A QUESTION OF

Mike Murphy asks who can we trust when it comes to business?

Good business is based on trust. We must trust the manufacturers, engineers, salesmen, distributors, trainers and all the other people involved in the production and sale of high-tech equipment. Our clients trust our judgement when buying such equipment for their treatments. Without this trust our lasers and IPL systems are just expensive wastes of money.

So what happens when this chain of trust is broken? Recently I became aware of a situation in America which concerned me greatly (published on theFairWarningwebsite).AnAmericancompanyhad been selling an expensive radio-frequency device for 'melting fat' called the 'Lipotron'. They had sold a goodnumberofthesedevices,atupto$85,000each, based on their claimed FDA clearance.

The device was described as "truly the only non-invasive way to reduce fat" and was sold all over the US. However, it turns out that the FDA had not cleared that device for that application! The company had submitted it for market clearance (the 510(k) procedure – see "CE no evil" - *Cosmetic News*, December 2011) but it was rejected due to lack of data, despite repeated requests from the FDA. Consequently the company re-submitted the device as a 'massager used for the relief of minor pain'. Since this was described as a Class 1 device by the company there is no requirement for 'clearance' by the FDA and therefore the company was allowed to market and sell the device freely.

When the FDA were informed by a whistleblower they began an investigation. At the time of writing they have not stopped the free sale of this device, even though it contravenes US law. An FDA spokeswoman said that if a device is not legally on the market, "a physician should not have been able to obtain it, much less use it on a patient." This leaves a lot of users in a precarious position. They had been duped into buying the system and had delivered the treatment to their clients, and many had even marketed the treatment as being 'FDA cleared'. Consequently, there is a lot of concern among clinics at this time. You might assume that this could not happen here. You would be wrong! This is not a new phenomenon – for years companies have been claiming FDA clearance for one treatment but then selling that equipment for other treatments, which had not been cleared. Some have been stopped from selling, but only in the USA.

The FDA has no jurisdiction outside of the US – just because they stop a company selling in the US doesn't mean they need to stop selling elsewhere. I remember a US company, Thermolase Corp, who were one of the first US companies to receive FDA clearance in 1995 for laser-based hair removal. After many complaints and a class-action lawsuit (in 1998) they were instructed to stop marketing their Nd:YAG laser for hair removal due to the company's false claims of "permanent, painless hair removal". They complied with this order in their home market otherwise they would have been breaking US law. But they continued selling the same equipment for the same application outside the US including Europe and Asia. While this was not illegal it was completely unethical and they were obviously lying to their overseas customers.

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Fortunately, by 2000 they had effectively come out of the market. When we submitted our Q-switched ruby laser for tattoo removal back in 1991 we had to undergo 18 months clinical trails in the US with a well-known US laser dermatologist. Backed with data from our own 10-year clinical experience in Scotland we finally achieved FDA clearance to market. But then, we were a British company and we had no choice but to comply with American law!

I recall having lunch with a well-known beauty equipment supplier some years ago. I was asked for my opinion on a new hair removal device, which he wanted to launch. It was immediately obvious to me that the device was completely inappropriate for the task (due to insufficient power). His reply was that the manufacturer was a massive blue chip company with impeccable credentials. While this was undoubtedly true the device was still the wrong choice for hair removal. Unfortunately my opinion was ignored and the device was launched shortly afterwards. It was recalled after a short time due to an increasing number of angry buyers. The company's reputation was severely damaged as a consequence! I remember thinking, at the time, that he was clearly abusing the trust of his many loyal customers.

Conclusion – be aware when buying your next piece of equipment. Ask yourself if you truly trust the salesman, the supplier, the manufacturer and your judgement. I always recommend potential buyers to ask other users for their opinions on the equipment, the results and the supplier/manufacturer. Other users are your allies – they will, invariably, be more honest than any salesman!

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