

Mandated Upgrade the law

FOR THOSE WHO WANT THE FDA LAW HERE IT IS

1. CES compliance in USA:

in the April 9, 2009 **Federal Register (74 FR 16214)**, FDA required all manufacturers of CES devices submit

information, consisting of all known research and safety data for their devices. QX Ltd complied.

Yet on **August 8, 2011, (76 FR 152)** FDA published its proposed rule related to CES and actually recommended that all CES devices go through the PMA

application process. **Federal Register (76 FR 152) FDA rule makes CES class 111 restricted to neurological med Dr only**

On February 10, 2012, the FDA convened an advisory panel hearing on whether to reclassify cranial electrotherapy stimulation (CES) devices. Despite being a low-risk device, CES stays in Class 3 in America

this change in the law required us to make a mandatory update - hence the 12-12-12 and the BIG

2, New HIPAA compliance Emphasis

On **July 9, 2012** President Obama signed into law the **Food and Drug Administration Safety and Innovation Act (FDASIA)**. The law provides for a host of changes to the existing FDA regulatory framework, including much-debated provisions relating to user fees, **Health data safety**, altered regulatory processes, and some incentive programs.

Section 618 of FDASIA provides that the FDA, within 18 months, must produce (and make publicly available) "a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication." The law requires that the FDA develop this report in consultation with the Office of the National Coordinator for Health Information Technology (the "ONC," which is also tasked with setting technical standards for the EHR Incentive program) and the Federal Communications Commission (FCC). The report will be published jointly on all three agencies' web pages.

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3, Biofeedback Display Concerns

21 CFR 50.54,

Software Validation, General Principles of, Guidance for Industry and FDA Staff

The primary purpose of this guidance is to outline general validation principles that the FDA considers applicable to the validation of medical device software or the validation of software used to design, develop, or manufacture medical devices.

May 16, 2012= The **Federal Trade Commission** and states across the country will now fight harder to detect and expose what it believed to be unfounded claims by any company.

"It is unlawful for any business to make unsupported, over-hyped advertising claims to sell its products," **Federal Trade Commission** said in a public statement. "With today's action, our **Federal Trade Commission** office continues its vigilance in protecting consumers against companies that attempt to trick or defraud the public."

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4, Indigo Biofeedback Function

[21 CFR 50.54,](#)

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This letter from the Federal Trade Commission can directly be applied to the Indigo QWV used deceptive advertising to sell a fraudulent biofeedback system that did not do biofeedback <http://www.ftc.gov/bcp/policystmt/ad-decept.htm>

The Federal Trade Commission also considers claims or omissions material if they significantly involve health, safety, or other areas with which the reasonable consumer would be concerned. Depending on the facts, information pertaining to the central characteristics of the product or service will be presumed material. Information has been found material where it concerns the

purpose,⁵² safety,⁵³ efficacy,⁵⁴ or cost,⁵⁵ of the product or service. Information is also likely to be material if it concerns durability, performance, warranties or quality. Information pertaining to a finding by another agency regarding the product may also be material.⁵⁶

June 2012, Indigo system tests in Budapest reveal the Indigo does not do biofeedback to the level of compliance. When we at QX ltd found the Old indigo system to not measure or perform biofeedback we alerted the QWV executives to the alert of fraudulent dysfunctional indigos using the old software. QX ltd then made a new compliance software the 12-12-12 and the BIG make any indigo compliant with the law.

This law required us to make a mandatory update for Indigos - hence the 12-12-12 and the BIG

these Four laws required us to make a mandatory update -

hence the 12-12-12 and the BIG are mandatory for legal sale and for legal use

This UPGRADE is MANDATORY, MUST DO, COMPULSORY, OBLIGATORY, IT IS REQUIRED FOR ALL

Some people wrote to Bill Cunningham saying he was extorting

Extortion is a [criminal offense](#) of unlawfully OBTAINING MONEY, property, or services from a person, entity, or institution, through [coercion](#).

But if Bill C is not asking for or in any way obtaining money, How could it be extortion???

Answer: it is not extortion, Bill is providing a service of knowledge, nobody is coercing anyone.

Bill is being a good neighbor warning there is a storm brewing. Bill is trying to help people. Bill is not coercing anybody. Bill will not hurt anyone in any way; Bill C is trying to help people who might not know what the truth is. (People who have been lied to by QWV.)

Stupid people think the weather man causes the weather when he predicts it

The weather man like Bill are just pointing out there is a storm coming

Smart people get ready for the storm and upgrade

Stupid people blame the weather man, make excuses to not upgrade and they will watch the storm blow down their house



Why do some of you have no respect for the Law? The CFR or FR mean Code of Federal Regulations, this means the law. When a law becomes published in the FR or CFR we are required to obey it. Federal Register (74 FR 16214), (76 FR 152) FDA, Food and Drug Administration Safety and Innovation Act (FDASIA section 618), 21 CFR 50.54, , <http://www.ftc.gov/bcp/policystmt/ad-decept.htm> These are laws; We must respect and obey the law.

When they change the speed limit with a new law they do not send out everyone a memo. When the FDA states a new law they do not send us out a memo, nor do they instruct us daily on how to do business or how to wash our windows. We do not wait for the FDA to tell us what to do; we are required to operate our business to the law and to comply with changing law. They do not send us out a memo on laws, they publish them in the CFR.

When the law changes, we must comply to the law. Why are stupid idiots not able to understand this simple issue? Why do some of you people have no respect for the law? Why are there over 1900 people knowingly using dysfunctional fraudulent software compromising their patient results, and their computer? Just how stupid can some of you people be??