Epilepsy drugs sold as intelligence boosters

A company in Cheltenham is selling treatments for Alzheimer's disease and epilepsy as IQ boosting "smart drugs".

Mail order firm Health Development Club (HDC) is exploiting a legal loophole to import the drugs from Europe and the US. Most of the drugs are unavailable or unapproved in the UK.

Prospective customers are sent lists of available drugs and HDC addresses in France and other parts of Europe from where they can be ordered. Section 13 of the 1968 Medicines Act allows anyone to import drugs for personal use as long as they are approved in their country of origin.

The drugs include Hydergine, developed in the 1940s to treat hypertension and later used to treat senility after tests showed it improved memory and concentration in elderly patients. In recent years, Americans have been taking Hydergine and other so-called smart drugs in the belief they will increase their intelligence.

The Royal Pharmaceutical Society told *Time Out* magazine it is asking the Department of Health to increase its vigilance over the kind of drugs being imported, but did not want to see the loophole closed.

"It's disgraceful that people are exploiting the loophole for financial gain. We're worried that no tests have ever been done on the effects these smart drugs have on young people. We're also worried about the kind of dosages being taken," a RPS official told the magazine.

Dr John Henry at New Cross Hospital's poisons unit told *Time Out* the drugs were unlikely to boost brain power but were probably not dangerous.

"There is a link between the content of these drugs, used to treat Alzheimer's, and the brain. However, if your brain is functioning to normal capacity, I don't believe that taking these drugs will make any difference at all, unless you count the psychological effects."

Hydergine is believed to stimulate the growth of connections between brain cells and boost the brain's blood supply.

HDC treasurer Stephen Cole, who set up the company to sell nutritional supplements to body builders, said he first took smart drugs while on holiday in the US and was impressed by the results.

"I have found my mental ability has greatly increased through taking "smarts" and I think it's the way of the future," he told *Time Out*. HDC supplies information about dosages, side effects and recent research with orders.

*The Medicines Act loophole is seen as invaluable by AIDS patients, who use it to access drugs unavailable in the UK.*
claiming to remove cellulite.

It criticised Express Newspapers for failing to produce any evidence that tablets offered by the Sunday Express Magazine performed as claimed. The Selite vitamin tablets, offered in conjunction with a company called Prideseek, were described as "Nature's way to fight cellulite."

The advert said the vitamin capsule "fights the problem where it begins - within the body." The ASA upheld a complaint from north Yorkshire based firm Natural Health Products, which questioned whether the claims could he substantiated. The Authority said it was very concerned about the advert, which the advertisers have promised not to repeat.

The ASA was extremely concerned about claims by Sparx Herbal Products for a herbal bath solution. A mail order advert in Health and Fitness Magazine headlined "No more dieting - bathe cellulite away" said the product contained "concentrated marine extracts to speed elimination of fat deposits. It has the benefit, in many cases, of inducing weight loss." The advertisers made no attempt to substantiate the claims to the ASA and said the advert was based on information from the manufacturer. The manufacturer, however, denied any input into the advert and said it did not support the claims. The ASA said the advert should not be repeated.

An anti-cellulite "skin firming" balm was among 16 health and beauty products advertised in a mail order leaflet distributed by Fairscore of Cheshire. Other products included Fat Destroyer, Bio-Tan and Instant Face Lift. Fairscore said the leaflet had been produced in association with an American distributor, US Nordic, but promised the ASA it would not distribute the leaflet again.

Call for clampdown

The Advertising Standards Authority has asked newspapers to clamp down on misleading advertisements for health products. ASA chairman Sir Timothy Raison called for renewed vigilance by publishers to catch misleading adverts before they are printed.

Addressing a Newspaper Society meeting, he stressed the need for cooperation from the Press in dealing with persistent offenders, particularly those making quasimedical claims.

He warned that publishers and advertisers must continue to demonstrate the effectiveness of self-regulation if they were to avoid the introduction of EC legislation.

Advertising body slams health critics

The Advertising Standards Authority has upheld two complaints against adverts attacking orthodox medicine. It has asked the National Anti-Vivisection Society to modify a leaflet implying heart disease is always self-inflicted.

The leaflet, entitled "Heart disease - the facts", said "only the patient can prevent or halt heart disease". It went on to claim that the disease "is the product of years of bad diet, neglect and abuse of the body, combined with gradual deterioration caused exclusively by human factors. It is illogical to attempt to recreate such a disease in animals."

The ASA accepted that lifestyle factors such as bad diet or smoking were the major contribution to the disease but said in some cases it was primarily a result of factors completely outside the control of the sufferer.

An advert by Herbal Health Organisation of north Wales headlined "... and they said Thalidomide was safe" was criticised by the authority for being unjustifiably alarmist. The advert claimed:

"It takes a few years of testing to get a licence to market a new drug. Yet side effects can take much longer to show up. Will the next so-called miracle cure ruin your life as drugs have many others?"

The ASA upheld a complaint from a pharmacist in Berkshire that the advert was likely to provoke undue fear of conventional medicines. The advertisers were further criticised for failing to prove claims that their herbal products could cure ailments, rather than simply relieve their symptoms.

Editorial: The Good Health Guide

The publication of this newsletter has been delayed for two reasons. It is partly because of technical problems, with a change in editor, and partly because your committee has been grappling with the problem of how best to
achieve our aims.

HealthWatch exists to improve the standard of health care by providing reliable information about methods of diagnosis and treatment on offer to the public, thus promoting an informed choice.

....is the sort of testing which is appropriate for motor cars or stain removers applicable to methods for detecting or treating disorders in the infinitely more complicated human body?

If we were not dealing with health care but, say, motor cars or stain removers, there would be no problem. The Consumers Association was set up many years ago to examine such products and publish a verdict in Which? magazine based on their own independent tests.

HealthWatch does not, and never will, have the resources to test all forms of health care on a similar basis. So how can we provide the reliable information which we promise? And is the sort of testing which is appropriate for motor cars or stain removers applicable to methods for detecting or treating disorders in the infinitely more complicated human body?

Within limits, we believe it is. Let us start with an easy example. There is not much difference between such tests for stain remover and those for hair restorer, even though one is used on inanimate fabric and the other on the infinitely complex human.

If the treatment is claimed to have a beneficial effect, then a controlled trial can test that claim. If the trial shows the treatment benefits the patient then let us give it credit and perhaps try harder to understand the philosophy.

In both cases we would try out different brands in a random order with a series of stained fabrics, or bald men, and ask a person who did not know which brand had been used to assess the extent of stain removal or hair growth. We would then rank the efficacy of the product on the basis of these judgements.

Most forms of diagnosis or treatment in health care are, of course, far more complicated than that simple example, but in most cases the same principle can be applied in the form of a controlled test. In most developed countries it is illegal to sell a medicine without a product licence. In the UK this is issued by the Department of Health when it is satisfied that the medicine is safe and effective in treating a specified condition. Evidence of efficacy is provided by controlled trials.

But how can you test an exotic treatment based on an incomprehensible philosophy? Well, never mind the philosophy. If the treatment is claimed to have a beneficial effect, then a controlled trial can test that claim. If the trial shows the treatment benefits the patient then let us give it credit and perhaps try harder to understand the philosophy. If no benefit is detected in a trial of sufficient size, we can be excused for saving ourselves the trouble of trying to comprehend the philosophy.

....the fact that a treatment has not been tested does not prove that it does not work: it just means nobody has shown it does work.

That, in a nutshell, is what we mean by reliable information about the efficacy of methods of diagnosis or treatment in health care: information based on properly designed trials. What about informed choice? This is where our members come in.

If you encounter a practitioner - orthodox or alternative - who claims that a method of diagnosis or treatment is effective for a certain condition, and you want to know if this has been proven, please write to us. Within the limits of our resources we will try to find out if this technique has been subjected to the sort of trial advocated in the Position Paper (see page 8) and will publish the answer.

In this way we will build up data on the range of health care procedures which have, or have not, been properly tested. Of course the fact that a treatment has not been tested does not prove that it does not work: it just means nobody has shown it does work. With this information you, the consumer, will be better placed to make an informed choice.

Why we must keep the lid on the black magic box

Petr Skrabanek is concerned HealthWatch could help alternative practitioners subvert medicine

One of the professed aims of HealthWatch is to oppose fraudulent treatments based on misleading diagnoses. Another is to promote testing of "alternative" diagnostic and therapeutic procedures. I would suggest this second aim lends spurious respectability to magic techniques and, as history has shown, is self-defeating. No amount of "testing" will convince a believer in, say, homeopathy or telepathy, that he may be mistaken. No single refutation of any particular claim of an acupuncturist would change his mind that there is "something in it".

Henry Poincaré said that the way to refuted irrational beliefs is not through experimental methods but through psychology and history. By this he meant demonstrating there is a certain frame of mind prone to irrational
beliefs and that the same kind of beliefs have existed throughout history without being weakened by any observations which appear to contradict them.

A similar point was made recently by a Mr Timerinan in a letter to Nature. He suggested that journals "stop publishing papers that deal with obscure techniques or nonsense theories, as it is very likely that they will be misused", and he used examples of recent homoeopathic studies which appeared in Nature, Lancet and British Medical Journal. One of these was an experimental testing of emanometer. While the results were negative, the author still thought that further testing may be desirable.

This bizarre method of diagnosis and treatment, modern versions of which are still used by British medical practitioners, originated in 1916, when Dr Albert Adams discovered that patients with certain diseases had small areas of dullness or percussion on their backs or abdomens. He also discovered that similar areas of dullness appeared in healthy people if diseased specimens, such as tubercular sputum or a container with cancerous tissue, were in their vicinity.

He subsequently developed a theory that every disease produced "vibrations" of a specific wavelength. To measure this wavelength, he constructed a coil marked with resistances in ohms. A specimen, such as a drop of blood, saliva or tear on filter paper, was attached by electrode to the forehead of a healthy naked person, which he called a "detector". When the specimen was moved along the coil it would elicit an "electronic reaction" in the detector, demonstrable by percussion dullness in certain spots on his abdomen. Cancer specimens would elicit this reaction at 50 ohms, acquired syphilis at 55 ohms.

Since various drugs moved along the coil also elicited a "reaction" through their "vibrations", Abrams constructed a box from which appropriate vibrations could be sent directly into the patient without a need for drugs. This "oscilloclast", or "Abrams' box" as it became known, sold in thousands, even though an investigative committee set up by the Scientific American declared the contraption as unworthy of serious attention. Being at best an illusion, at worst, a "colossal fraud". The American Medical Association denounced Abrams' method as quackery and refused to conduct an investigation in fear that it would "dignify that which was preposterous on its face".

At the same time in Britain, Dr E W Boyd designed a similar apparatus, called an emanometer. A special committee set up by the Royal Society of Medicine and chaired by Sir Thomas Horder (later Lord, and physician to King George V) concluded that the use of Abrams' black box or Boyd's emanometer was scientifically unsound and ethically unjustified for clinical practice. However, in their lengthy report they conceded that there may "be something in it". It is such failures to clearly demarcate the absurd which hamper attempts to separate new, testable advances in medicine from obscurantist hokum. And as Timmerman noted, the emanometer is still being "tested", albeit with negative results.

Meanwhile, new developments in the area of "bioelectronic regulatory medicine", as it is now called by its practitioners, has led to further variations on Abrams' theme. In Germany, a Dr Voll invented a system called "electroacupuncture according to Voll", a black box with dials. Instead of the healthy "detector" of Abrams' system, Voll measured "vibrations" in specific acupuncture points to locate various diseases and determine "energetics connections between the teeth and the bodily organs". The box costs $5,000 to $10,000, depending on accessories.

Similar black boxes are used in two modifications of Voll's system. In one, called MORA therapy, the patient holds two electrodes, inputting "pathological" vibrations into the box through one lead and receiving good "therapeutic" vibrations through the other. Whereas Voll's treatment required intramuscular injections of 15 to 40 homeopathic preparations, MORA treatment is simplified to drops of sterile water "electronically patterned" by the box.

In the other method, called Vegatest, one electrode is applied to a big toe while the other is held in the patient's hand. A "honeycomb" with numerous cavities containing homeopathic preparations is placed in the circuit. This may serve both diagnostic and therapeutic purposes. In volume three of the magnum opus of bioelectronics, Modern Techniques of Acupuncture. A Scientific Guide to Bioelectronic Regulatory Medicine and Complex Homoeopathy, Dr Julian Kenyon recommends putting appropriate homeopathic ampoules into the circuit for "pretests" to determine the "terrain" of a new patient.

This terrain includes the presence of the Yang or Yin polarity, "geopathic" stress, "global-grid" stress, "radioactive" stress or "electromagnetic" stress. "Premalignancy" can be detected with "Psorinum D24", and "micro-malignancy" with "Carcinominium D60", while "Epiphysis D4" informs about "psychic" stress. Kenyon believes nearly all patients with malignancy have geopathic stress. "Its removal is therefore of crucial importance to these patients if they're going to have any hope of survival," he says.

The "vibrations", whether pathological or therapeutic, take place in an "ultra fine energy region" and are physically undemonstrable as they are said to occur in two occult dimensions of a six dimensional model of the universe.

Elsewhere, Dr Kenyon observes that "no patient, no matter how clinically healthy, is found to have no abnormalities, whatever bioelectronic regulatory medical technique is used". Combined with the frank admission that these techniques have "many similarities with dowsing", that it is "important to think positively about what is
being put in the honeycomb as it appears to have an effect on the reading” and that “the psyche of the practitioner plays an important part in these techniques”, can members of HealthWatch still believe that to promote testing of these methods would get us anywhere? Is there no one to protect cancer patients against this exploitation?

In his 1986 book Twentieth Century Medicine: A Layman’s Guide to the Medicine of the Future, Dr Kenyon states it is extremely important for their movement “to establish a real foothold within scientific medicine”. The door to physics journals is forever closed to papers which lack a sound scientific basis for their hypotheses, but medical journals would serve as a backdoor to "scientific" respectability. I believe that HealthWatch should drop the pretence of being able to "test" meaningfully preposterous claims. Let us not be accessories to the perfidious plan of the alternativists to infiltrate medicine and subvert it from within.

Petr Skrabanek is based at the University of Dublin's Department of Community Health

See also Newsletter no 6 and Newsletter no 8b

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**Physician, heal thyself**

*John Garrow puts orthodox therapies under scrutiny*

Registered medical practitioners face a problem trying to protect a gullible public from unlicensed practitioners promoting quack remedies. If licensed medical practitioners use only effective, scientifically validated treatments, everyone else can be dismissed as charlatans. A moment of honest introspection will reveal to each of us, however, that no clear line can be drawn between the scientifically rigorous licensed practitioner and the corrupt and ignorant charlatan.

A recently published analysis of the therapies used in obstetrics lists a total of 276 practices, of which only 91 are deemed to have been shown to "reduce negative outcomes of pregnancy and childbirth". A further 37 "appear promising, but require further evaluation", 88 "have unknown effects, which require further evaluation" and 60 "should be abandoned in the light of the available evidence".

I see no reason to believe that obstetrics is significantly less scientific than medicine in general, so this suggests we have evidence of efficacy for only about a third of the forms of health care we adopt. So if we are to advise the public to shun charlatans, there is a lot in our own house which we must first put in order.

To compare the quality of science, I sorted a selection of popular books on diet into four groups and marked those written by registered or former medical practitioners with a star.

**Popular science - simplified and dramatised a bit, but basically sound.**

- Audrey Eyton "The F-plan diet"
- *A Maryon-Davis "Diet 2000"
- Susie Orbach "Fat is a feminist issue"

**Scientific evidence seriously overstated, with unsound speculation.**

- *R Mackarness "Not all in the mind"
- *David Reuben "Save your life diet"
- *George Watson "Nutrition and your mind"

**Scientific basis misunderstood**

- Geoffrey Cannon "DiETING makes you fat"
- *R Mackarness "Eat fat and grow thin" *

**Nonsense**

- Judy Mazel "The Beverley Hills diet"
- *Robert Linn "The last chance diet" *

It is evident that by this test - in the only field in which I feel competent to make a judgement - the professionals did not rank higher in scientific rigour than the amateurs.

Medical practitioners should beware of claiming that they are the sole custodians of safe and effective treatments. The only satisfactory basis for claiming efficacy for a treatment or a diagnostic procedure is a properly controlled trial. If conventional medicine is to retain the respect of the public, it must be on the basis that conventional practitioners are willing to submit their practice to this test, and to accept the verdict of the trial. If alternative practitioners are willing to follow the same rules they are entitled to the same respect, and we
should all try to learn from unconventional treatments shown to be effective.

Conventional medicine is facing a challenge from alternative therapies which pervert science and exploit patients, in other words health fraud. We must respond by putting our own house in order and clarifying which conventional therapies stand on proven efficacy, and which are in the category of harmless placebo. We will then be in a stronger position to challenge alternative practitioners to do likewise.

John Garrow is professor of human nutrition at St Bartholomew's Hospital and chairman of HealthWatch.

Media Watch: A low fact diet

Newspapers cannot be trusted to provide reliable information about health, says John Garrow

The Sunday Times is generally regarded as a quality newspaper: we would not expect to see articles on foreign affairs, economics, or chess written by people confused or ill informed about their topic. Why, I wonder, do different standards apply to diet and health?

Its colour supplement recently serialised a book by Michel Montignac called "Dine out and lose weight". Montignac had tried unsuccessfully to lose weight by dieting. He worked in a large pharmaceutical company and "was surprised to learn there was a lot of scientific information available, but only to specialists".

It was a big shock to him to learn that "as long as you count calories you will never get results". The reason was that "after an initial weight loss, the body's survival instinct reacts to calorie deprivation by storing fat, the same way a dog buries a bone when it is starving".

This deposition of fat in the absence of food is achieved, he says, by the pancreas pumping out excessive quantities of insulin. The result is that we are in a permanent state of hyperglycaemia (sic), susceptible to fatigue and irritability.

This explanation is in violation of the laws of thermodynamics, which have otherwise proved very serviceable. The secret is known only to an esoteric band of specialists, of which I am not one.

The scientific basis of the means for getting around the problem is still more difficult to understand. Carbohydrate foods are ranked according to their glycaemic index, or ability to raise blood sugar levels. This is a respectable, indeed old fashioned, concept, but the values assigned by Montignac will surprise some people: white bread rates 95, wholewheat bread 50 and whole cereals 40.

Even if this ranking was correct, it is not very helpful, since the glycaemic effect of bread depends on the foods eaten with it. The ultimate sin, according to Montignac, is to eat bread and butter, since the insulin secreted in response to the bread will cause lipid energy to be "abnormally stocked away in the form of fat reserves".

Fair enough: if you can persuade people not to eat bread and butter, or to eat fruit only on an empty stomach (even if the reasoning is crazy) you will achieve weight loss, because ultimately this will have the effect of reducing calorie intake.

Montignac, however, does not even play the game according to his own rules. He informs us smugly that "the amount of chocolate I eat is really quite impressive". He should know that plain chocolate is a mixture of sugar and cocoa fat, so why, by his rules, does that cocoa fat not get "abnormally stocked away"?

I suppose innovators should be allowed some artistic licence, but I think they should at least be consistent within their own scheme. Rules change from week to week. In week one olive oil was classified among fats which have "no effect whatsoever on the cholesterol level", but by week three it is commended as a fat which will reduce cholesterol level.

I ask again: why does the Sunday Times not apply similar criteria of professional competence to contributions about diet as it would to other subjects? Is the editor so bedazzled by words like "glycaemia" or "hormone" that he is bereft of his critical faculties? Or does he care less about truth when related to diet and health than when related to politics and economics?

HealthWatch exists to enhance informed choice about health matters by supplying reliable information to the public. It is evident this is not a task which can be safely left to so called quality newspapers.

John Garrow is professor of human nutrition at St Bartholomew's Hospital and chairman of HealthWatch.
Designing clinical trials

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One of the principal objectives of HealthWatch is to promote the testing of treatments and the conduct of clinical trials. There are three false arguments used to claim trials are unnecessary for certain types of treatment.

1. If patients feel better after the treatment, nothing else matters.
2. Trials of truly holistic treatment are impossible: there can never be a control patient with whom the result can be compared because each patient is different and the treatment is tailored to the individual.
3. Clinical trials cost huge sums of money which small independent practitioners cannot afford.

We believe that due to a lack of proper testing, patients are offered treatments which are less effective, less safe and more expensive than they need be, both in conventional and alternative medicine.

If a patient feels better after a treatment, it is very satisfactory but does not mean the treatment is effective. The patient might have shown similar benefit without any treatment or there may have been even more improvement with a simpler, cheaper or safer treatment. The best way to find out, almost always, is to do a suitable clinical trial.

Every good practitioner, whether conventional or, alternative, should practise "holistic" medicine, in that a treatment should be chosen to suit the whole patient in his environment and not simply the particular pain or lump of present concern. Therefore similar pains or lumps may be treated differently in different patients.

Despite this, it is still possible to do valid clinical trials using the guidelines set out below.

The onus of providing evidence of efficacy is on those who promote a treatment and not, as is sometimes stated, on the scientific community in general. It is true large scale multicentre drug trials may be very costly, but most of the expense is in administration and biochemical tests. The latter are not an essential part of the comparison, but to see if there are any unexpected harmful effects of the treatment.

Some minimum conditions for a proper trial to compare two treatments:

1. It is explained to a patient thought to be suffering a certain condition that on the basis of existing evidence the two treatments are equally appropriate and it is not known which is better. So the two are to be compared using two groups of patients, one for each treatment. To be as sure as possible that the groups are otherwise similar, the choice of patients will be random. Is the patient willing to take part?

2. Let us suppose the trial is comparing methods for relief of pain. Then:
   - we want to compare as many of the advantages (including such things as duration of benefit) and disadvantages (such as side effects) as possible.
   - we need to devise a method of scoring the intensity of pain.
   - we need a third person (often contacted by phone) who can record basic data before carrying out the randomisation and then inform the caller which treatment is to be used.

3. Ideally, to prevent any possible bias, neither the patient nor the person who assesses the effects should know which treatment is being used. This is not always possible.

4. Each patient is free to opt out of the trial at any time, though it is hoped they will not. Patients who fail to complete treatment for this or any other reason should not be excluded from the final analysis, as comparison should be on an "intention to treat" basis.

5. Any apparent differences in results must be analysed to determine the probability of their arising by chance. A probability of less than one in twenty is often regarded as a reasonable indication of a real difference. For this reason, the more patients who enter a trial, the smaller the differences that can be detected. Small numbers can reliably detect only big differences. There is also less assurance that the two groups are comparable in important respects other than the treatment.

This is a very simple summary of what we see as some minimum points to follow. HealthWatch is very willing to give advice to anyone seeking to make reliable comparisons of this kind, which is equally suitable for any method of treatment and any type of benefit or side effect.

This position paper was drafted by J Garrow and T Brewin and endorsed by the executive committee of HealthWatch on 5th December 1991.

A revised version of this position paper was agreed in January 2005.
Maastricht University spoke on "Assessment of Alternative Medical Treatment". Professor Knipschild has performed meta-analyses to evaluate a number of conventional therapies and has a special interest in the assessment of complementary therapies. This was the first time that a guest speaker had been invited, and it is hoped that this will form the pattern for future meetings.

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