

Alternative Medicine Fiasco



By [Jonas Paulauskas](#) , freelance writer: August 12, 2013: 8:00 AM ET

Two years ago in 2011 I wrote a story exposing FDA recalls. Then I stumbled on an incredible story of almost 2000 people resisting a recall. Since I have a background from the recall investigation I wrote two years ago "Recall Exposed" (published in Medical Expose') it was apropos for me to dig into this story. This is the bizarre story of Quantum World Vision and the Indigo.

To get this story I interviewed FDA officials, local law officers, the software developer, Microsoft Windows and several users. The story is so bizarre we wanted to check all facts many times. We verified the Indigo was a class 2 medical device registered as biofeedback manufactured by Quantum World Vision. It seems that someone in their zeal forgot to check the biofeedback activities prior to 2012. This was the responsibility of the QWV of Mesquite Nevada, with Ken Wilkerson listed as the contact person on the FDA establishment page.

The software developer inadvertently discovered the biofeedback functions were deficient in June 2012. They immediately alerted QWV and the key business agent resigned just days later. The remaining staff was notified of the problem. The software developer was given the firmware; then they made changes to the software to solve the problem. The software developer said this was the 12-12-12 version with the BIG that would make the Indigo compliant with FDA requirements. The software developer issued an internal mandatory recall of software to remedy the problem. We verified and attested the developers comments were true.

But for some bizarre reason QWV did not mandate the software update. Instead they assisted the users to falsify medical records and backdate their computers to avoid the mandated software. Microsoft said that backdating the computers will compromise many functions and it is definitely not allowed. The software developer said there were many Indigo functions not operating properly when the system is backdated. Backdating compromised many functions and was a crime of falsification of medical records. There were approximately 2000 Indigo units sold and 95% of these Indigos still do not have legal compliant systems. Bizarre!!!

We interviewed FDA regulatory officials. They said that there is definitely an investigation into QWV. Their inability to mandate repair actions is a very serious breach of the law. The officer said that all fraudulent biofeedback systems must be confiscated. They have reviewed the QWV situation and all with working biofeedback will be safe, but those with nonfunctioning biofeedback system will face punitive consequences. QWV's role in interference with compliance will have to be dealt with. QWV officers who did not mandate the remedy will face disciplinary action.

Local law officers (Police in Los Angeles) said that if they heard of a person using a fraudulent biofeedback system and or falsifying medical records knowingly, they would be arrested and face multiple criminal charges.

But it is a simple online procedure to repair the system and upgrade to the compliant software. Why would QWV not mandate this simple correction process? Why would the users not do this? I invited all of them to discuss the situation. None of the QWV officers would agree to be interviewed. But a few of the owners of the Indigo did. They were very angry and they felt completely misinformed by QWV staff. They were fuming mad at everyone even me. But as it came down it, their anger was all about a few hundred euros. The resistive issue was just money. It would seem that someone buying a 15,000 euro system they could afford a few hundred to save their original investment from confiscation, and prevent them from being embarrassed or worse criminal charges, but sanity and logic seemed to take a small part in this.

Rationalization, misinformation from QWV leadership, simple penny pinching greed, has come together to place a black mark onto the alternative medical market scene. What a Fiasco.