# HealthWatch

for treatment that works

Registered Charity No 1003392

## Newsletter no 24: February 1997



## The vanishing defendant

***Trading Standards Officers have found a new and effective tactic against companies making misleading claims, which has just resulted in a successful prosecution against an outfit marketing "slimming patches". Health Watch Chairman, Professor John Garrow reports.***

In recent Newsletters we have complained that laws to control misleading claims for healthcare products were largely ineffective for two reasons. First, the Advertising Standards Authority had little influence on advertising claims made in some local newsheets which were distributed free, or in material distributed with mail-order goods.

Second, when a company which made such claims was brought to court by a local Trading Standards Department, the date for the trial was postponed as long as possible by the defendant company, and just before the trial was due to start the company went into liquidation, so there was no defendant remaining who could be fined.

Events at the Coventry Magistrates Court on 25th November 1996 suggest that that the officers charged with enforcing the Trade Descriptions Act 1968 have found a more effective tactic. Charges were laid against Newtons Traditional Remedies Ltd of 82 Silhill Road, Solihull concerning an "ANTI-FAT PATCH" which cost £8.75 for a week's supply. The advertisements in *Health Express* said that "based on long established herbal principals *(sic)* combined with the latest trans-dermal technology" the patch would help the wearer to lose weight, whereas expert evidence showed that the said goods had no effect on body weight or weight reduction. So far there is nothing new. However similar charges were laid against Joseph Leonard Killeen, since it was attributable to his neglect as a Director of the said company that these false claims were made, so he was guilty under Section 20 of the Act. What was new was that the Coventry Trading Standards Officer, Mr Christopher Williams, had convinced the court that Mr Killeen was responsible for the claims made by Newtons Traditional Remedies. It was not a trivial accomplishment to trace the labyrinthine connections between the company and its director. At various times there have been three companies: Newtons Traditional Remedies Ltd (Company number 2932365), NT Remedies Ltd (2486418), and Newtons Traditional Remedies (DM) Ltd (2972548), all of which had their registered address at 82 Silhill Road, and all had Christine Killeen as Company Secretary, and Joseph Killeen as Director. Since they had different company numbers they were legally different companies. The first two companies were formerly called Glorycreek Ltd and Skillville Ltd respectively. The sole shareholder of NT remedies Ltd and Newtons Traditional Remedies (DM) Ltd is Newtons Traditional Remedies Ltd. However there are another two companies, Jacaranda Ltd (2835703) and Artvent Ltd (2638459) of which Mr Killeen is or has been Company Secretary. Previously Artvent Ltd and NT Remedies Ltd have also been found guilty of applying false descriptions to slimming aids. Artvent Ltd was originally called Jacaranda Ltd: the registered office of Artvent was in Leicester

The task of the "expert witness in such court cases is to help the magistrate to decide if it true that a sticky patch containing *fucus vesiculosus* (an extract of seaweed containing a minute amount of iodine) would have the claimed effect on weight loss. It is rather easy to show that it will have no such effect. In the event Mr Killeen and the Company pleaded guilty to the charge that the claim was false, and were fined a total of £7,500 and ordered to pay costs of £7,000. However the really skilful part of the prosecution is correctly to identify the defendants, for which Mr Williams should be congratulated.

John Garrow Health Watch Chairman

**Top of page**

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## Sir Richard Doll receives HealthWatch award

***The Fourth Annual HealthWatch Award was presented to Professor Sir Richard Doll OBE MD DSc FRS of the University of Oxford, at the HealthWatch Annual General Meeting on 14th October, in recognition of his 50 years of work at the highest level in clinical epidemiology.***

It was Sir Richard who, in the 1950s, led the landmark research study of 34,000 male doctors which showed that people who smoked were significantly more likely to develop lung cancer. He has more recently studied links between vitamin D and the brittle bone condition osteoporosis.

The presentation of the HealthWatch award followed Sir Richard's fascinating talk, "Help and hindrance in epidemiology". The help, he said, came from GP's, who are highly cooperative when invited to give information for epidemiological studies. Patients are similarly willing - out of thousands of patients studied he recalled only one letter which asked how the scientists had obtained their information.

Employers, on the other hand, have a tendency to "lose" records of past employees who may have been exposed to dangerous materials such as asbestos or poison gases. He found that questions asked in the House often prompted renewed searching and the subsequent discovery of missing documents.

Fears about patient confidentiality can also hinder epidemiological research. A study which hoped to investigate the possibility of a link between road traffic accidents and tranquilising medication ran into difficulties when the police questioned the ethics of looking at details of patients' medical prescriptions.

The Department of Health have raised objections to anonymous HIV testing of blood samples routinely taken on hospital admission; and a study of the effect of natural radon emission on lung cancer was interrupted by a non-research-minded committee who insisted that they alone should be responsible for choosing the subjects for the trial.

Sir Richard's talk was beautifully delivered and provided an enjoyable and thought-provoking conclusion to this year's AGM.

**Top of page**

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## HealthWatch featured in *Independent on Sunday*

***A full page of the Independent on Sunday was recently devoted to a feature on HealthWatch in which journalist Emma Brooker took a balanced, if slightly cynical, look at the controversy surrounding the charity.***

Brooker traced HealthWatch's history since the early days (then named the Campaign Against Health Fraud) through interviews with past and current committee members as well as a number of the organisation's opponents.

She took a wry view of theories touted by HealthWatch's critics that the organisation is a front for drug companies - sums donated by industry in previous years are described as "hardly princely" (these totalled £3,750 in 1989, and drug company funding for HealthWatch has now been non-existent for several years); and the word "trivial" is used for some of the information contained in Martin Walker's 1993 book, *Dirty Medicine*, which attempted to expose alleged connections between HealthWatch members and the pharmaceutical industry.

**Top of page**

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## TSOs warn against "Svelt-patch"

A stick-on patch which advertisements claim can "eliminate fat naturally" with "no missed meals" has been investigated by Trading Standards Officers and the Advertising Standards Authority, according to *Which*? magazine.

The ASA has upheld complaints against ads for the Svelt-Patch, and TSO's at the Corporation of London have also warned against ordering the patches, which cost from £17 to £91, after receiving complaints from customers who sent money or tried to claim on the money-back guarantee but received nothing, says *Which*?

Which? December 1996

**Top of page**

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## Complaints upheld against holistic hypnotherapists

The Advertising Standards Authority has upheld two complaints made in response to a mailing that claimed to, "treat arthritis more successfully than a hospital consultant.. .How to relieve diabetes.. .How to help with strokes, heart attacks, tumours and cancers."

The circular; from John Howard of the National Association of Holistic Hypnotherapists, also promoted a "psychotetic lamp.. to induce effortless quality hypnosis."

The Authority considered that the claims made in the circular implied that the advertisers could treat the conditions mentioned, and the advertisers did not provide documents to support the claims made for the lamp.

The advertiser was asked not to repeat the claims.

ASA Monthly Report, December 1996

**Top of page**

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## Regulation of complementary medicine

***Healthwatch is concerned that anyone can set up as a complementary (or alternative) practitioner and claim to provide healing services for which there is no evidence of either efficacy or safety.***

Historically the attitude of "conventional" medicine (or at least of the BMA) was that any components of such therapies which could be shown to be safe and effective should be incorporated into conventional medicine, and the remainder should be, as far as possible, discredited and suppressed. However with the publication in 1993 of "*Complementary Medicine: New Approaches to Good Practice*" the BMA changed tack, and advocated that the way forward was for each therapy to set up 'A single register of members, open to public scrutiny, entry to which is limited to competent practitioners." (page 143). This was seen as a method for providing protection to the public: if a practitioner of therapy X behaved badly (either ethically or professionally) he could be removed from the register by his peers, and thus would not be a danger to patients.

The HEA Guide to Complementary Medicine and Therapies (1994) provides a section entitled "Finding a qualified practitioner" which lists professional organisations and registering bodies. However, while the BMA book lists only 17 therapies (Acupuncture, Alexander technique, Aromatherapy, Bach flower remedies, Chiropractic, Crystal therapy, Healing, Herbalism, homeopathy, Hypnotherapy Iridology Kinesiology Massage, Osteopathy, Radionics, Reflexology and Shiatsu) as "non-conventional therapies", the HEA Guide adds another 37 to the list. Even these 54 therapies for which practitioners exist is not an exhaustive list, since many more are mentioned by Jack Raso in his guide to "*Alternative Healthcare*" (see review in *HealthWatch Newsletter* issue 18, page 7): he points out that many therapies are amalgams of other therapies, and many practitioners practice more than one system. Furthermore even within one therapy (such as Kinesiology) there are several different versions, and several different bodies which claim to set standards for their own graduates. For some such registering bodies the qualifying examination is a mockery (see HealthWatch Newsletter 21, page 7 for the "Nutrition Consultant" diploma of the British School of Yoga).

So what hope is there for the single register of members for which the BMA now yearns? It appears that there is strong pressure for such a register from certain sectors of alternative practitioners, who see European bureaucracy as a fatal threat to any non-registered practitioner.

Regulation of Complementary Medicine was the topic of a recent well-attended meeting of the Parliamentary Group for Alternative and Complementary Medicine which was addressed by two lawyers: Julie Stone (co-author of Complementary Medicine and the Law - see review in Health Watch Newsletter 23, page 9) and Emma Melville who is writing a Doctoral thesis on the subject. Ms Stone made the point that the purpose of registration in conventional medicine was primarily protection of the public: the doctor was the expert and the patient a suppliant, so the responsibility for the safety and efficacy of the treatment lay squarely on the doctor. However in complementary medicine the relationship was more of a partnership between therapist and patient, so if the therapy failed the blame should be shared. Instead she saw registration as a means to achieve three objectives: High uniform standards within the therapy, Identification of competent practitioners, and Accountability to some governing body. In view of the different doctor/patient relationship in complementary medicine she did not see evidence of efficacy as a necessary component for registration - if up to 25% of people wanted a therapy there was no need to demonstrate formally that it worked!

Ms Melville in general agreed with what had been said, especially that complementary medicine involved a therapeutic alliance between patient and therapist: this required human skills which were difficult to control by legislation. Registration in general controlled *title* (ability to designate yourself medical doctor; osteopath, chiropractor) rather than *practice,* except in the case of dentists: only registered dentists could legally do dentistry. It would be to the advantage of complementary therapists to achieve registration as a protection against "medical colonization", and to assure the public of the competence of practitioners, but she did not see randomised controlled trials as an appropriate method to demonstrate the efficacy of complementary therapies.

In this issue of the *Newsletter* a complementary practitioner, Dr Lattan, wittily illustrates the difficulty of investigating by randomised control trial one very important aspect of medical treatment: why do patients prefer

one doctor to another when both are prescribing by the same rules from the same pharmacopoeia? It is a fundamental belief of HealthWatch that medicine should be, as far as possible evidenced-based, but how far is this possible in the field of conventional medicine?

The speakers at the PGACM meeting denied that the RCT was an appropriate measure to apply to complementary therapies, but claimed that registration would help to maintain uniform high standards of practitioner competence. How can you distinguish a competent complementary practitioner from an incompetent complementary practitioner if you have no method for assessing the efficacy of the therapy? And if the RCT is not appropriate, how else do you decide that one complementary practitioner is more competent than another?

Members of HealthWatch this year did me the honour of election to be Chairman. I propose to try to find answers to the questions above, and would be very grateful for advice which members may send as letters to the Editor. I hope the ensuing debate will be productive.

Professor John Garrow Chairman, HealthWatch

**Top of page**

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## Through a glass, darkly

***The concept of freedom of information is at last penetrating the UK drug evaluation processes. But getting hold of that information is another matter Michael Allen, HealthWatch's Treasurer; explains.***

Information about the way decisions are taken by government to allow a medicine to reach the market has traditionally been secret. The UK Medicines Control Agency has always explained that all information in its possession is "commercial in confidence"; other European agencies have been similarly discrete and one has had to turn to the US where Freedom of Information (FOI) is a way of life.

The US often registers medicines at a different time than the EU, so it remains hard to make a rational decision on the quality of data available when a drug is launched. The infamous "data on company's file" reference inspires little confidence. It is therefore good to see that the European Agency for the Evaluation of Medicinal Products (EMEA) has set itself a policy of openness (in Eurospeak: transparency), which is beginning to be meaningful.

The EMEA is in its second year of activity; by 1998, though all the member states will retain their own Regulatory Authorities, it will be through the EMEA that all products which are to be marketed in more than one member state must be registered. If that sounds like a formula for some easy times in the member states' authorities, don't believe it. The EMEA does not, in fact, evaluate anything, but farms this work out to the member states. I described the structure and function of the EMEA in an earlier article in the *HealthWatch Newsletter* (issue 15, June 1994).

Medicines can get two types of authorisation in the EU. They can go the centralised route, leading to a single community authorisation; or they can go the decentralised route (or, till 1998 direct to each member state) leading to individual authorisations in each member state based (in principle) on identical indications, dosage recommendations and contra-indications, often subject to considerable variety with older medicines.

### European Public Assessment Reports (EPARs)

When a medicine receives its community authorisation through the centralised route, it is now an obligation to release an EPAR; as the name implies, this is available to the general public. Information in the EPAR has certain solid virtues:

- It is derived from the (confidential) assessment report prepared by the "Rapporteur" member state around which the EU Committee on Proprietary Medicinal Products (CPMP) has made the decision to permit the medicine to be marketed. Therefore the report reflects very detailed verification of the trial design, statistics and conclusions presented by the company. This is equivalent to a severe "peer review" (assessors have at their disposal a panel of specialists from which to choose the appropriate expert). This must provide more reassurance than the "data on company's file" description or Proceedings of Industry Sponsored Symposia (Andrew Herxheimer suggests the acronym is appropriate - I think him unkind) which was what there was to go on before;
- All clinical trials performed in the EU since 1991 and in the US from 1980 must have had data verified in detail by monitoring and audit as required under Community rules for Good Clinical Practice. This standard is far beyond anything that a peer reviewed journal could achieve;
- This process provides a valid decision, consistent with the current ideals of evidence-based medicine.

***A brief study of the EPARs of five new AIDS treatments which have reached the market in the EU in the last few weeks provides interesting general information, for example:***

- All five products were registered under an EU provision permitting a provisional authorisation, subject to reassessment when the results of on-going trials and general experience with the products are available;

- With the GlaxoWellcome product Epivir, there were more than 10 times as many patients treated in compassionate-use open label studies than there were in controlled clinical trials. While plays such as "Angels over America" informed me that AIDS activists would do anything to obtain a new treatment (reasonable enough if you are going to die without it), I had not realised these had deflected patients from controlled studies in such numbers;
- With all the products, the actual numbers of MDS patients assessed in well-controlled studies at the time decision was made were small relative to most drug-development programmes today. Numbers were usually below the minimum 1,500 recommended by the ICH guideline followed by regulators in the three predominating areas (EU, Japan and the US) for approval of medicines for non-life threatening illnesses, confirming the often repeated need for flexibility where there is an urgent need for a medicine. These relatively small numbers also reaffirm the wisdom of the provisional nature of the approval, referred to above;
- The EPARs also hint at the difficulty there has been in deciding upon efficacy criteria. The US Food & Drug Administration (FDA) is more ready to accept surrogate endpoints (CD4 lymphocyte count and HIV- 1 RNA levels) than the EU CPMP and the design of many of the studies was targeted initially to meet FDA requirements. The clinical endpoints required by the CPMP had to be correlated with the surrogates during assessment.

### Other Information Available

What else is transparent? Quite a number of things are released by the EMEA:

- Press Releases are issued within a few days of the conclusion of the monthly CPMP meetings;
- a comprehensive directory of EMEA personnel identifies their roles and gives a direct line telephone location. Members of the CPMP and the experts that they can call upon to assist in the decision-making process are identified;
- guidelines are available to guide clinicians when addressing trial design issues
- the internal operating procedures of the CPMP and EMEA are issued;
- an information Newsletter is issued quarterly to detail the activities of the CPMP and its veterinary equivalent.

This standard of FOI may not match that of the FDA, but is much superior to what we have had previously.

### A Darker Side to Transparency!

Getting the information is another matter. In general, companies can go through their trade organisations, but for non-industry users, to be truly transparent and save cost, the EMEA has put its information out on the Internet. Obtaining the relatively large files has proved difficult because information is distributed by the EMEA through the Joint Academic NETwork (JANET). You will need to try at odd times of the day (till I changed my service provider; the only time I could get these things was 8 am Saturday morning!) or use an information service provider that has a "peering" connection with JANET if you are to avoid considerable frustration. (Please don't ask me what a peering connection is; I don't know-ask your service provider!).

But this is better than the UK Medicines Control Agency Internet site which has an enticing name including open.go"', but which does not, in fact, exist! Is this a metaphor for contemporary Britain or what?

Michael E Allen, who is treasurer of HealthWatch, is a regulatory consultant to IBRD-ROSTRUM GLOBAL LIMITED

**See also articles on EMEA by Michael Allen in Newsletter 15 and Newsletter 29**

**Top of page**

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## Book Review: Complementary Medicine: an objective appraisal

Edited by Edzard Ernst, Oxford: Butterworth Heinemann 1996. 176 pages, paperback £16.99 ISBN 0 75063141 4

***Edzard Ernst is the first and so far the only professor of Complementary Medicine in Britain, perhaps anywhere. His task is to encourage and conduct sympathetic but scientifically rigorous studies of complementary therapies, relating them to mainstream medicine wherever possible.***

The ten essays in this book describe different aspects of such studies, and major difficulties that need to be overcome. The number of studies of good quality is still small, so for most types of complementary therapy an objective appraisal is not yet possible, but the authors do their best to prepare the ground for such studies and review much of the relevant literature.

The book begins by clarifying some basic concepts. First, Andrew Vickers from the UK Research Council for Complementary Medicine incisively examines what might be meant by the often stated view that fundamentally different concepts underlie different systems of medicine - that they use different "paradigms". He demonstrates that this idea is nebulous and not useful in debates about research methods. Next, Karl-Ludwig Resch and Edzard Ernst explain that essentially the same research methods apply to complementary as to mainstream medicine: in

both types of setting we are looking for reliable and valid information about the size and frequency of the benefits to be obtained from different treatments-and about the disadvantages. The first question to be answered about any treatment is "does it work?". Only if the answer is reliably positive is it worth asking "how?", and "how can the benefit be maximised?"

Two chapters then deal with placebo effects; in another, George Leweth considers how far evidence from controlled trials can be applied in general practice - he concludes that often it cannot. The widespread failure to distinguish between "placebo" and "placebo effect" has caused much confusion. The term "placebo" usually refers quite narrowly to an inactive medication, eg a dummy tablet not containing a medicine. A "placebo effect" on the other hand refers to the positive therapeutic effect caused by any non-specific factor present in the therapeutic situation, eg touch, a good bedside manner, or a healer's optimistic and pleasant attitude. Better terms for this are "context effect" or "non-specific effect". These also have the advantage that they cover not only positive but also negative effects, eg the effect of a harsh and insensitive doctor, or of a dirty and ugly consulting room. All specific treatments - whether effective or ineffective - are accompanied by such context effects. In investigating treatments (both complementary and mainstream) we want to know (1) whether the effects are specific, and (2) how in the particular condition we are treating we can identify and optimise the context effects. The first of these two questions has been central to therapeutic research for at least 50 years, but we have hardly begun to ask the second. The scientific study of complementary medicine has brought it to the fore. Experimental designs for tackling these newly recognised problems are only now being developed, and these chapters by learned placebologists from Amsterdam and Boston will tax general readers.

The remaining essays are more down to earth. They discuss the consumer-led boom in complementary therapies, why people choose them, and whether they offer value for money. Wayne Jonas, director of the Office of Alternative Medicine in the US National Institutes of Health, convincingly deals with safety in complementary medicine. Purity and standardisation of the products and of practitioners' competence are primary:

"Without assurance of a good product and a well trained practitioner to deliver the therapy, the risk-benefit ratio will be higher than necessary." Direct risks of complementary therapies are succinctly reviewed separately.

This is an important book, essential for all researchers in complementary medicine and valuable for everyone who wants to evaluate the research that is done. That should include all HealthWatchers who want more than predigested information.

Dr Andrew Herxheimer FRCP Emeritus Fellow, UK Cochrane Centre

**See also letter from Dr Gus Plaut in Newsletter 26**

**Top of page**

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## Risky business

***Perception is more important than numbers, says Dr Neville Goodman as he looks at Sir Kenneth Calman's proposal for defining the language of risk.***

People's lives are affected by perceived risk, not real risk. The media know this well. The Chief Medical Officer, Sir Kenneth Calman, has made "a proposal for clarifying the language of risk.. .for discussion and debate"', which extends the point touched on briefly in an earlier *HealthWatch Newsletter* (October 1996, page 7): new risks are meaningless unless related to known risks and the risks of everyday living.

Calman's main idea is to define the language of risk. When we speak of 'negligible' risk, we need to know what it means (less than 1 in a million in one year) and be able to relate it to other levels of risk, for instance 'low', which Calman puts between one in 10000 and one in 1000. In the *British Medical Journal* article, but not reported in the *Guardian's* comments on it (27 September 1996, pages 7 & 18), Calman suggests alternatives for each level of risk ('negligible' is 'remote' or 'insignificant'; 'low' is 'reasonable', 'tolerable' or 'small'). He emphasises that 'safe' does not mean no risk.

So far, so good. Anyone watching medical news stories knows how easily distortions occur. I am sceptical that the words will retain their precise definitions. Examiners in medical undergraduate and postgraduate examinations are exhorted to avoid 'frequently', 'often' and 'rarely' in their questions because doctors within a medical specialty cannot agree what they mean. A common view held by the public and doctors on what 'negligible' means may not be attainable. At least, not in words. I am surprised that Calman did not suggest that, once the "discussion and debate" is over; a diagrammatic scale is a better way of putting a risk in context.

Calman also considers the value-laden language of risk: is the risk avoidable or unavoidable; justifiable or unjustifiable; acceptable or unacceptable? Unlike the language of level of risk, which can be defined even if the definitions are ignored, these are qualities that depend heavily on individual perception. Calman does not make the distinction, although it is implicit in much of the article, that prompted Sir Hermann Bondi to comment that people demand safety at work so "they can get away safely to go hang-gliding" (2).

Calman, as Chief Medical Officer; is in a good position to begin this dialogue of risk. He may be undermined as

more unravels in the BSE story, because we can judge a level of risk only if we are told the truth, and it's not certain how much of the truth we've been told. "If that's true for BSE..." is an easy response.

And it is how people respond to all this that matters. As someone who has written before about risk, and about getting people to understand it, I can only applaud Calman's campaign. But there is a flaw: the assumption "that people respond rationally to risk when the real facts are spelt out for them. The evidence, unfortunately, suggests otherwise." David Runciman's cynical but realistic summing-up *(Guardian, 3* October 1996, page 8) warned Sir Kenneth that people don't worry about how likely something is to happen, their worry is based on their response to the event if it were to happen. People don't alter their lives according to risk; the way they live underlies how they see the risk.

As Calman quotes Kant ("We see things not as they are, but as we are."), he knows full well the importance of perception. Perhaps, though, he has not quite faced up to it.

Neville Goodman, Consultant Anaesthetist Southmead Hospital, Bristol

References


1. Calman KC. Cancer: science and society and the communication of risk. BMJ 1996; 313: 79-802.
2. Bondi H. Risk in perspective. Ch. 1 in Cooper MG (ed). Risk: man-made hazards to man. Oxford: Clarendon Press, 1985.


**Top of page**

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## Electromagnetic fields "not harmful"

There is "no conclusive evidence" that electromagnetic fields (EMFs) are linked to cancer, reproductive and developmental abnormalities, or learning or behavioural problems says a US federal panel of scientists. EMF controversy was the subject of a recent *HealthWatch Newsletter* feature (issue 21, April 1996).

The panel's findings, released on October 31 by the National Academy of Sciences' National Research Council, follow 3 years of work, involving a review of 500 studies completed since 1979.

The evidence, says the report, supports a "weak but statistically significant" link between nearness to high voltage electrical cables and childhood leukaemia, but EMFs are not necessarily to blame - the link could result from other factors associated with living in these areas, such as traffic density, air quality and construction features of older homes.

*Lancet* 1996; 348: 1305

**See also Newsletter no 23**

**Top of page**

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## Letter: Melatonin use in jetlag

***Dr Andrew Herxheimer, Health Watch Committee member, responds to a news item in issue 23 (October 1996).***

Dear Sir,

The report on melatonin (Issue 23, page 1) gave almost no context and was needlessly alarmist. The letter to the Lancet to which it drew attention briefly described a small study of its effects on sleep in artificial laboratory conditions, designed to investigate melatonin entrainment of circadian rhythms. The participants took 5 mg or a placebo at 8 pm (if awake at that time) for 5 days in a cross over design.

The best established function of melatonin is to coordinate biological rhythms, and it seems most useful to regard it as a switch that can set the time of sleep. In a short review in the Lancet (1) Dorothy Bonn says (1) that over 100 placebo-controlled trials suggest that synthetic melatonin helps to alleviate jet lag, and (2) that it appears safe in healthy adults. The evidence on these two points seems stronger than that for the effectiveness and safety of many products on sale without prescription. In the UK a prescription is now required, but no manufacturer has applied for a full product licence. One UK supplier* has a special licence to sell capsules containing 2, 2.5 and 5 mg synthetic melatonin, for named patients only, and without any accompanying information. The company may not advertise or otherwise promote it, so few people know that it is available. Anyway few doctors or pharmacists know enough about melatonin to advise travellers on how to use it.

Last October at Singapore airport I bought a bottle of 3 mg tablets made in USA. The label includes this text, which is helpful, though it could be improved:

> "Read 'Warning' Statement on label before use. Dosage: Take one or two tablets 20 minutes before sleep. If sleep well after taking but feels sleepy in the morning, cut the dosage into half. WARNING: If

you are under medical supervision or using any tranquilizers or sedatives, seek the advice of your health practitioner prior to using. Consult your physician if you have an autoimmune condition, depressive disorder or are a pregnant or lactating woman. Do not take when operating machinery or driving a vehicle."

I used the recommended dosage during and after a flight to Australia. I slept well at the appropriate times after arrival, a great improvement on my experience of previous trips to Australia and Japan. I think it is worth trying melatonin to attenuate jet lag for the first day or two in a distant time zone, especially when travelling eastwards. It seems best to avoid alcohol and caffeine, since these often interfere with sleep-wake and other rhythms. Other uses of melatonin are unproven, though one might expect it to help shift workers and perhaps people with some forms of insomnia.

Yours sincerely

Andrew Herxheimer

**Reference:** 1.Bonn D. *Lancet l996;* 347:184.

*Penn Pharmaceuticals Ltd, Unit 23, Tafarnaubach Ind Est, Tredegar, Gwent NP2 3AA (fax 01495 711225; tel 01495 711222). 100 2 mg capsules cost a retail pharmacist £67.50.

**Top of page**

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## Letter: Is scientific method always the method of choice?

***Dr Lattan of Manchester writes with a conundrum for HealthWatch members.***

Dear Sirs,

HealthWatch tells that testing of treatments is best done by controlled clinical trials. I have been reading HealthWatch Newsletter for many years, because my niece thinks she must teach me "scientific methods". She was medical student at St Mary's Hospital in London, with many Prizes. Her holy book is Oxford Textbook of Medicine because authors revise book every seven years, so must be true. My book was written 1800 years past, and has not been revised, so Dr Brewin says book cannot be true. (My niece's husband is English clergyman and his book was written even more years past, and has not been revised. Can his book be true?)

Now my niece comes to me with this problem. She works with two men partners: Doctor Hard works quickly and has published letter in Lancet, Doctor Soft works slowly and has white moustache. She did Audit in Practice and found many patients like Dr Hard and not Dr Soft. Equal number like Dr Soft and not Dr Hard. Next year Dr Soft must retire. Dr Hard and my niece must choose new partner who will please patients who like Dr Soft. I tell her choose doctor who has right *karma* to balance the *vata, pitta* and *kapha* of patients who like Dr Soft, but she says this is not "scientific method".

My niece is ashamed to ask wise people at HealthWatch, so I am asking for her, and she will read reply. Must she make randomised trial on Dr Soft's moustache to make it white one month and black one month, to see colour of moustache which gives best *karma?*

Yours sincerely

S. Lattan PhD, FFAc, DNT Centre for Healing Arts, Manchester.

**Top of page**

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## Papers withdrawn over fraud

Five research papers from the US National Institutes of Health Laboratory of Gene Transfer were withdrawn in October; said to contain a "stunning series of data misrepresentations and outright deceptions" by a trusted graduate student.

The papers, on the mechanism of leukaemogenesis, had been published over a period of 2 years without raising suspicion. Faked data was detected only after a paper was examined by a particularly conscientious reviewer for the journal *Oncogene.* When confronted, the student confessed.

Fraud in mainstream scientific research was reported on recently in the *HealthWatch newsletter* by Dr Stephen Lock (issue 22 page 1).

*Lancet* 1996; 348: 1303

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**Top of page**

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