HealthWatch

for treatment that works

Registered Charity No 1003392

Newsletter no 29: April 1998

Why Nick Ross supports HealthWatch

Broadcaster Nick Ross is President of Health Watch and one of its founder members. Here, he talks to Mandy Payne about why he feels so strongly about making a stand for the good of the nation's health.

Most people know, deep down, that magic cures can't possibly work. But they're attracted to the unknown and mysterious and they yearn for that Hollywood-style happy ending, no matter how improbable. Which is why, says Nick Ross, the media feel compelled to portray bizarre and unproven remedies in a positive light. rather than trying to expose nonsense.

"I'm bewildered and appalled sometimes that journalists can appear so scientifically illiterate. But then they're giving people what they want - a story. Readers and viewers don't like having their beliefs knocked down.

"You only have to look in the small ads of any newspaper. I've just seen an advertisement for a treatment that will non-surgically increase the size of a man's penis. People must know it's all tosh. But they also like to believe that the impossible might just be true.

Then idea of starting an organisation along the lines of the American “Quackbusters” was first put to Nick Ross eight years ago by the eminent cancer specialist Professor Michael Baum. “Michael told me about some tragic cases he’d seen at his breast cancer clinic - women whose condition had disintegrated into suppurating sores because they'd shunned conventional treatment in favour of various alternative therapies that were just not working”. Ross was among a small group of professionals who met to share Professor Baum’s concern at patients risking their health, not to mention wasting their money, on unproven treatments. HealthWatch was born, with Ross appointed joint president with Michael O'Donnell.

He doesn’t see HealthWatch as simply a crusade against complementary and alternative medicine, though. “A lot of the methods used even in conventional medicine are scientifically unproven. The issue is to make sure that people receive treatments that are proved to be effective, whether they’re alternative or conventional.”

Nick Ross has also been a member of the Committee on Public Understanding of Science (COPUS). “We’re trying to push science not as something that happens in test-tubes, but as a fundamentally important principle. It doesn’t matter if our children never understand how a magnet works, for example, but they need to know how to form a hypothesis, put it to the test, and see if it is reliable. It’s terribly important because only by assessing complex information can we make decent democratic decisions. Unfortunately there’s a feeling today that science is just a way of thinking, like a religion that you might not choose to believe in”. Most people pushing unproven therapies are not out to rip their patients off, he says,. “In the US there is more of a problem with genuine fraudsters, whereas in this country you’re more likely to find ineffective treatments being sold by people who are completely sincere in the belief that they are helping the patient.”

Having strong beliefs has not prevented Ross from maintaining balance and accuracy in his media work. "It's a principle of good journalism that you work with facts, and demonstrable facts, so there's no real conflict. I've only ever had one or two letters criticising my views, but because I take the same stand towards unproven methods in conventional medicine as in alternative therapies I'm not much of a target."

Nick Ross is especially concerned about the growth in popularity of traditional Chinese medicine, having been to China himself and seen how the methods are practised there. "Traditional treatments survive in rural areas largely because there's a lack of trained doctors and facilities. I've seen a pharmacy the size of a small larder at a medical centre serving a population of 300,000. Most doctors I spoke to used traditional remedies because they couldn't do anything else. Given the choice, most greatly preferred scientific medicine.

"I do have sympathy for people for whom conventional medicine has failed, for example people with

terminal cancer, who'll try all kinds of complementary and alternative methods. They'll waste their money of course, sometimes tragically, but the pressure to find a cure is often profound. The trouble is, you'll be told all about the amazing 'success' stories, but you tend not to hear about the failures and the desperate cases like those seen at Michael Baum's clinic, who arrive too late for help."

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Psychics baffled by skeptic

The latest issue of the Skeptical Intelligencer, the magazine of ASKE (the Association for Skeptical Enquiry) has an amusing account of a 'psychics versus skeptics' debate held recently during a science fair in Derby.

Guest speaker Tony Youens, a Health and Safety Training Officer at Nottingham Trent University, was invited to present the case for the skeptics. After listening to psychic Jenny Bright divine personal and health information about a female member of the audience simply by handling the woman's lipstick, it was time for his own presentation.

He began by performing a music hall-type trick, in which someone in the audience placed a personal possession - a wristwatch-in a bag while Youens was out of the room. When he returned to the room, Youens correctly ascertained the wristwatch's owner.

Next, Youens further baffled the audience with his first slide, which read, "I CHEATED", then went on to admit that his entire performance had been a trick.

During the question and answer session that followed this confession, he was surprised to find himself challenged by a member of the audience who, because he would not explain exactly how he cheated, seemed to persist in believing that Mr Youens had in fact used psychic powers after all.

For more information about ASKE, write (enclosing a stamped self-addressed envelope) to the Honorary Secretary Anne Corden, 15 Ramsden Wood Road, Walsden, Todmorden, Lancs OL14 7UD.

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Dowsing for.. .food allergies?

There seems no limit to the public craving for magic cures. Now, jumping on the band wagon, come the dowsers with, "Dowsing for Health - the safe alternative".

A leaflet sent in by a member of HealthWatch advertises the practice of two dowsers who emphasise that they are professionals and who go on to say that dowsing 'can find the unknown cause of long lingering, or any other illness". Apparently, "the body, unknowingly, might be under stress by sleeping in an unsafe place", unsafe because of "harmful earth energy and electromagnetic disturbance". Dowsing can locate this.

Finally, moving even further away from their usual domain. it seems that dowsers are now joining all the others anxious to tell you if there are any food ingredients that you are allergic to, so we can be sure that they will not be short of customers.

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Sky TV documentary features HealthWatch experts

From psychic healers to homeopaths to herbalists, it seemed that no alternative therapist was safe from criticism in a recent Sky TV documentary. The half-hour programme, a Sky News feature which went out at 9.30pm on 7th February, reported on aspects of alternative medicine from the ridiculous to the tragic, and included expert comments from a number of HealthWatch members.

The most unorthodox types of therapy featured hardly needed comment. The programme opened with a process called "Breath of Life" which, it was said, can be used to treat alcoholism. A naked patient was shown climbing into a bath with his therapist. The therapist held the patient, who began to hyperventilate violently. Unlike traditional addiction treatments which rely on our knowledge of biochemical and psychological processes "breath of life" therapy, it was said, "frees the fear.. .the cells get the message that it's safe to release the need for alcohol."

Talking about alternative therapies in general, HealthWatch committee member Professor Vincent Marks was concerned that patients are at risk of being misled, "...quite often deliberately, sometimes innocently by the practitioners who believe in what they're doing even though there's no evidence," he said.

The programme featured the tragic story of a young man with testicular cancer who spent £3,000 in the course of a year on a range of alternative therapies. His widow recalled conversations with therapists. "We were told, 'We'll try and make you better, if you don't get better it's because you didn't believe enough.' That's very cruel

when someone's very ill," she said. Her husband saw a psychic surgeon-who "operates" without a knife and leaves no wound-several times. After being told that the tumour had "de-materialised" he stopped taking his painkilling medication, only for the agonising pain of late-stage cancer to return. He died soon afterwards, aged 32.

Another HealthWatch member, Southampton GP Dr Peter May, cited cases of patients who had attempted suicide after stopping their antidepressant medication on the advice of alternative therapists.

Some interesting statistics emerged. In Europe, alternative medicine is the second biggest growth industry (after micro-electronics). Here in the UK we spent £72m last year on homeopathy, aromatherapy and herbal remedies combined, and the market sector is showing 20% year on year growth. And it is not just amongst the public that alternative therapies are growing in acceptability-no less than 40 health authorities now refer to the Royal Homeopathic Hospital in London, the programme claimed.

It was a little unfortunate that, in the programme makers' glee at showing us some of the weird treatments that people are prepared to pay money for, the programme's main argument - which was surely that therapies need to be properly tested and patients given correct information about their efficacy and safety before buying- sometimes became confused. While it's entertaining to see some of the more bizarre therapies, and easy to poke fun at them, it dilutes the argument somewhat when they are bundled together with methods such as chiropractic, acupuncture and herbal medicine that do have some scientific backing - and all slated indiscriminately.

Fortunately the experts interviewed offered more coherent arguments. Professor Edzard Ernst of Exeter University's Department of Complementary Medicine said that just because a treatment has been around for a long time doesn't mean it is any good. "Bloodletting has been used for 2,000 years and has killed many. The length of time it's been used for proves nothing. You need proper clinical trials," he said.

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The EMEA celebrates its third birthday

Regulatory consultant Michael Allen congratulates the European Medicines Evaluation Agency on achieving good progress on a daunting task - to coordinate drug evaluations made by all the European Union's member states.

In 1994 an article in HealthWatch Newsletter No.15 welcomed the proposed location of the new European Agency for the Evaluation of Medicinal Products (usually abbreviated EMEA) in the UK, but displayed some anxiety that all might not go smoothly.

This agency was set up in January 1995 with a remarkable structure: in brief the Agency's role is not to evaluate drugs, but to coordinate evaluations made by EU member states. EU-wide decisions are made by the Committee on Proprietary Medicinal Products (CPMP), made up of two representatives from each member state's Regulatory Authority; the task of the EMEA is to manage the process and ensure the agreement of all. This management task must be one of the most daunting that could be imagined, until the EU decided upon monetary union.

When the EMEA was set up there was a three-year transitional period (now expired) during which two systems of managing pan-EU decisions ran alongside the traditional mode of registering a drug country by country. Applications made to market a new medicine in the EU now must go through one of these procedures.

The first is the *Centralised procedure.* This is mandatory for products made by biotechnological methods and can be used for new products of special medical interest and all new active substances (NAS). The regulatory authorities of two member states are appointed by the CPNW to perform a single community assessment upon which all other member states must agree, with the EMEA to coordinate and the CPMP to decide. If agreement cannot be reached without it, binding arbitration will be applied. This grants to successful applicants the right to market the product throughout the EU, a European Marketing Authorisation.

The second method is the *Decentralised* procedure. In this, a product is first registered in one member state, whose Regulatory Authority will then send its assessment to others in which the company wishes to go to market. The CPMP will decide disputes between member states, and can apply binding arbitration if agreement cannot otherwise be obtained. Successful applicants obtain a number of individual member state Marketing Authorisations, all of which should be harmonised with respect to indications for use and other critical features.

As from 1st January 1998 the traditional option, to register a product individually in each member state, will only be available for a small number of generic products where conditions of use have not been harmonised throughout the EU.

It is clear that the intention to obtain a consistent high standard of medicines control throughout the EU depends upon the effective functioning of the EMEA and CPMP for Centralised products and of the CPMP (with some administrative assistance from the EMEA) for Decentralised products. However, what is more critical is the ability of each of the 15 member state Regulatory Authorities to be consistent in their assessments.

The EMEA also has the task of coordinating other established activities of the member states' regulatory authorities, including:

- Good Manufacturing Practice (GMP) and inspections to assure the consistent quality of medicines;
- Good Laboratory Practice (GLP) and inspections to assure correct performance of animal studies and humane treatment of test animals;
- Good Clinical Practice (GCP) to assure the validity of clinical trial results and the protection of the rights of human subjects;
- decision making upon the results of post-marketing information on the safety of medicines (pharmacovigilance in Eurospeak).

The third annual report from the EMEA shows what progress has been made since the opening day, when a large block of offices in Canary Wharf were occupied by the Executive Director alone, awaiting the European Parliament to come through with the funds required to get the Agency up and going. In 1997, expenditure was 28.5 million ECU and 150 staff had been recruited.

A functioning unit capable of managing a staff recruited from throughout the 15 member states of the EU has been achieved. While the working language is English, obviously directions aimed at doctor and patient must be in all the 11 official languages of the EU. The task of translation is largely devolved to the companies, but the EMEA has generated templates in the 11 languages to ensure that at least the headings of the Summary of Product Characteristics (information for the doctor) and the Patient Information Leaflet are consistent. The EMEA has scientific staff who act as project coordinators, but who are not themselves responsible for the evaluations upon which regulatory decisions must be made. As mentioned before, the task of evaluation is sub-contracted to the member state's Regulatory Authorities and all member states are involved in preparing assessment reports upon which judgements can be based Previously there could be as many opinions upon a single set of data as there were member states and it was rare to get close similarity in the assessments made of the same file; this variability has been greatly reduced with the new Systems.

This consistency can be judged because of the openness that is a feature of the EMEA. Traditionally, decisions on marketing of drugs were kept confidential: in the UK all such information was classified as "commercial in confidence" and other member states had similar attitudes. The EU has decided that information should be more open and a European Public Assessment Report (EPAR), giving an abbreviated version of the assessment upon which the decision was made, is issued with each drug approval coming through the Centralised procedure.

Before the systems started, it was feared that there would be a great deal of inconsistency and scientific disagreement and that this would clog up the regulatory processes. In the event, the Centralised procedure maintained generally rapid decision making, despite the need to involve all the member states, including those with little previous experience, in performing assessments. Enough consistency was achieved by discussion at CPMP level to obviate the need for arbitration in the large number of decisions made to date. Member states managed to tailor their individual regulatory procedures to fit in with the strict timetables established by the EMEA.

There were initially delays in the Decentralised procedure, which lacked a structure and secretariat to keep matters moving. Structures were soon evolved, however, and fairly rapid approvals achieved. Companies used withdrawal strategies to avoid arbitration, because this required a massive time commitment during which the product could not be marketed in any member state. This means that certain member states do not have available on their markets the same medicines as the others, so cannot be seen as ideal.

There is clearly more difficulty agreeing on matters of pharmacovigilance. Much of the information upon which judgement must be made is hard to interpret. The EMEA has set up methods for rapidly communicating decisions, but member states seem more likely to go their separate ways on matters of the safety of established drugs than when considering if to register new ones. Thus the same information concerning a possible excess of thromboembolic disease with third generation hormone contraceptives was interpreted one way by the UK, differently in Germany and differently again by the rest of the member states.

With GMP, GLP and GCP the principle of subsidiarity means that the actual inspections required to assure these "good practices" are maintained are performed by the member states, not by a central audit unit. Getting consistency is another powerful challenge to managerial competence, as a target aim of the EU is to achieve sufficient standardisation throughout the member states that memoranda of understanding can be reached with the other major Regulatory Agencies, especially the Food and Drug Administration in America. Currently there is a wide variety of approaches to GCP needing to be unified.

We have in the UK much healthy scepticism about EU agencies and administrative competence. Yet in the complex and important area of medicines control a revolution has been achieved without evident chaos nor with too much conflict.

This success may allow us to take a more positive view of the Union in its other activities.

Michael E Allen, Health Watch Committee Member

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Book review: Studies Show - a popular guide to understanding scientific studies

by John H Fennick, Prometheus Books, New York. £14.99

The word scientific has two meanings. On the one hand, there's the wrong but popular idea that science refuses to recognise anything that can't be explained in a laboratory. On the other, the much more accurate and useful concept that scientific thinking is simply a rational weighing of evidence, from whatever source.

It is the same with statistics. We have the notion that "you can prove anything with statistics", often quoted because (as one statistician put it many years ago) a contempt for statistics is widely regarded as a sign of a robust personality. On the other hand, we badly need statistics if we are not to come to false conclusions.

"Statistical thinking will one day be as necessary for efficient citizenship as the ability to read and write" wrote HG Wells. He would be disappointed to see that by the end of the century we still have such a long way to go. What he realised is that many of the most important basic points of so-called "statistics"-and the ones that are most often not understood-do *not require any mathematics.* They are more a matter of simple logic that ought to be understood by every school teacher and taught to every teenager, leaving the more mathematical refinements to the statisticians.

Before we jump to conclusions we should always consider very carefully all possible explanations for what we observe. This simple principle is not confined to statistics. It's not even confined to science. It's only what every good detective and every good judge and jury aim to do. It is just a way of approaching the available evidence in as rational a way as possible. Strong associations may well have some explanation that has nothing to do with causation. If A is correlated with B at least three possibilities have to be considered. That A is causing B, that B is causing A, or that both are being caused by some third factor.

Secondly, you don't need any mathematics to see that if you want a valid comparison, whether it is of the performance of two schools or of the outcome of two medical treatments, you must "compare like with like". When one school or one medical treatment seems to be getting better results, the comparison is unreliable unless we look at the possibility that one of the groups of school children were already more intelligent (or more motivated), or that one group of patients were already likely to do better for reasons other than the treatment they were given.

In no way can this sort of thinking (not as universal as it should be in mainstream medicine, and totally absent from most "complementary medicine" literature) be considered as just part of the "current paradigm of western science and medicine". It is rock hard, timeless logic and whenever we ignore it we risk making foolish mistakes.

"Studies Show" is written by a statistician, working in the USA for the Bell Telephone company, but interested in such things as the statistics of road accidents (25 pages) and heart transplants (60 pages). All possible fallacies are discussed. And in much more detail than would be expected in a "popular guide". But much can be learned by studying these examples of the sort of difficulties that statisticians encounter.

Light, humorous and entertaining, say the publishers. Well, so it is, at least in parts, though not always in a very elegant way ("Well, my gosh! Something significant is going on here, even Dr Watson would say so"). But there is also plenty that many readers will find difficult, needing maximum concentration and effort. To be fair, the reader is warned of this ("Brace yourself, here comes the technical stuff". And later, "Caution, this lesson is tough, I'll have to get more technical than ever").

Presumably to get away from a text book image, many of the headings are light hearted to the point of obscurity. For example, near the start of his book he gives "five basic rules" and these contain some good sense, but Rule 1 is headed "Extol or ignore the obvious (whimsically)" and Rule 2 is called "Promote ignorance as knowledge." This sort of thing means that you have to read the text in full before you can locate discussion of any particular problem. Coupled with the fact that the book has no index, this can be frustrating. And no mention of randomised controlled trials in the glossary. Nevertheless, no reasonably intelligent person could fail to have a better understanding of statistics after working carefully through the text.

Surprisingly, the author is taken to task in the Forward (written by another statistician) for "over simplifying". But that's unfair. You can't popularise without over simplification. Popularising means saying things that are broadly true. That may not be good enough for a purist, but for John or Joan Citizen it's ten times better than gross misconceptions.

Occasionally something is said that applies only in the USA, for example references to the Food and Drug Administration. And on page 93 the writer assumes that the whole world will know what he means when he asks, "If you are participating in a craps game, will you bet for or against the shooter if his number is nine?" This mistake was avoided in the similar (but, to me, easier to read) "How to lie with statistics" by another American, Darrell Huff (a writer, not a statistician) which came out nearly 45 years ago. But the more books we have of this kind the better.

Homepathy studies stir up a storm

Dr Neville Goodman reports on the flurry of correspondence in the medical press that has followed the recent publication in the Lancet of a meta-analysis of homeopathy which suggested it may be more effective than placebo.

A bit of a storm has blown up in the correspondence pages of the *Lancet* over the meta-analysis of homeopathy and subsequent commentaries on it (see "Homeopathy effect not all placebo?", HealthWatch Newsletter issue 28). The letters include one from Benveniste, whose claim of demonstrating a memory in water upset the journal *Nature* a few years ago.

He describes 10 years of reproducible research, including the ability to transfer the activities of high dilutions via the Internet, the activities being a molecular signal of specific, kilohertz frequencies. Another correspondent cites work in which various physical techniques have been successfully applied to homeopathic preparations, from which an electromagnetic signal can be obtained.

Other writers are less happy with the result of the meta-analysis: there are difficulties with the size of the included trials and with publication bias. Ernst and Barnes point out quite rightly that the commentators were critical, but did not raise any argument not already considered by the meta-analysts. They then add some new data, from trials published or not considered in the meta-analysis, none of which support that homeopathy is better than placebo. This will obviously disappoint the correspondent who enthuses over "an effect that is over twice the benefit of placebo therapy", and considers the mechanism by which homeopathy works to be of secondary concern.

A number of correspondents are worried by the logic which dismisses observations on homeopathy consequent on a lack of belief that it could work. And this is indeed the problem. There is no getting away from what the most extreme homeopathic dilutions are: Peter Skrabenek explained them as one molecule in a volume equal to that of the solar system, itself diluted in another billion spheres of the same volume. When faced with this knowledge, I simply cannot accept that homeopathic remedies-by which I mean the contents of the bottles, not the practitioners of homeopathy - can possibly have any effect. Yes, for me this does put the homeopathists in a double bind, because I could not accept a randomised controlled trial favouring homeopathy (and, I hasten to add, would decline the opportunity to peer review any such research). I regard that sort of result as an important demonstration that randomised controlled trials are no gold standard at all; there are all sorts of problems with them.

The point about the lack of mechanism for homeopathy is not just that we don't know how it *might* work. There are many other observations without clear explanations: we don't, for example, know how anaesthetics work but they clearly do. The difficulty with homeopathy is that the proposed explanation runs counter to the way we know the world *does* work; or at least the best coherent explanation we have so far. When Chinese medicine is proposed as a cure for something, at least we know that the herbs contain substances that are biologically active. There is a mechanism (though the evidence for it is weak and contentious) by which acupuncture might relieve pain. It is not fanciful to suggest that the manipulations of the osteopath and chiropractor might help backache. It *is* fanciful to suggest that dilution beyond the point of disappearance provides effective treatment.

To use an overworked word, I cannot accept homeopathy because it does not fit within the current scientific paradigm. We have to work within this paradigm until there is sufficient or strong enough evidence that it is wrong. If I am wrong, then it will only be a matter of time before that evidence accrues, and little harm will have been done. Better that, than acceptance of a treatment that in truth has no effect, whether or not 42% of general practitioners (according to a *Lancet* letter) prescribe it for their patients.

There will be those less critical of homeopathy but still worried by the "aftertaste of double standards" left when the findings of a randomised controlled trial are not accepted because they clash with our beliefs. I ask them what they would think of a randomised controlled trial (or subsequent meta-analysis) showing a positive effect of pendulums or laid-on crystals in curing disease? Would they think it "certain to be part of a whole new understanding of energy", or the spurious effect of chance in a complicated world of confounding variables?

None of the *Lancet's* correspondents mentioned that meta-analysis is no gold standard either. One of its problems is heterogeneity of the aggregated studies, which is a worry even when the meta-analysis is of the same treatment of the same disease. The difficulty, some say the fatal flaw, of meta-analysis is that it sacrifices methodological rigour at the altar of statistical precision. Bailar (3) has written that meta-analysis "does not work nearly as well as we might want it to work. The problems are so deep and so numerous that the results are simply not reliable." It may be over-hasty to put undue faith in the outcome of a meta-analysis as heterogeneous of conditions and treatments as that of Linde and colleagues.

Neville Goodman, Consultant Anaesthetist, Southmeads Hospital, Bristol

References

1. Linde K, Clausius N, Ramirez G et al. *Lancet* 1998; 351: 365-8.
2. Charlton BG. *Journal of the Royal College of Physicians, London* 1996; 30: 112-4
3. Bailar JC III. *New England Journal of Medicine* 1998; 338: 62.

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Letter : More on vitamin B6

Linda Lazarides, Director of the Society for the Promotion of Nutritional Therapy and author of Principles of Nutritional Therapy and The Nutritional Health Bible, writes:

Dear Sirs,

Your Expert View articles on the vitamin B6 controversy (issue No 28) contain some statements which show an incomplete grasp of the issues in question.

First, limits have not been set on the amounts of vitamin B6 which may be sold in food supplements. Limits have been proposed, and at the time of writing these proposals are being submitted to interested parties for comment.

Second, your readers may be misled by the statement that "for the first time a distinction has been drawn between nutritionally relevant levels of intake of a vitamin and levels of intake that are used to treat a medical condition, and which therefore should be considered like any other drug or medication." The Government's proposed placement of higher-range vitamin B6 products on prescription is not because these products are used to treat a medical condition but because the Government's Committee on Toxicity claims that they are too toxic to continue on sale as non-pharmaceutical consumer products. We note that your experts appear to agree with ours that the COT's conclusions are based on a linear-type model which is appropriate for xenobiotics rather than nutrients.

There is no legal provision to enforce medicines legislation on nutritional supplements simply because they are high in potency. The law states that medicinal products are substances administered for a medicinal purpose. In fact, unless it is sold with a medical claim, there is no proof that any consumer product placed on the market will be used for a given medicinal purpose. If the mere possibility that it might be used medicinally formed the basis of the law, then everything from whisky to coffee, glucose or bran tablets and carrot juice would have to be medicinally licensed before going on sale. Clearly this is nonsense, apart from the question "For what medicinal purpose would you license it?" For instance, there are dozens of high-potency multi-nutrient formulas on the market. Some women may take them to combat pre-menstrual syndrome, others simply because they feel more fit and well when they use them.

Finally, we doubt that the postal survey of vitamin B6 users commissioned by the Council for Responsible Nutrition (CRN) was a mere "counter-attack" against the flawed Dalton & Dalton study'. The Government and the COT have in fact repeatedly offered to consider any new evidence of the safety of vitamin B6. Dr Garrow omitted to mention that one of the conclusions of the CRN survey was that an equal number of women from the vitamin B6 and the control group reported symptoms of peripheral neuropathy. Since neuropathy is a common symptom of pre-menstrual syndrome, the lack of a control group in Dr Dalton's work is the reason most often given for discounting it.

At a meeting with MAFF and DH officials in March 1997, representatives of complementary medicine organisations reached a consensus that a limit of 100 mg of vitamin B6 per tablet sold as a non-pharmaceutical consumer product would be acceptable. We continue to reject reassurances that consumers could buy licensed products if others are banned, on the grounds (a) that the consumer would ultimately have to foot the bill for the massive costs of licensing, without gaining any particular benefits, and (b) that we are more concerned about the loss of multi-nutrient products containing 10-100 mg vitamin B6, few of which would survive, thus depriving the consumer of virtually all choice.

Yours faithfully

Linda Lazarides

Reference: Dalton K, Dalton MIT. Characteristics of pyridoxine overdose neuropathy syndrome. *Acta Neurol Scand* 1987; 76: 8-11.

David Bender, of the Department of Biochemistry and Molecular Biology, University College London, replies:

Dear Ms Lazarides,

Surely, in restricting the sales of vitamin B6 above a certain level to pharmacies because of potential toxicity the DoH has implicitly, if not explicitly, created a distinction between nutritional supplements and pharmaceutical uses to treat a condition. My argument is that in so doing the way has been opened for a major advance in consumer protection - if supplements are to be sold for medicinal, rather than nutritional, purposes, then there

will have to be scrutiny of the evidence of efficacy (and safety) at some future date. I do not suggest that there should be the same expensive process of testing and licensing as is applied to new pharmaceutical preparations.

The main questions that the consumer will ask are: What evidence is there that this supplement will do any good? Will I be wasting my money? Is it safe? These are questions that can be answered by a qualified pharmacist, but probably not by the checkout staff in a supermarket. A supplementary question that the consumer would not ask, but which a pharmacist would, is whether the supplement might interact adversely with (other) medication-vitamin B6 does indeed interact adversely with a number of prescription drugs.

Yours sincerely

David A Bender

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