Public Comment – PACCARB

As a recipient of Bone Morphogenic Protein in my neck, I feel the FDA's embracing an of effort to increase the speed of approval for device/drug hybrids raises significant safety concerns.

In addition, AHRQ's presentation on chlorhexidine is of concern, especially considering the integrity issues which have been raised regarding the REDUCE MRSA study. This was also a subject of a recent Reuter's investigative report by Deborah Nelson, which centered on conflicts-of-interest and on the FDA warnings regarding this type of Chlorhexidine use.

On the Health Watch USA's website (<u>www.healthwatchusa.org</u>), there is a YouTube presentation from Matthias Maiwald, MD, who raises serious questions regarding integrity problems in the Meta-analysis which was used by the World Health Organization for their recent recommendations regarding surgical antisepsis using chlorhexidine.

And there was the NQF/Chlorhexidine/Charles Denham debacle regarding chlorhexidine in patient safety recommendations.

All of this appears to be forming a pattern. which I feel needs careful evaluation and is also of significant concern.

Finally, it would be very interesting to have a world map which designates the countries having over-the-counter antibiotic sales. What percentage of the world population can obtain antibiotics without a prescription?

Thank you,

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