

# **FDA Taken to Task by Prominent Oral Surgeon**

The Associated Press

"FDA, You Were WRONG!" is an eye-opening account of how the FDA agency of the federal government, which is supposedly there to help protect the public, has actually been doing more harm than good in recent years; this is the story of Dr. Bob Christensen and his small medical device company, TMJ Implants, Inc., and how they confronted and overcame the corruption, abuses of power, conflicts of interest, and ignorance within the FDA in this tragic yet ultimately purposeful story. While similar to the Erin Brockovich case, Dr. Christensen's "David vs. Goliath" experience offers lessons for any small business entrepreneur needing an FDA approval as well as holding the FDA accountable for uniform approval processes.

Dr. Christensen's company, TMJ Implants, Inc., originally held the earliest U.S. patent, in 1960, for the reconstruction of the degenerated or missing temporomandibular joints, and the product sold extremely well and helped thousands of patients, including hundreds at the Mayo Clinic. After nearly 40 years of success with TMJ patients, the FDA implemented the Medical Device Amendment in 1999 for TMJ devices -- and curtailed Dr. Christensen's sales; as a pre-1976 Medical Device Amendment item, the device should have been grandfathered under earlier law. There had been no adverse patient reactions to the implants.

According to Dr. Bob Christensen, "At this time, the FDA disapproved of the Premarket Approval (PMA). I had been warned by Dr. Susan Runner, Director of the Dental Division of the FDA's Center for Devices and Radiological Health (CDRH), not to attend the upcoming panel hearing as I would surely be turned down; however, I boldly brought my staff of scientific experts with me and received a 9-0 approval from the initial FDA panel. Dr. Runner, however, saw to it that a second panel was convened, a panel that disapproved my device by a 8-0 vote. As a result of the second panel, the devices were removed from the market for a period of some 20 months, which cost the company millions of dollars in lost revenue and a staff reduction from 38 to 15 individuals." Throughout the process, there was evidence of conflicts of interest and bias that Dr. Christensen and his company had to endure. Several allegations have recently come to light that detail the connection between Dr. Runner and TMJ Concepts, a competitor of TMJ Implants, said Dr. Christensen.

Download "FDA, You Were WRONG!" at <http://www.Amazon.com>, where you can purchase the Kindle version today. Dr. Christensen is a retired oral and maxillofacial surgeon who pioneered the design and implantation procedures for temporomandibular devices in 1960 which were used to correct the internal derangement disorder caused by this degenerative joint disease -- of which 90% occurs in younger women.

CONTACT: Dr. Bob Christensen Phone: 303-549-6674

<http://www.DrBobChristensen.com> Email: [tmjsurgeon@gmail.com](mailto:tmjsurgeon@gmail.com) This press release was issued through eReleases(R). For more information, visit eReleases Press

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