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The impact of faulty hip replacements and breast implants on recent medical device regulation in Europe and the United States

Steve Jwanouskos

OptiMedica, USA

Abstract

An enormous change is underway in the scope and rigor that will be applied to medical device regulation in Europe and the United States. The two direct causes are the adverse reactions reported for metal debris in patients treated with metal-on-metal (MoM) hip replacements. The second was the exposé of fraud associated with the Poly Implant Prosthese (PIP) breast implants, which affected perhaps as many as 400,000 patients in the United Kingdom and Latin America. As a direct result, the European Commission has implemented new rules under Council Directive 90/385/EEC (for active implantables) and Council Directive 93/42/EEC (for medical devices). In the U.S., the FDA Safety and Innovation Act will prove to be the most rigorous course of regulation brought to bear upon an industry since the U.S. Congress passed the Pure Food and Drug Law in 1906.

Biography

Steve Jwanouskos has over 25 years of medical device industry experience, all involving novel medical technologies that have transformed medicine. Special areas of focus have been new devices for cardiovascular, ophthalmology, radiation oncology, immunology, and orthopedics. Devises have included intravascular ultrasound, laser and radio-frequency ablation, software-controlled electronic systems, permanent implants, combination products, and wireless diagnostic telemetry. Network includes professional contacts in Japan, Taiwan, Canada, U.K., Germany, Hungary, Poland, Benelux, and Australia. Educated at the University of Minnesota (Bachelor of Science, Rhetoric: Scientific and Technical Writing and Editing).