

Vitamin seller made a criminal

After three years of apparent persecution by the UK medicines regulator, a Swansea man, Jim Wright, was yesterday criminalised by the Swansea Crown Court for selling vitamins and herbs.

Jim Wright had operated a small business selling natural health products for some years before being raided for the first time in May 2003, then again two years later, by the Medicines & Healthcare products Regulatory Authority (MHRA). During these unannounced dawn raids, his stock was taken, thus preventing him from running his business. The vast majority of his stock comprised common garden herbal products the like of which can legally be bought from high street health food stores across the UK.

Emerging from the Court room, Wright said, 'I think given the wealth of false evidence that was presented in Court, the whole thing's been a total farce. Yet in the process they've managed to make me a criminal. The Judge gave me a £1000 fine, £1000 that I haven't got, and 120 hours of unpaid community service. I was accused of selling products that I wasn't selling and we even showed the Court that the supplier of vitamin B-17, as found in apricot kernels, was itself shut down by the US Food & Drug Administration on 30th September 2003. They found nothing in two raids on my house. I was set up.'

Wright, like others who had been selling vitamin B-17 up until it was made illegal in 2002, was made aware of the change in government policy and withdrew the product from sale. He had always made a point of complying with any advice or requests by the UK medicines enforcement agency.

In 2003, the MHRA worked with BBC Wales to entrap Wright. A women and her partner who, he was told, had a myeloma in the leg that had been operated on and that had subsequently spread, approached Jim Wright with a view to buying products that would help the cancer patient. The couple forced Wright to meet them in a car park on two separate occasions to deliver a range of natural health products. Wright thought this a most strange request, yet the customers were adamant this is how they wanted their products delivered. They filmed him covertly the first time, but on the second occasion, the cameras were revealed as he passed over the products. He was devastated to find the customers were really a BBC reporter and her perfectly healthy colleague.

Shortly after this, Wright saw himself on the BBC, being made out to be a criminal, despite the fact the products he was selling were 100% legal. About one week later, the MHRA raided him, confiscating all of his stock, and so handicapping his small business operation.

No legal proceedings followed, but Mr Wright's stock was also not returned even after three requests. The enforcers went peculiarly quiet on Mr Wright.

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Two years later, Wright received an order for vitamin B-17. Unknown to him, the order was from an MHRA enforcer who, posing as a member of the public, presented a heartwrenching story about her husband dying of prostate cancer. The lady was very specific about her desire for vitamin B-17, that Wright was well aware had been banned some years earlier. Wright made it clear that he could no longer sell B-17 and had none in stock. After continuous pressure, however, Wright succumbed to providing a single pot that he still had in his home office that had been returned to him by a customer and that he hadn't yet posted back to the original supplier in Mexico. He was given a mailing address that happened to be the accommodation address for the MHRA. On receipt of the product, a warrant was obtained the same day from Bow Street Magistrates and Wright was raided for a second time, in May 2005.

Speaking about this second raid, Jim Wright said, 'They were hoping to find a big stash of vitamin B-17 - that was what they said they were after when they barged into my home. They of course found nothing. So they again took all my stock, all my accounts, a folder with all of my correspondence with the MHRA and another with thank-you letters and customer contact details. It was frightening - and deeply disturbing.'

Dr Robert Verkerk, executive director of the Alliance for Natural Health responded today to Wright's sentencing, 'The Swansea Crown Court Judge took the opportunity to condemn the natural products industry. He said the manufacturers of these supplements are exploiting people's misery and making lots of money out of them. Jim Wright, he said, was a victim, and clearly hadn't made a lot of money himself.'

Reflecting on the sentencing, Verkerk added, 'To prey on someone's intent to help others - to set them up like this - is astonishing and deeply unethical. Jim Wright and his family have been through hell and back - his business has been irreparably damaged, yet no illegal products were found in either raid. The lack of reasons given during and after the raids, and the confiscation of legal stock that included extra virgin olive oil, beggars belief. We are heartened to hear that Jim Wright and his legal counsel have every intention of mounting an Appeal.'

It is expected that Jim Wright's Appeal against his prosecution will be launched within 9 months.

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EDITOR'S NOTES

Background and detail on the Jim Wright case

Wright first got involved with the MHRA when he was caught up in the relentless battle carried on by the US Food & Drug Administration (FDA) against laetrile, also known as vitamin B-17. He began selling apricot kernels around 1998, at a time when it was legal to do so in the UK. When the law changed around 2002, making laetrile a prescription only drug, Wright was asked under compliance procedures to stop its promotion and sale on his web site. Although he complied with this and a number of other requests from the MHRA, it did not stop the agency working with BBC Wales in 2003 to entrap Wright into selling products to a reporter and her colleague, who posed as a cancer patient

This sale, however, did not involve any products which were prescription only, or shown on the MHRA site as being restricted, or that had been the subject of any compliance procedures, nor did Wright make any claims for these products. Despite this, Wright's home in Port Talbot, South Wales, was raided by the MHRA working with the local Trading Standards Office. In the raid, MHRA investigators seized his computer and the whole of his stock, worth over £3,000. The seizure included sugar substitutes and herbal tea bags, the raiders found no laetrile or Vitamin B-17, despite this having been the cause of the raid.

A few weeks after the raid, Wright was called to a meeting with investigators. At the meeting, under caution, he agreed to a number of compliance issues. No further legal proceedings followed this meeting nor was there any mention of returning his stock. He continued with his business, incorporating a number of products from the Alpha Omega Labs in North America, where Greg Caton had developed a range of complementary health products based on herbal remedies used by Native American Indians and Indians of Latin America.

In May 2005, although he had stopped selling it or advertising it on his web site, Wright received an order for B-17. The customer, who it later transpired was an employee of the MHRA Borderline products unit, calling herself Rose Davies, told Wright a pack of lies about her dying husband's prostrate cancer. Although no longer selling B-17, Wright still acted as an agent for the suppliers of the product in America and he did happen to have one pot of tablets which had been returned to him a couple of weeks prior to the phone call. Wanting to save the customer the time of waiting for delivery, Wright send this off to the accommodation address operated by the MHRA.

In August 2005, Wright and his family were subject to a second early morning raid by MHRA investigators again looking for Vitamin B-17. The men who searched the house were even less accommodating than previously. As well as again taking away his whole stock and his accounts, they seized thank-you letters from customers and his critical correspondence with the MHRA.

A few months after the raid, Wright received an e-mail from an employee in the MHRA Medical Devices department. The letter was polite and to the point; they had noticed that Wright was now selling Dr Hulda Clark's 'Zapper', and they wanted to discuss this with him with a view to him complying with their ruling that this was not a legal medical device. Wright, as had always been his policy, immediately agreed to remove the advert from his web site and stop selling the product. The MHRA wrote back to him thanking him for his compliance.

Again for some perverse reason, Wright heard nothing from the MHRA about the raid, which had found no B-17. He began to form the view that both the raids and the television 'exposé', were forms of government backed harassment. On this basis, he

approached a solicitor to challenge the MHRA for the return of his stock and gain assurances about the legal grounding of the raids.

Wright's solicitor received no answer to his enquiries of the MHRA, but in March 2006, he received an informal phone call from an MHRA investigator telling him that Wright would soon be prosecuted. Both Jim Wright and the solicitor came to the logical conclusion that by challenging the MHRA they had stirred the agency into moving against him.

Between June 2006 and October 2006, Wright was charged on 12 counts of having in his possession medical products which he intended to sell. At the start of his trial at Swansea Crown Court in November, he pleaded guilty to having sent the laetrile (or B17) to the MHRA accommodation address. He had done this, he told his family and friends, because his conscience would not let him lie about it, and he did not want to get off on a technicality. Ten of the remaining 11 counts on the indictment all involved herbal preparations that had been found on his premises in the 2005 raid, none of which appeared on any lists as prescribed products. The final Count 12 was in relation to a claim that Wright was said to have issued on a web site based in Uruguay. Wright had not been contacted by the MHRA under their compliance procedure about any of the products included in the indictment.

The prosecution case rested on the assertions that Wright had in his possession medical products - that is, products which made 'medical' claims in their presentation or on any web site promotion linked to them, that they were a part of his business, and that he intended to sell them. The products were, in order of Counts 2 to 10: Quick Heal Green, Omega UR Tonic, AL Heart Drops, Exeema, Temporal Tension, Mico +, Onconat Gell, Para-spezial, Agaricus Mushrooms and Supergreen.

The defence made three applications prior to the trial; the first looked at the ordeal that Wright had been subjected to over a period of three years. It referred especially to the lack of proper legal procedure following the first raid; this, the defence argued could be seen as abuse of process.

The second application involved the reams of web page evidence, the prosecution brought to support links between products and claims they said had been specifically issued by Wright. The defence argued that web page print-outs could not be considered *real* or *original* evidence because they were unsupported by witnesses and sworn statements; in effect they were hearsay. The defence also argued that anyone could put up a claim on a web page and that its validity could become obscured by time and distance - to present it as evidence solely and recently attributable to the defendant was wrong. Particularly the defence claimed that an archived web page might reflect a historical situation which had now been changed and therefore would be unsafe as evidence. The judge denied both these applications.

The last application made before the trial was made on the day that the trial opened. This final application went to the very core of the defence case. The defence argued that the specific provision of section 3ª, incorporated in 2002 into the 1994 legislation describing the work of the MCA, clearly stated that before any prosecutions took place the agency should enter into compliance negotiations. The clause stated plainly that the Agency could proceed to prosecution only after pursuing compliance procedure.

This enabling clause had been included in the statute for a number of reasons but most particularly because the large number of non pharmaceutical products coming on to the market meant that it was now not always possible to determine prior to marketing whether a specific product was 'medical'. Customers, patients, community groups, health food shops, trade associations, and producers of supplements and supplementary treatments, had campaigned strongly throughout the 1990s to ensure that the MCA, as it

was then, did not gain powers to raid, arrest or randomly charge people without first issuing a warning about specific products.

The judge ruled against this application, maintaining that the jury could make the decision about what was a medicine, and there was nothing wrong with taking individuals directly to prosecution and trial. In one of his arguments against the application the judge suggested that it would be very hard for the MHRA to keep up with a quack salesman who quickly and frequency changed the name of his quack remedy. Nothing would budge the judge from the argument that what was a medical product could be decided on the basis of claims made by the seller and in turn this designation could be agreed by the jury. In his opinion 12 lay people from the Swansea area and the seller of the product were able to determine a question which remains a bone of contention between, global regulatory agencies, consumers and practitioners.

The judge, rejected the application, and maintained his position throughout the trial. To the evident glee of the prosecuting counsel, all mention of the MHRA statutory compliance procedure was disallowed. This ruling was so dutifully enforced that the prosecuting counsel took the opportunity, when it was raised, to interrupt the defence counsel's closing speech. When the defence counsel mentioned to the jury that the MHRA did have an alternative way of proceeding - to discuss compliance procedures in the case of each product that they had obtained during the raid - the prosecuting counsel had the jury go out and addressed the judge. The judge's initial decision on the compliance procedure severely hampered Wright's defence, which was in part that he would have expected to be involved in compliance discussions with the MCA or the MHRA over the specific products named in the charges.

The defence argued that all the products, which were found in small quantities, whether considered medical products by the jury or not, had anyway not been for sale. They had either been for Wright's own use, or received as samples or products which he had decided to stop selling. His defence was strengthened by the fact that the AO lab which had produced 5 of the preparations had been shut down after a raid by the FDA in September 2003, this being the last time Wright could have obtained the products found on his premises.

The jury evidently took to heart their duty to decide what was and what was not a medicine and agreed that Wright *did* intend to sell some of the products found on his premises. They returned a guilty verdict on 4 of the counts, which, including Wright's own plea of Guilty, made 5 guilty verdicts. On the other 7 counts, they failed to agree a majority verdict or brought in a verdict of Not Guilty or on one count were instructed by the judge to bring in a Not Guilty verdict.

At the conclusion of the case, Jim Wright said, 'The case has been a terrible strain, particularly on my family. There were a number of issues which the trial did not explore, particularly the fact that MHRA is heavily funded by the pharmaceutical companies, and therefore, in effect, so are its investigators and employees. Dragging out actions against me over a three-year period and failing to use the compliance procedure, was tantamount to intimidation. The trial achieved nothing except to prevent me following my lawful business. It failed to clarify the situation with respect to the products in question and it entailed the seizure of all my stock on two occasions, and the MHRA is still in possession of all my accounts and letters from customers which were never alluded to during the case. But perhaps most important, the trial drives a coach and horses through clause 3a of the regulations that are meant to guide the MHRA and presumably means they are now illegally able to ditch compliance procedures whenever they want'.

Wright's counsel is presently preparing an Appeal.

Alliance for Natural Health

The Alliance for Natural Health (ANH) is a UK-based, EU-focused, international, legal-scientific, non-governmental organisation that is working on behalf of consumers, medical doctors, complementary health practitioners and food manufacturers and distributors, to protect and promote natural healthcare, using the principles of good science and good law.

The ANH's principal objective is to help develop an appropriate legal and scientific framework and environment for the development of sustainable approaches to healthcare. Within this setting, consumers and health professionals should be able to make informed choices about a wide range of health options, and in particular those that relate to diet, lifestyle and non-drug-based or natural therapies, so that they may experience their benefits to the full while not exposing themselves to unnecessary risks.

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