

The Tandem

I.Q.

Story



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Contents

The Tandem I.Q. Story - Part 1

The Tandem I.Q. Story - Part 2

Key Points from the Court Case at
Shropshire 1992 - 1994

Important Quotes

References

First I.Q. Trial

In August 1985 Gwilym Roberts, a science teacher from Wrexham in Wales, contacted Larkhall Laboratories. He proposed to undertake a nutrition trial. He would divide children into groups and give some of them a comprehensive nutritional supplement, some a similar tablet, but without any nutrient value, and another group would not have any tablets.

The children would be assessed for behaviour and for non-verbal I.Q. both before and after the trial which would last some three months. Of the 10 companies that Mr. Roberts approached, only Larkhall were prepared to take part in the trial and they supplied the products for the start of term in September 1985. All information regarding the identity of the placebo (non-nutrient) and the nutrient tablets were withheld by Larkhall until the trial was completed.

Mr. Roberts contacted the local press to tell them about the trial taking place. All parents agreed to the trial and 30 children took part. 10 were on active tablets, 10 on placebo and 10 in the control group. Non-verbal I.Q. was measured before the start of the trial and at the end after three months. Behaviour was assessed by both parents and teachers using a specially designed questionnaire. A three day dietary assessment was made on all children before they entered the trial.

The results of this study were entirely positive. Greater non-verbal I.Q. increase and better perceived behaviour were found in the supplemented group over the other two groups, which were very much the same. A privately published report by Mr. Roberts was guarded in its conclusions but drew attention to the fact that the children who followed what Mr. Roberts perceived as the least healthy or nutritious diet, benefited the most from the supplements. Often, these were the underachievers and whilst in the long term it was in their interest to improve their general diets, in the short term, supplementation could have an important part to play in enabling them to perform and behave better. Correlation of the I.Q. and behaviour data also made the study more than just an anecdotal observation.

In all statements relating to this trial, it was explained that it was diet which was being improved by the supplements and that they were not magic stimulants or drugs. This was emphasized in other

literature and advertising matter relating to the introduction of the Tandem IQ tablets, which were marketed as a result of the trial in February 1986. Even in press articles and interviews, Larkhall and Gwilym Roberts put all the emphasis on dietary improvement.

Immediate Opposition

Even so, the opposition to the idea of a supplement being of any value was great. Academics and doctors mostly dismissed the claims because they said all children obtained adequate vitamins and minerals from their diet. In hindsight these critics had a cynical view of the trial because they considered it commercially orientated research. This, despite the fact that independent bodies were reporting concern at the general state of childrens nutrition. As Dr. Woodward wrote to Gwilym Roberts at the time – there are a number of doctors who would not believe in vitamins, even if they prolonged life by thousands of years!

Second IQ Trial

One scientist, Dr David Benton, who read about the trial, accepted a challenge from Gwilym Roberts to administer a large experiment, involving 90 children, over a longer period. This study produced a scientifically significant difference between the active and placebo groups. The results were published in January 1988 in The Lancet and on the BBC TV programme QED. In the same programme, parallel work on I.Q. and diet being carried out in the USA by Professor Stephen Schoenthaler was reported. All the data indicated that many children were not eating a good diet, and vitamin and mineral supplementation had positive benefits on both non-verbal I.Q. and behaviour.

TV and Magic Pills

The power of television was demonstrated dramatically and within a few days of the programme, vitamin and mineral tablets were cleared from stockists' shelves. This was because no specific formula had been indicated as being needed and even the BBC did not

publicise the Tandem IQ brand either on the programme or to follow up enquiries. Gwilym Roberts and Dr. Benton also refrained from mentioning the brand and always emphasised that it was diet which was important, and that the supplements were to be used whilst dietary correction took place. The QED programme had been clear that diet was on trial and no reports gave the impression that the tablets were a magic way of making all children brighter.

Trading Standards Officers Take a Look

During 1987, Trading Standards and Advertising Authorities began to take an interest in the Tandem IQ product. IQ had the double meaning "Ideal Quota" or "Intelligence Quotient".

The pack was colourful and had a picture of a boy and girl holding books on the front. Larkhall needed a distinctive pack for their product because all their competitors were anxious to take the market. Many even used the research on Tandem IQ and tried to intimate that it was their product which had been used in the successful trials.

Trading Standards seemed to be taking a stronger line against Tandem IQ than other products in the food supplement field with clever names like Zincold, PM Pack, Waterfall, Vita Youth, etc.

Larkhall claimed, in their replies to critics, that their product was clearly a vitamin and mineral supplement and was indeed the "Ideal Quota" for helping school performance for poorly nourished children and had been proved in the research in 1985 and 1987. Larkhall were in a competitive market and had the duty to ensure consumers were not misled into buying products which had not been tested in the I.Q. research.

This argument seemed to satisfy their critics so long as promotion was kept low key. It is a fact that when the QED programme broke the news in 1988 – Tandem IQ was outsold by other products on the market which jumped on the bandwagon. This certainly showed that the low profile had prevailed, but it is ironic when one considers what happened later.

So Called 'Replication' of 2nd Trial

The second Darland trial, as the study reported on QED and in The Lancet became known, caused an uproar. Critics focused on minutiae in an effort to rubbish the research. Letters to scientific journals, newspapers and the BBC attacked Benton, Roberts, The Lancet and the QED programme. Behind the scenes, academics in the Nutrition Department at Kings College, London, set about what they termed "a replication of the Benton and Roberts Study". The leader of this research was Professor Donald Naismith whose well known view about childrens' nutrition is neatly summed up by his contention that "a packet of crisps is as good for you as an apple". He was an adviser to the Snack Industry and other powerful food industry groups.

This so called replication took place at the school where Professor Naismith's wife was a teacher. A quite different tablet was used, a much shorter time - one month - instead of nine, different I.Q. tests and a different age group of children. The research was partly funded by the World Sugar Research Organisation.

Publicity Machine Brought into Play

The results, which were negative, were hurriedly published in abbreviated form in The Lancet in July 1988. Even before the preliminary report was published in The Lancet, a National Newspaper had the story and headlined as a fact "Pills do not raise I.Q.". Other newspapers carried similar stories and obviously, a publicity campaign had been organised by someone – probably a professional public relations company. This is not something one normally associates with academics involved in scientific research.

Naismith and his chief assistant Dr. Nelson were widely interviewed and succeeded in persuading the media and most consumers that the whole idea of I.Q. being helped by supplementation was nonsense. Children were mostly well nourished and if anything, they might lack some carbohydrate for energy and therefore, a boost with something like a packet of crisps or a few biscuits would be all that they needed to help them work and perform at school!

Sales of vitamin supplements fell back. In the media, it became generally accepted that since Professor Naismith had found no

connection – that must become the accepted position. The fact that his trial was not a replication of Benton and Roberts's or even Schoenthaler's work was totally overlooked. After all, he was a professor.

Gwilym Roberts Disheartened

Critics of the Benton and Roberts's study and QED programme, said that the impression given was that the answer to better school performance was a pill. This is not true. The QED programme, Roberts and Benton constantly emphasised diet as being the answer. Roberts tried to overcome this problem by doing a road show sponsored by Larkhall for over a year to promote this fact and try to improve diet without supplements. He visited many schools and Larkhall never received one complaint regarding any commercial aspects of his talk because there were none! Neither he, nor Larkhall, was given credit for this attempt and in 1990, he left the UK to go back to teaching science overseas! A misunderstood man? No, just one of those Brits who was before his time!

A Challenge to Critics

It is undoubtedly true that improvement in diet is what is needed, but how do you achieve this and test it? Use of the supplement is the only way to prove that there is a deficiency in the ordinary diet – now the problem is to replace the supplement with food precisely. A challenge which must be satisfactorily answered by the critics of supplement use.

Further IQ Studies With Mixed Results

1989 was a quiet year with little publicity on I.Q. and food, but research was continuing both in Belgium and Scotland. There were rumours of a large scale study involving many hundreds of children in three different countries. That study became known as the DRF trial – more about that later.

In March and April 1990, the controversy deepened as Benton reported positive results in Belgium and the Scottish team at Dundee reported negatively. The Scottish trial was a great disappointment to Larkhall who had provided the tablets. In the event, the positive results from Benton in Belgium offset the disappointment in Scotland. However, there was strong evidence that the Scottish children were better nourished than the Welsh children. Well nourished children would not be expected to benefit from supplements. The problem is detecting the poorly nourished – remember even oranges can be bought which contain little vitamin C because of their long storage period – they look fresh even though they may be several weeks old!

A small trial carried out at Reading University in 1989 produced positive results, but too few children completed the study to enable a significant result to be reported. It was very like the original study of Gwilym Roberts in Wales. A consensus was now developing that only poorly nourished children benefited.

It was the effects of vitamin and minerals on their behaviour, attention, concentration and attitude which was producing the higher I.Q. scores. The supplements enable the children to reach a higher I.Q. potential – a poor diet depressing their innate abilities. Whatever the mechanism, the fact remained that children on poor diets improved their non-verbal I.Q. scores more when given supplements. Even the Scottish study had shown a trend in that direction. Arguments about how or why are just red-herrings and put about by the opponents of the idea of a supplement of vitamins and minerals being needed by anyone.

The DRF Study and the Second QED Programme

In February 1991, Schoenthaler and his associates, who included some very eminent scientists, reported results in one of the leading psychological journals. A large number of children had been involved and a second QED programme was broadcast which concluded that the case for supplements was now proved until the whole diet improved substantially. The programme included a report on some of Benton's latest work. There was now overwhelming evidence that poorly nourished children who did not show obvious signs of

vitamin and mineral deficiency, could benefit in their school performance when given quite modest strength supplements with a comprehensive formula. All the studies since 1991 have confirmed this as a fact.

Indeed, when the Scottish trial results were reanalysed using a different, but equally valid statistical test, those children also showed major, although not quite statistically significant improvement in non-verbal I.Q. For those who might not be familiar with statistics, the normal probability level accepted by science as conclusive proof of a theory is 95%. In the Scottish trial, the level was 94%. If just one child in either group had changed just one answer, the 95% level would have been reached! This means that all the trials in this area since 1985 have shown the same positive results, except the Naismith and Nelson work - which has subsequently been shown to be totally flawed and can safely be ignored, since it was a poor piece of rushed science.

The Present Position

Even in 1994, there remain a hard core of sceptics, but they are now in a minority. It is widely accepted that there are many children in Britain, USA and other developed countries who do not eat a good diet. Whilst every effort should be made to improve that diet, in the meantime, the use of modest supplementation on a regular basis is advisable for a substantial number of children.

The real problem that remains is how to detect a poorly nourished child without costly blood analysis, and therefore ensure proper targeting of supplementation and dietary education. It is almost certain that caring parents who can afford it, will give their children supplemental insurance - should the Government not now review urgently its attitude to supplementation for the poorest members of the community, who stand to gain the most by such a change in policy? We can't wait as long as we did for Folic Acid to enter the mainstream - things are moving too fast now.

The Tandem IQ Story - Part 2

The Trading Standards Problem

Brand Names

When Tandem IQ was introduced to the health supplement market in February 1986, there were many other brands of supplements which had special brand names to indicate their use. For example, Zincold (for colds), Magnesium OK (to feel ok), PM Pack (for pre-menstrual tension), Waterfall (to lose water) and Zest (for energy). Even today, these brands which often carry pictorial illustration to assist their marketing, continue to be widely available and have not, as far as we are aware, been attacked by Trading Standard Officers.

Political Correctness?

When we introduced the Tandem IQ brand, we did not appreciate that we had ventured into an area where political correctness had an influence.

Some people saw what Larkhall were doing with Tandem IQ and the idea that diet could hold a useful answer was unacceptable to the way they saw the world. They thought media attack, coupled with exploiting any possibly illegal aspects of packaging, could stop these dangerous ideas getting a hold. Although Larkhall pursued a fairly low profile after the first study, there were several attacks, but nothing compared with those which followed the publicity of the Benton and Roberts study in The Lancet and on BBC QED in 1988.

Trading Standards Officers and the ASA

Several Trading Standards Officers complained about the pack and the Advertising Standards Authority upheld complaints against advertisements, including a professional leaflet about the product. However, these problems were all overcome without difficulty because Larkhall cooperated fully with both the ASA and Trading Standards Officers. Larkhall felt it was vital to hold on to the I.Q. reference in the name to build awareness of the positive connection between supplementing a poor diet and I.Q.

A Sinister Turn of Events

Although some of the Media were aggressively against us, we were able to hold our own against our critics until around the middle of 1990 when things began to take a different, and perhaps more sinister, turn.

A Grey Area

There has always been a problem as to what constitutes a health claim and what a medicinal claim. The border between the two groups being considered a grey area. Some Trading Standards Officers believed that in this area, they could attack Tandem IQ and for that, they required the expertise of scientists opposed to the supplement I.Q. connection. It is usual for Trading Standards Officers to negotiate with companies regarding small changes that they believe to be necessary in packs or promotion, and not to take immediate legal action. Professionally, it is also expected that Trading Standards Officers from outside the area in which the product is made or marketed, should always consult with the local Authority where the company operates, before taking any action.

Reasons for Changes

There are probably two reasons why things changed in 1990. One was the publication of the MRC sponsored Scottish Supplement I.Q. Trial which apparently showed negative results. These were later found to be not so negative, having only missed the significance which would have made the result positive by, the narrowest of

margins. The other was that an organisation known as the Campaign Against Health Fraud, Quackbusters or Health Watch was becoming more active against what they termed "unproved" or "fraudulent" health claims.

Measurable Benefits for Vitamin Supplements

Perhaps some of our opponents were worried about the I.Q. supplement link because this was the first time anyone had actually succeeded in showing a measurable benefit for supplementation. The subjective measurements usually used in nutrition trials for things like skin health, pre-menstrual tension, anxiety, rheumatism, menopausal symptoms, etc., could easily be criticised, but when actual I.Q. numbers became involved, they were in difficulty with their criticisms. For the first time a measure (albeit perhaps not very precise) was found to investigate the benefit of supplements.

BBC 2 Food and Drink Programme

In the Autumn of 1990, things began to come to a head. There were telephone communications from Journalists working for the BBC 2 Food and Drink Programme. They were interested in the I.Q. supplement research and the products on the market. They gave the strong impression that they believed Tandem IQ was misleading the public into believing that it would improve all childrens I.Q., whereas they contended that we currently said that it had still to be proved. It is true that we had said that further research was going on, but the wording of a recent press story was slightly ambiguous. The fact was that Dr. Benton was researching into poorly nourished six and seven year olds because he believed this group could give results quicker than trials with older children. Research periods could be cut from nine months to two months. The journalists were not interested in this detail, they just wanted to go for a story putting over their biased point of view.

Naismith on BSB TV

At about the same time, Dr. Woodward went on a BSB TV programme with Dr. Benton and Professor Naismith. Dr. Woodward's views, and those of Dr. Benton, were given little attention by the presenter, and Professor Naismith was allowed to let his view prevail that there was not a connection between supplements and I.Q. and that the whole idea was nonsense. I think it is appropriate to note here that the presenter was none other than Dr. M. Stoppard who had been Managing Director of a multinational pharmaceutical company.

After the broadcast, Rita Greer had a word with the chain smoking Professor Naismith. He told her that he thought Dr. Woodward had obtained a PhD by paying fifty dollars for it in the USA and had never done any academic studies. He was quite surprised to learn that Dr. Woodward had not only Academic but also Professional qualifications in the scientific area. Rita Greer had quickly corrected him on the points. She also asked him about his well known view that a packet of crisps was better than an apple. She asked him whether a snack company was perhaps funding the department, he just chuckled and said "Yes, Golden Wonder". Academics who widely accept grants from industrial interests seem to believe that their independence is beyond question, whilst the researcher who has his own funds and carries out his own scientific work – perhaps with commercial links, must be biased and worthless.

Shropshire Trading Standards Officers Enter The Picture Through TV

In late October 1990, there was more contact with journalists acting for the BBC 2 Food and Drink Programme and also from officers at Shropshire Trading Standards. These Officers wished to interview Dr. Woodward about Tandem I.Q., but denied that they had any contact with journalists at the Food and Drink Programme.

Imprison- ment and Arrest Possible

After taking legal advice, Dr. Woodward declined to be interviewed because it was obvious that this would have been confrontational. Equally, no permission had been given by the local Trading Standards office in Wandsworth for Shropshire to carry out their interview in Putney. On the telephone, the Officer told Dr. Woodward he could possibly be arrested and imprisoned for the offences they were investigating. Dr. Woodward had visions of being handcuffed and led from the building following any interview with these officials!

The Food and Drink Programme is Transmitted

On the 30 October, the Food and Drink Programme was broadcast, and it was claimed that there was no scientific evidence that vitamin supplements could improve I.Q. and that Naismith's and Crombie's (the Scottish study) studies proved that there was not a connection. The products Boost I.Q., Top Marks and Tandem IQ were criticised and the reporter said, "We referred these packets to Shropshire Trading Standards Office who told us they are considering whether they breach the existing laws".

The programme was totally biased and ridiculed Larkhall's Dr. Woodward and, ironically, the Managing Director of the firm - since gone into receivership - who sold the Zincold product (for colds) for which there was hardly an overwhelming scientific case, was interviewed and said he decried the IQ products when there was no scientific evidence for their effectiveness. Meanwhile, we waited for Shropshire's next move.

Woodward Likened to Nadir?

In early November, Shropshire wrote to Dr. Woodward saying that in view of the recent "Nadir" Polly Peck decision, they did not need to disclose anything about the offences before an interview. Dr. Woodward was hardly flattered to be compared with an alleged billion pound fraudster but nevertheless, politely declined to be interviewed.

No Benefit to IQ

Correspondence on pack details took place between Larkhall's solicitors and Shropshire in November 1990. This was very detailed but largely irrelevant to the basis of the case that the product was of no benefit for improving the I.Q. of children.

The First Summonses

Summonses were ultimately received in early January 1991 and were heard in court towards the end of January. It is interesting to note that the journalists at the BBC 2 Food and Drink Programme were fully aware of the issue of these summonses before Larkhall actually received them.

The wording of the two summonses was basically turgid but the gist of them was as follows:-

- 1) The packs of Multivitamin and Mineral Tablets had a false trade description. A statement "British made naturally" was applied when those goods were not produced by natural methods. This summons was eventually dropped by the prosecution.
- 2) Multivitamin and Minerals to which a false trade description of the words "Tandem IQ Pack accompanied by a depiction of a boy and a girl each holding a book was applied when they were not fit for the purpose of increasing the intelligence quotient of a child." This was clearly an allegation that the whole I.Q. claim was false.

Expert Helped by Larkhall Helps the Prosecution

Statements to back these charges were presented by officials and expert statements were made by Dr. Nelson (Professor Naismith's associate from London) and Dr. Todman (Dr. Crombie's associate from Dundee). Larkhall had been the donors of the tablets which had enabled his team to carry out their research.

Even at this time, it was acknowledged that the tablet could help the health of children whose diets gave cause for concern, but not the I.Q. of normal children. Whilst some children's health could benefit, not their performance. A strange concept, since common sense alone would make one expect that healthier children would perform better.

Larkhall's Hearing Postponed But Another Producer Found Guilty

Larkhall applied to have the hearing postponed, which was agreed so that further correspondence could take place. This case, if it was to be fought to a conclusion, would take a long time to put together. This was appreciated by the Trading Standards Officers, who, I think, began to realise this matter was far from clear cut and that as research results became available, could change dramatically. Meanwhile, the makers of Boost IQ (Seven Seas) gave up the fight and were heavily fined and withdrew their product from the market. Their product had not been researched and perhaps justice was done.

A Possible Withdrawal of the Prosecution

In January 1991, Shropshire began to have doubts about their case and offered to reconsider their position if other evidence cast sufficient doubt on the prosecution's ability to prove its case. It was of course well known that the results of a further major study were about to be published.

DRF IQ Vitamin Study Published

In February 1991, with the hearing postponed yet again, the major DRF (Dietary Research Foundation) Study was published by Schoenthaler and others and this brought a product, Vitachieve by Booker Nutritional Products, into the market place. Great media criticism ensued and still the message failed to get across that the improvement in I.Q., as expected, only occurred in those children on deficient diets. As in all the other studies, the children taking part had not shown overt symptoms of dietary deficiency. If children were nutritionally satisfied from their diet, then supplements would be unlikely to have an effect. The problem was knowing the deficient children to give the tablets to. Bad nutrition is not like a headache, that's the problem. Symptoms aren't obvious and there is no simple way of detecting them - so it is wrong to say producers are not aiming their products at the target group - they can't! No expert can tell who is deficient and who is not. Using averages for food intakes to interpret that everyone may be getting a balanced diet is a very false picture. It is much worse than using the word average when expressing the results from a group I.Q. test!

Further Postponement of the Case

The publication of the DRF Study led to the Summonses being postponed "Sine Die". Larkhall had won a respite and the Trading Standards Officers in Shropshire had to go back to basics. Our opponents were not going away – too much was at stake.

Illogicality continued unabated and the Medical Research Council were called upon to arbitrate on the I.Q. supplement research. Dr. Woodward asked why pick on this research for arbitration? Why not arbitrate on all research. Obviously, it is a matter of political correctness again. I.Q. is involved with emotion, not science any more!

Change of Direction by Shropshire

The publication of the DRF study which clearly supported the claims of Larkhall must have caused problems in the minds of the Shropshire prosecuting authorities. They had previously given the impression to Larkhall's solicitors that if the further studies supported Larkhall's scientific claims, the prosecution might not be proceeded with. What were they to do now? They were pressed to drop the prosecution but refused to do so. They decided to do two things.

Firstly to see if they could find some mistake in Larkhall's very detailed formulation of their tablet as printed on the packets. This at least could be a face-saver and result in a conviction of some sort.

Secondly Shropshire obviously realised that it would have been extremely difficult for them to have obtained a conviction on the wording of the main Summons to the effect that Larkhall's tablets were not fit for the purpose of increasing the I.Q. of a child.

Larkhall had not been involved at all in the DRF study and here were scientific results clearly supporting the connection between the taking of vitamin and mineral supplements and the raising of some children's I.Q. This study had been under the control of most eminent scientists. Professor Schoenthaler in America, Professor Peritz (one of the world's leading statisticians) from Israel. Professor Eysenck, the inventor of I.Q. tests and Professor Yudkin, a well known nutritionist, both from London. Shropshire could hardly claim that the results were false and put forward falsely to boost the sales of vitamin and mineral tablets.

So the Shropshire prosecuting authorities decided to amend the original Summons and to issue a new one claiming that the marketing of Larkhall's tablets contained a representation that tablets would have a "widespread and general effect of raising the I.Q. of children".

In other words the prosecution were no longer contending that the whole claim was rubbish, but were conceding that the claim was or might be true, but it was only *some* children who would benefit.

But this was precisely what Larkhall had always claimed.

Packaging and Labelling Under the Microscope

By May 1991, the authority was struggling with minutiae in their prosecution and going into inordinate detail to find flaws in labelling and packaging so as to obtain more charges.

This continued to be their ploy even after long interviews, both with Larkhall's solicitor and in a day long meeting with technical staff in Putney. In August 1991, we had to agree for them to come and see all our documentation, both technical and advertising, because they threatened us with a charge of obstruction if we did not agree.

Health Food is a False Trade Description

In July 1991, it is interesting to note that the Shropshire Chief Trading Standards Officer, D. C. E. Roberts, went on record in a food law seminar in the following terms:-

"Claims for (healthfoods) – the phrase is probably a false trade description – have increased enormously in the past year or so and the recent MAFF/DH working groups paper has to be set aside the claims of the health food manufacturers and PAGB for recognition of health claims rather than their proscription as the law, domestic and EC lays down. Already several cases have been taken and more are in the pipeline. There have been cases also on allegedly false advertising, etc., of vitamin pills and their effects on children. Watch this space".

**Another
Larkhall
Product
Interests
Shropshire**

Around this time, Shropshire Trading Standard's Department decided to investigate another Larkhall product Ruthmol, The Salt Substitute, which had been on the market for nearly 50 years and is probably the most medically acceptable salt substitute available. It is widely recommended by doctors who are prescribing a low salt diet for their patients. Although no more was heard from Shropshire, this product was subsequently investigated by Leicester Trading Standard's Department but after correspondence with our solicitors, they agreed not to pursue the matter any further.

**Visit of
Shropshire
Trading
Standards
Officers to
Larkhall's
Putney
Laboratories**

On the 16th August 1991, a Trading Standards Officer from Shropshire, together with his assistant, visited Larkhall Laboratories in Putney. He saw two of our technical staff. He gave the impression of being determined to find discrepancies, however minor, in formulas used to make the Tandem IQ tablets. He had no technical knowledge of tablet making but he was a very good proof reader. He cautioned our staff that anything they might say would be taken down and could be used as evidence. His female assistant wrote busily all day. He failed to differentiate between the active nutrient ingredients and the natural additives used to enable the processing of the tablets. There are often minor variations in the quantities of particular additives when one makes tablets because of the technical characteristics of the active materials. Variations would be very minor and amount to just a few milligrams of something like Lecithin or Di-Calcium Phosphate. He thought that such minor alterations constituted major changes in formulation. Good pharmaceutical practice demanded that all minor changes are noted in working formulas to which he now had access. In the Food Labelling Regulations, such variations are meaningless. The basic active ingredient list remains unchanged. He returned to Shropshire and these minor changes and some printing errors on cartons became major points for charges of a criminal nature to be brought against Larkhall.



**The New
Charges**

We received on 3 December, five new charges making the total now faced seven. These new charges were basically an extension of the I.Q. claim and labelling inconsistencies relating to minor ingredients such as Lecithin, Silica, Gua Gum and Safflower Oil. They were such trivial points caused by printers errors and could never be construed as deliberate attempts to mislead consumers. Indeed, all the points had been amended on subsequent printings of the cartons. All these charges were later dropped.

**All
Children
Must
Benefit**

By interpreting certain phrases on the leaflet previously enclosed with pre-1990 supplies of the product. They said that we were claiming "a widespread and general effect for the supplement". So they succeeded in bringing "all children benefit" into the case. The hearing of all the Summonses was scheduled for 22 January 1992.

**One
Guilty
Plea
Needed**

During 1991, several experts offered their assistance to Larkhall and this was encouraging. Professor Arnold Beckett, the world renowned authority on Medicinal Chemistry and drugs in sport, agreed to join our team. At the end of 1991, Dr. Woodward was convinced that Shropshire were determined to settle but needed at least one guilty plea to save their costs. What they failed to realise was that he was determined to see the matter through because this research had been based on his deep scientific interest on the benefits of vitamins and minerals as supplements. He felt that this came above profit. Whilst a law was stacked against him, how could he continue in vitamin research after giving in to the very powerful Shropshire bureaucrats..



**Vitachieve
Guilty
and
Withdrawn**

1992 started quietly. The first point of interest was that Booker Nutrition capitulated to Shropshire and lost the case against their Vitachieve product on Trading Standards technicalities. We understand that these largely revolved around the meaning of the word "average". As a multinational company with huge dividends and profits needed to sustain them, they took the commercially prudent step at pleading guilty and cutting their losses. Good business, but poor support for the pro-vitamin cause. Didn't they believe in their product? Where is scientific integrity?

**Reduction
to One
Charge**

Shropshire probably thought Larkhall would follow suit and offered them a reduction to just one charge of guilty. That is just one out of seven! A guilty plea to one Summons was apparently acceptable and that Summons was one that was later withdrawn! To settle would have been an expedient way out but again, they had not looked at Dr. Woodward's track record against oppressive bureaucrats. He did not worry about the financial loss. It was the loss of his integrity which interested him. Politicians, when they enact laws, usually have good reasons and intentions but bureaucrats in their interpretation of those laws, can cause an oppression of individuals which was never intended by parliament. Dr Woodward saw the I.Q. case brought by Shropshire against his company as just such an issue.

**New
Expert
Report
from
Shropshire**

Booker capitulated largely because an expert report had been produced by a private consultant Dr. S. Blinkhorn. A statistician with psychometric experience. In his report, he looked at the published literature and, whilst he criticised the Benton and DRF Studies as well as the products produced from those, he appeared to have no criticism of the prosecution research of Naismith and Crombie. He was probably retained by Shropshire because he had written a very critical paid for article in Nature, at the Editors request, following the publication of the DRF Study. Doubtless, Dr. Blinkhorn is a good scientist, but he would appear to have quite good commercial instincts having charged Shropshire about £15,000 for his expenses and advice before and during the case! Indeed, in the

witness box, he actually admitted that he had not read all the papers!

Happily, in February 1992, Larkhall were told that both Professor Hans Eysenck and Professor S. Schoenthaler would join their team of experts. This was a major breakthrough and made the winning of the scientific argument certain.

**Commercial
Research
Suspect –
More
Power
Needed**

In March 1992, another Shropshire Trading Standards Officer Mr D. Walker, made a presentation at the Royal Society of Medicine about health claims. He came out in his true colours as a zealot and missionary Trading Standards Officer. He wanted greater power – he did not think that research funded by commercially interested parties should necessarily be valid – implication of all consumers benefiting is wrong on a product. It is just what Larkhall would have expected – they were up against an extremist who craved power. Had the man ever asked himself how much research would have been done without commercial help? How could Britain exist except by innovation and research however funded? Does he really think that people believe medicines and health products always help them? Does he know of any clinical trial which shows 100% effectiveness apart from 1gm of strychnine? When Dr. Woodward read the report of this meeting, he just hoped that the Magistrate in Shropshire who heard the case would be more open minded. Walker even said he always took the Home Authority with him in prosecutions. He certainly had done no such thing in Larkhall's case because he said it was much too serious a matter.

**A Review
of the
Case**

The Court decided to review the case and the hearing was in March 1992. Although Shropshire were not proceeding with the original complaint to the effect that "the whole matter of vitamins and I.Q. was a nonsense" they appeared still determined to obtain a conviction. "We do not need any experts to give evidence" they said. "The prosecution experts say there is no connection at all between I.Q. and vitamins: The defence experts say that there is a connection which is proved by the various trials, however even if you are right (and we

do not admit it) you are still guilty of an offence under our amended Summonses in that not all children will have their I.Q. raised anyway".

Larkhall were not prepared to plead guilty or to fight the case on this basis. In putting forward the connection between vitamin and mineral supplementation and the raising of children's I.Q., we had not put forward anything that was untrue and to plead guilty to a trading standards technical offence or to fight the case with one hand behind our backs by not calling our experts, would have been disastrous for us. We were quite determined to establish before an independent court that the tests which supported the I.Q. connection were honest and valid and that our claims were put forward in good faith.

Ultimately although found guilty of what many people would describe as a technicality, we were able to win the scientific argument and vindicate our good name.

Campaign Against Health Fraud

In April 1992 at an informal interview, Mr. Walker of the Trading Standards Office said that he knew nothing of the Campaign Against Health Fraud or their associates. However, it is interesting to note that this organisation boasts cooperation with Trading Standards Officers on cases.

Were any of Larkhall's protagonists at Shropshire members?

For example, was the Chief Trading Standards Officer a member? Were any of his staff, the witnesses, Nelson, Blinkhorn, Todman, and the researchers Naismith and Crombie? It would be interesting to know for certain. What is certain is that at least one of the BBC 2 Food and Drink team was an associate of the organisation at the time of the 30 October 1990 programme.

At this time, Dr. Woodward wrote to Nicholas Soames the Parliamentary Secretary at the Ministry of Agricultural Fisheries and Food but only a brief reply was received.

Guilty But Commended For Research Efforts

On 21 September 1992 the case opened. At last, the prosecution admitted that some – a small minority perhaps 10% (1,000,000) could benefit from the vitamins. However, their case rested on the pack and leaflet which they said could mislead. In fact, they produced no witness who had been misled and the original complaint was by the BBC 2 Food and Drink who said the science was nonsense not the minutiae of the pack. In British law, if the magistrate believes someone could be misled, the prosecution win on that point of law. After five days, the science was overwhelmingly won, but the pack interpretation being such a subjective matter, was lost. Larkhall were commended for their research but told that their pack could have misled some people. Justice? No. But as Dr. Woodward feared, the guilty verdict on the technicality was translated by the press into the link between vitamins and I.Q. being wrong.

An important battle remained to be fought. The Tandem IQ pack remained on the market with a disclaimer on the pack. Most consumers could not tell the difference. Shropshire had lost in their initial endeavour to stop the pack and its marketing. Indeed, the actual changes which were made could have been negotiated over a cup of tea in ten minutes of Trading Standards Office time! The Food and Drink programme announced the verdict without qualification. There was no fraud, the science was good and even Dr. Todman admitted that the Scottish research was in favour, but did not quite confirm the I.Q. vitamin connection when analysed by a different statistical test.

The Appeal

In order to sustain interest in the case, Larkhall decided to appeal. The appeal procedure enabled them to see how the magistrate had reached his verdict. From this, it was obvious that the Trading Standards Act wording was so broad that they were caught and if many other products in their general field of food supplements including Zincold, Casilan and Magnesium OK were put to such a legal trial, they would probably lose. By not proceeding with the appeal, we ensured that the Shropshire verdict against us would be unlikely to set a dangerous precedent for all products in this area. If we had lost on appeal, then the matter would become more solid and

that was one of the reasons that our lawyers advised against proceeding. Don't make a rod for everyone's back – you proved the science was right – the law is an ass!

The Magistrate's Decision

In finding Larkhall guilty of having possibly misled some unknown and unidentified customers, the magistrate had particular regard to the Trading Standards Case of Doble versus David Greig Ltd 15 February 1972. The case referred basically to a price dispute in a supermarket and was to do with how the refund of a deposit on a bottle was interpreted by a customer.

Apparently, the words "the deposit on this bottle is 4d. Refundable on return" are considered to be equivocal. They might be interpreted to mean that the price marked on the bottles included 4d, earmarked as a deposit. Alternatively, that an additional 4d over and above the price marked would be asked for as a deposit.

In the appeal, it was specifically stated that where a price ambiguity was concerned, then things should be made clearer.

It seems strange that such an apparently dissimilar case should have been the main precedent for the judgement against Larkhall.

Could All Children Benefit?

Shropshire won on a point of law, but they lost on the main basis which everyone understood the case to be about i.e. that vitamin supplements do benefit at least 1,000,000 children. The problem is knowing which 1,000,000 today and which 1,000,000 next week. Probably several million are at risk sometime during the school year! Mr. Walker's comment on TV at the end of the case illustrates his blinkered view of products of this kind always being effective. Incredible, but that is the mentality of a dedicated Trading Standards Officer. Here is the quotation:-

"For those parents who generally believe that feeding these supplements to their children would *always* increase their I.Q., those parents would have been wrong and would in fact have been wasting their money".

Libel Victory – Damages Paid To Charity

Whilst there was no doubt that Larkhall were not convicted of fraud – it came to their notice that the organisation Health Watch (previously known as the Campaign Against Health Fraud) had intimated in one of their newsletters that we had been found guilty of fraud. This organisation has many experts in its membership who are called on for instant opinions by newspapers, magazines and TV programmes. It also provides Trading Standards Officers with experts. Some of their members have been vociferous against Larkhall and its products including Tandem IQ. This same organisation could not get its facts right and accused Larkhall of collaborating with the BBC QED Programme to publicise Tandem IQ – even to the extent of bringing the product onto the market after the 1991 programme. Tandem IQ was on the market in February 1986 long before even the first QED programme in January 1988! As a result of these statements, Larkhall and Dr. Woodward threatened to sue Health Watch for libel. In an out of court settlement, costs, damages and a full apology have been given by Health Watch and their past Chairman Professor Garrow, together with an undertaking not to criticise Larkhall or its products in the future unless they have thoroughly checked their facts. Larkhall donated the damages to ASBAH – The Association For Spina Bifida and Hydrocephalus.

Key Points from the Court Case at Shropshire 1992–1994

1 Acceptance by prosecution that 10% – 1,000,000 children could possibly benefit from supplements.

2 Nelson data – Failed to supply raw data to the defence in time for it to be analysed by their experts before the case. He was asked to provide this six weeks before the hearing, and only a few days before the hearing did the computer disc arrive, but no password was available in order to break into the data - nor the time to analyse it before the hearing.

Scientists are usually very happy to disclose their data to a researcher in the same field, but even before the case arose, Dr. Nelson had refused to supply his data to Professor Schoenthaler, who carried out some of the original I.Q. studies.

When the data was analysed by defence experts in connection with the appeal proceedings, one expert reported that in his opinion, the study was virtually worthless since the measurement of I.Q. was not credible, and another expert criticised the psychometric aspects of the paper, and concluded the limitations of the study were such that Nelson was not justified in coming to any conclusion about the effect of diet on intelligence.

The tests given to the children were limited to two tests instead of the normal five, and the tests were apparently poorly carried out. The data reveals that the group of children taking supplements started off with a higher I.Q. than the group of children not taking supplements. The probability was therefore that the children taking supplements were well nourished and one would not expect their I.Q.s in any event to be raised by supplementation.

3 Dr Todman – Admitted that the wording of the summary of the research paper published in The Lancet about the Scottish Study was slightly incorrect, and gave the impression that the results were totally negative. In fact, he admitted in the witness box, that if he had used a different statistical test, as was proper in this case, his results on the non-verbal I.Q. measurements would have only just missed reaching the 95% probability level. This work almost proved, beyond doubt, a positive connection between non-verbal I.Q. and supplementation.

4 Dr Blinkhorn – This prosecution expert admitted he had not read all the papers. He criticised Schoenthaler and Benton's work but gave no view on Nelson or Crombie (Todman).

5 Dr Benton – Confirmed his belief that the minority who benefited, perhaps up to 50% in very deprived areas, made there appear to be an average increase. This is quite usual in clinical trials where group measurements are involved and an average improvement is reported.

6 Professor Eysenck – Fully confirmed his beliefs that the connection between non-verbal I.Q. and vitamin supplementation was proved beyond doubt.

7 Professor Beckett – This expert was convinced of the positive effects of supplementation on non-verbal I.Q., but was also alarmed at the always effective interpretation which has a profound implication for all health and medicinal products, none of which are ever 100%, and many only 30%, effective. He was also concerned at how you determine which children are at risk, because in the trials, no child was showing overt symptoms of vitamin or mineral deficiency. If you have a headache, at least you know that is when an aspirin is needed. How do you know, without extensive blood testing, if you are vitamin and mineral deficient?

- 8 Professor Schoenthaler – He was heavily criticised by the prosecution for a book he had written for the BBC and unfortunately, because he was unwell when in the witness box, he did not do himself full justice. However, he defended his research and confirmed Benton's views.
- 9 Magistrate's Verdict – Was given not on the science but on the Trading Standards technical points for which he fined Larkhall modestly, but said he could clearly distinguish this case from that against Boost IQ (Seven Seas) and Vitachieve (Booker). He commended Dr. Woodward for undertaking the research into the connection between supplementation and I.Q.
- 10 The outcome was that Larkhall marginally changed the pack to put a disclaimer on the front as follows:- "For children who do not eat a balanced diet".

Otherwise, the illustration of the boy and girl reading books and the word "Tandem IQ" remain. The reference to Ideal Quota is now omitted since it is fully acknowledged that I.Q. in the title means "Intelligence Quotient".
- 11 Fines were levied on Larkhall on two charges, the third being struck out and were:- £500 on each ie. £1,000. Prosecution costs were awarded against Larkhall and this amounted to:- £35,000 although they had claimed considerably more. The magistrate allowed Larkhall three months to pay.
- 12 The Appeal – Since Larkhall appealed, the fines did not become payable until the appeal had been heard. The appeal was dropped just before Christmas 1993 and all the formalities had been completed by the end of January 1994.

- 13 In the meantime, Larkhall had agreed to pay the costs and fines on a monthly basis of £3,000 per month from March 1. That date being within the 3 months allowed by the magistrate at the time of the judgement. This had been agreed by the Shropshire Court. However, the court said they did not have facilities for monthly payments so would transfer this to the South Western Magistrates Court.
- 13 The South Western Magistrates Court did not contact Dr. Woodward but on February 11, sent bailiffs to Larkhall with a Distress Warrant for £36,000 plus bailiffs costs of £8,600. They wanted immediate payment and threatened to remove items to that value unless payment was made by Bankers Draft. Dr. Woodward showed them all the papers relating to the case and that he had agreed a method of payment with Shropshire. South Western Magistrates refused to have anything other than the immediate payment and this meant that Larkhall had to find £44,600 within the hour. This was done but certainly makes an appalling conclusion to this case. Of course, Larkhall are now contesting this through legal channels.
- 14 Finally – Perhaps this Shropshire Trading Standards Case was a moral win for Larkhall but it was truly a Pyrrhic Victory.

Important quotes from the Shropshire Trading Standards Officers either in correspondence, lectures or interviews.

**Mr S.
Henshall
14/11/90** "On the basis of the recent Nadir Polly Peck decision, the investigating body is not required to present either the case or the reasons for investigation to any person or company under investigation".

**Mr S.
Henshall
23/11/90** "All citizens have a duty to help investigating bodies and their authorised officers to prevent crime and discover offenders. It is a civic rather than a legal duty".

**Mr. D.
Walker
21/1/91** "Clearly, the issue before the court will be whether the claims attributed to this product by your client can be justified.

Whilst the evidence available to the authority at present in our view goes against your clients, we would of course reconsider our position if other evidence casts sufficient doubt on the prosecutions ability to prove this case".

**Mr. D.
Walker
3/5/91** "I would advise you that the authority is not at this time seeking to put forward an alternative case against your clients. Your clients are alleged to have made a false statement about the claimed link between supplementation using their product and increased I.Q. That claimed link is not only open to challenge on the basis of the scientific data itself, but also on the merits of their specific claims, even if the scientific evidence could not be challenged".

Health Foods

**D. C. E.
Roberts
July 1991
Seminar
on Health
Foods**

"Claims for health foods – the phrase is probably a false trade description – have increased enormously in the past year or so and the recent MAFF/DH Working Group's paper has to be set aside the claims of the Health Food Manufacturers & PAGB for recognition of health claims rather than their proscription as the law – and EC – lays down. Already several cases have been taken and more are in the pipe-line. There have been cases also on allegedly false advertising etc., of vitamin pills and their effects on children. Watch this space".

**Mr S.
Henshall
2/8/91**

"If this request is not complied with by the 14th day following the date of this letter, then I will be recommending that a further charge of obstruction is put before the courts".

**Mr S.
Henshall
7/8/91**

"May I remind you that your client has until the 16th August 1991 to comply with my request before my recommendation that a further charge of obstruction be put before the courts".

**Mr D.
Walker
19/3/92
At a Private
Meeting
asking for a
Pre-Trial
Review.**

"We are in the fortunate position of being able to agree with the defence experts. That is to say there is a body of opinion both for and against the idea that vitamins will help raise I.Q., but none of this expert evidence is relevant to whether there has been a breach of Trading Standards Regulations".

At the Same Meeting, Mr. Walker was asked why he was not working with the Home Authority which was the usual expected practice. He said. "I couldn't possibly delegate such a serious matter".

List of References

1. Benton D, Roberts G. Effect of vitamin and mineral supplementation on intelligence of a sample of schoolchildren. *Lancet* 1988; 1: 140-143 (the original Benton Study reported on QED January 1988).
2. Schoenthaler S, Amos S, Deraz W, Kelly M, Wakefield, J. A controlled trial of vitamin-mineral supplementation on intelligence and brain function. *Personal Indiv Diff* 1991; 12: 343-50 (Schoenthaler trial reported in the QED programme 1988).
3. Nelson M, Naismith D, Burley V, Catenby S, Geddes N. Nutrient intakes, vitamin-mineral supplementation, and intelligence in British schoolchildren. *British Journal of Nutrition* 1990; 64: 13-22 (This study did not truly replicate (1). It covered just one month and used a different tablet. At the hearing in Shropshire, the results were heavily criticised).
4. Crombie S, Todman J, McNeil G, Florey C, Menzies, I, Kennedy R. Effect of vitamin and mineral supplementation on verbal and non verbal reasoning of schoolchildren. *Lancet* 1990; 335: 744-747 (This paper did not confirm the connection between vitamins and non verbal IQ but showed a trend in the positive direction. At the hearing in Shropshire, it was admitted that if it had been subjected to a different and perhaps more appropriate statistical test, the conclusions would have almost agreed with those in (1).
5. Benton D, Butts J. Vitamin-mineral supplementation and intelligence. *Lancet* 1990; 335: 1158-1160.
6. Benton D and Cook R. Vitamin and mineral supplements improve the intelligence scores and concentration of six year old children. *Person Indiv Diff* 1991; 12: 1151-1158.
7. Schoenthaler S, Amos S, Eysenck H, Peritz E, Yudkin J. Controlled trial of vitamin-mineral supplementation: effects on intelligence and performance. *Personal Indiv Diff* 1991; 12: 351-62. (There are other papers due for publication based on the results of this study. This study was the main subject of the second QED programme 1991).