients act as antioxidants in certain amounts but as pro-oxidants in larger amounts and themselves help to form free radicals.
- High body stores of iron convert vitamin C from an antioxidant into a strong pro-oxidant.
- High levels of vitamins A and D are unsafe.

We know approximately how much of each of the nutrients will satisfy the requirements for growth, development and maintenance of health—that is the recommended daily amount or reference nutrient intake but apart from the antioxidant vitamins and minerals there is no evidence that an increased intake of any of these confers additional benefit. Nor is there evidence that meals rich in carbohydrate or protein or amino-acids affect mood or performance.

**Two products exemplify old and new ingredients of functional foods:**

1. **The old product is soured milk** - sometimes referred to as "lactic acid bacteria" - since Metchnikoff at the end of the 19th Century postulated that mild-souring bacteria in yogurt oust putrefactive bacteria from the intestine and confer health benefits. The modern approach is the use of a range of fermented products made
from a variety of micro-organisms which are claimed to be beneficial in cancer of the colon, to stimulate the immune system, and reduce blood cholesterol levels. Groups of medical scientists in various countries do support such claims but a recent authoritative review of the subject dealing with 100 papers reporting human trials as distinct from animal experimentation, concluded that many of these claims are premature (Sanders. In: Goldberg I, ed. Functional Foods. Chapman and Hall, 1994: 294-322).

2. The new group of products consist of a range of about 15 sugar derivatives - mono- and oligosaccharides. They occur in small amounts in some foods and are made chemically or through the action of bacterial enzymes from various sugars and starch derivatives. Some of them are not digested but are fermented in the intestine, some are absorbed but not utilised, some are poorly absorbed but that portion is metabolised. The health properties claimed include the absence of stimulation of insulin, no damage to teeth, reduced energy content and "improvement" of intestinal flora. They are therefore claimed to be beneficial in obesity, heart disease, diabetes, colonic cancer and dental decay. While they are certainly of use in food processing as semisweet, low-energy bulking materials, the evidence of health benefits is not convincing.

Conclusion

There is sufficient evidence to suggest that some claims may eventually be shown to be valid. But the kind of marketing of functional foods now being practised in Japan and the USA must be viewed with considerable caution. Apparently healthy people are probably more likely to benefit from a change in lifestyle than they are from adding functional foods to their diet.

HealthWatch believes that there is a need for further regulation in this area based on the advice of a specially constituted expert committee, which will screen products and examine all claims from the point of view of both efficacy and safety. Each product and each claim must be treated individually.

This position paper by Professor Arnold Bender endorsed by the Executive Committee, July 1995

Opinions expressed in letters and articles published in the HealthWatch Newsletter belong to the authors and do not necessarily reflect the views of HealthWatch. The editor reserves the right to amend text if necessary but will, where possible, consult the author to ensure accuracy is maintained. Letters and articles for publication are welcomed and should be addressed to: The Editor, HealthWatch Newsletter, HealthWatch, Box BM HealthWatch, London WC1N 3XX

Letters and articles may also be sent to the Editor by e-mail to: newsletter@healthwatch-uk.org

Copyright © 1995 HealthWatch.