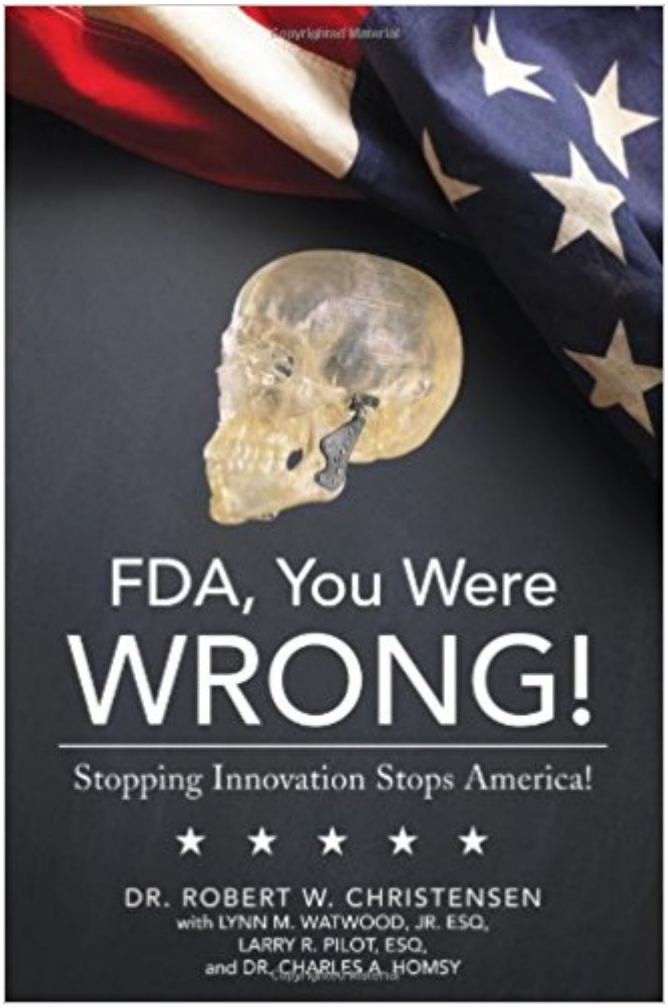
FDA, You Were Wrong!: Stopping Innovation, Stops America!



Synopsis

FDA, You Were Wrong is an in-depth expose of the atrocities Dr. Robert Christensen and colleagues suffered in their attempt to help patients suffering from TMJ (temporomandibular joint) issues. Follow along with their struggle against the FDA as Dr. Christensen shows how the FDA set up obstacles at every turn on the road to providing TMJ implants for the patients who desperately needed them.

Book Information

Paperback: 371 pages

Publisher: Tate Publishing & Enterprises (October 30, 2012)

Language: English

ISBN-10: 1621472582

ISBN-13: 978-1621472582

Product Dimensions: 8.7 x 5.8 x 0.9 inches

Shipping Weight: 1.2 pounds

Average Customer Review: 4.0 out of 5 stars 9 customer reviews

Best Sellers Rank: #2,820,971 in Books (See Top 100 in Books) #64 inÃ Â Books > Medical Books > Medicine > Surgery > Transplants #83 inÃ Â Books > Health, Fitness & Dieting > Diseases & Physical Ailments > Organ Transplants

Customer Reviews

I understand the issues faced by this company, but I do not understand why Homsy is a co-author. Isn’t this the man who destroyed thousands of lives with his Proplast-teflon TMJ implants? I have no sympathy for anything that happens to Homsy, and cannot muster any sympathy if Homsy was involved with Christensen either. If Homsy was not involved with Christensen, then the patients are still the real victims because we NEED a good implant. Homsy blames everyone, but himself for his failed device...the FDA, the doctors, even the patients. Christensen appears to be an honorable man. So why is Homsy part of this book?

I recommend!!Critical to understand what went wrong - and is extremely important to anyone that wants to innovate. If you design or develop - you need this story!!.

I would recommend this book to anyone. It is very good. I am currently reading it, and I have to say everything in the book is true. I had this implant.

Well written, informative and concise. A rather dry subject but assembled in a coherent fashion. Nice job Dr. Christensen.

This makes me very sad! I was a recipient of Mr. Homsy's implant. Dr.s were reporting issues with this implant within a few years.The patients however did not receive any information. After this implant was inside my body, it fragmented. After 8 yrs and a recall letter from the FDA, the implant was removed...or shall I say part of it was. It had broken up and only minute pieces could be removed. Because of this I have developed multiple auto immune diseases. My body continues to try to destroy these pieces but can't so instead they attack my own body.I am in constant pain and, not just my jaw/head area but my entire body because of these auto immune diseases.You can write a book and say what you wish, I understand we NEED medical implants but I cannot believe when this failure occured...I kid you not...when the realization of this implant was known, instead of trying to work on what went wrong,..he(Homsy) immediately blamed the patients! The implant was put inside our bodies...yet it was our fault because they failed! This is nothing short of insanity! As I mentioned before,I am aware we need medical devices. But if Dr.Charles Homsy is "tied" to an implant that would litterally save my life...with the constant pain I'm in now...I would choose death first!! It is my opinion that the FDA was NOT Wrong by recalling the implant,but they also shared some of the fault by allowing the Homsy devices to be grandfathered without proper testing on load-bearing joints. It was when the FDA "Manned Up and Grew a Pair" that Homsy was shut down and prevented from destroying future lives. I would NOT reccomend this book.

This was a book worthy of the spin by Fox "News". A simple search will show the court documentation and the FACTS behind this case.Dr. Christensen went after the FDA by defying them at every turn - it was his crusade, not the other way around as he claims.Claiming he cannot comply with the law and file the necessary adverse event reports because it might affect his competitive position was an exercise in twisted logic. And to top it off, he offers to file the necessary MDR reports if the Courts suspended the fines imposed on him!The fact that Homsy is another author on this book adds to its complete lack of integrity.FDA has to ensure that the likes of Homsy and Christensen don't market any medical devices. These two men seem to be a text book case of narcissistic grandeur!

Dr Christensen is my hero- after 16 surgeries and devices by other doctors- I finally connected with

him and have had the most relief from his device than any other. So sad that the FDA dragged this compassionate, caring, American Veteran, through so much . Dr C- you have changed my life- what a blessing you are!

Dr. Christensen has presented a horrendous report on FDA misapplication of its regulatory authority and worse. The public needs to heed his clarion call for corrective pressure by Congressional oversight on the FDA. FDA. in my experience, can behave to crush small business in the interest of avoiding any publicity that might suggest that they have acted improperly. FDA is nor overseen meaningfully by its Congressional creators. That needs to be corrected without having to spend vast sums to hire lobbyists. The details of my own experience with FDA may be read at [...]. We all owe gratitude to Dr. Christensen for documenting his terrible experiences with FDA regulation which was not in the interests of improved patient care.Charles Homsy Sc.D.J. Ashely's comments deserve a fuller response:Your anguish deserves a more full response. Here are the answers available from every court record on the multiple lawsuits that were filed:a. Dr Kent invented the interpositional TMJ implant at issue. He fashioned it from a product we sold for plastic surgery uses.b. He wrote to us (1980) that he had had much improved results over the prior implant over at least seven years and gave us patients' summaries and published papers in the premier oral surgery journal. We tested the plastic surgery implant to simulate human TMJ use and found it durable.c. We applied to market the Kent implant to FDA in 1982. They approved it for sale after examining the patient and scientific data.d. When some surgeons reported problems, I stopped the sale of the implant (1986) pending clarification and convened a conference of experienced oral surgeons to review the situation. They concluded that the problems were not derived from the implant but from factors heavily dependent on surgical procedure and how the patients cooperated in post-surgical care. I wasn't satisfied and permanently stopped selling the implant.e.When lawsuits were filed in 1989 and 1990, the FDA descended on us as if there were no other facts than alleged in the law suits. The several Federal courts of Appeal that reviewed hundreds of cases concluded neither I nor the products were blameworthy.f. My companies helped over 100,000 patients with its other implants used in a wide range of surgical procedures. These are no longer available.g. I and my companies became FDA's scapegoats for the matter. You and we suffered mightily thereby and surgical care suffered as well.

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