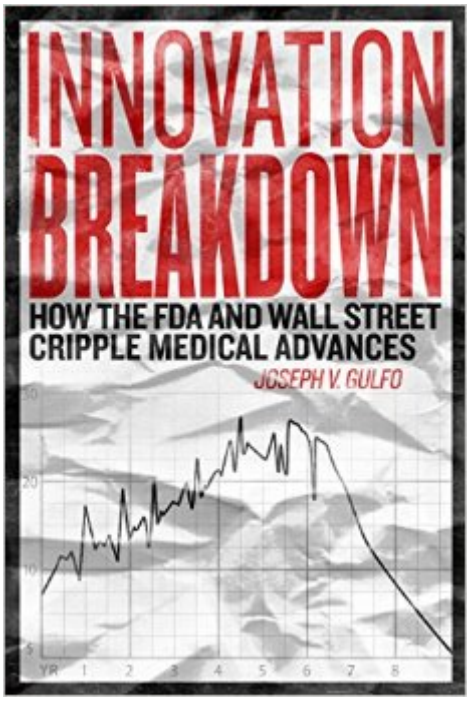
Innovation Breakdown: How The FDA And Wall Street Cripple Medical Advances



Synopsis

Winner of Maverick of The Year Award and Ernst & Young Entrepreneur of the Year Finalist, and featured by WSJ, Fortune and Bloomberg TV for his battle to defeat unlawful actions by the FDA, Dr. Joseph V. Gulfo provides a first-hand riveting account of an against-all odds fight that demonstrates what it takes to advance breakthrough medical products that truly benefit patients. Having been responsible for the development and FDA approval of three innovative cancer products, he provides the reader with ringside seats to the struggles that entrepreneurs of biotech and medtech companies must fight to successfully bring ideas to marketed innovative products that truly advance the lives of patients. As exclaimed by one real-life witness to a high profile public battle recounted in the book, â œIt was like watching Gladiator!â • The only difference is that this really happened. Sometimes life is more dramatic and unbelievable than fiction; the courtroom-like trial in front of FDAâ ™s medical Advisory Panel is certainly one of those times. A second was the â œdeclaration of warâ • â " filing a Citizen Petition against the FDA demanding that it follow its own laws and acts transparently in honoring its binding agreements. A third was a Congressional Hearing at which the FDA subsequently admitted that a mistake was made. The book contains public record facts woven together in a series of compelling stories complete with unique characters and deeply personal insights. Unrelenting focus, even to the level of personal destruction, and leadership through crises are other major themes. Part One describes how medical innovation occurs in small companies and details the challenges in moving those start-ups along a course that is anything but straightforward. It addresses issues such as the psychology of inventors and founders versus investors, the challenges of attracting and retaining talent, and the vagaries of early phase product development. Part Two takes a deep dive into the unlawful actions and cover-ups by the U.S. FDA that had to be overcome in our effort to obtain approval of a non-invasive product that saves lives. It is a brutal blow-by-blow account of a public slugfest that forever damaged the company. Part Three explains how the unnecessary and very public battle with the FDA left an indelible mark on the company, a taint that was exploited by nefarious Wall Street actors who then preyed on the company for their own benefit. It details how with a Scarlet Letter on its back and an albatross around its neck, Wall Streetâ ™s short sellers and dark pool traders hamstrung the course toward widespread use and adoption. The book concludes with The Innovation Manifesto, an actionable list of changes to help fix this horribly broken system, including reform to the legal system to reduce meritless shareholder lawsuits; securities reform to stop manipulative trading, analysis, and predatory shorting of small companies; and FDA reform that will bring in leadership that is committed to, and unafraid of, promoting health by proactively advancing the development and

approval of innovative products, rather than simply blocking drugs and devices that are not deemed to be safe. The FDA needs to get back to its first principles and to stop the propaganda - the author knows how to make that happen. In medical school and residency, the author was taught to â œsee one, do one, and teach oneâ • as the means to master a procedure and to complete the â œcircle of education.â • With respect to biotech and medtech companies that have been severely compromised by an untenable system, having â œseen one, done one, and taught oneâ • he now seeks to â œprevent a hundredâ • similar unfortunate examples. Continued advancement of our national health depends on it.

Book Information

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Customer Reviews

Dr. Gulfo shares his experiences in a VERY transparent and personal style, which drew me in and kept the pages turning quickly. I felt every twist and turn with him, and held hope for the survival of his company and the patients his product could help.That he was able to recount his experiences in such a constructive way during what was clearly a trying part of his work life, is admirable. Turning these experiences into a tool for sharing with the public how healthcare innovation should and could be better is both noble and unselfish, and a testament to someone who seems to truly be able to rise above and see the good.Bottom line, this is a must read for anyone in business for whom innovation is important, anyone who deals with government regulations, and anyone who wants to learn the truth about healthcare and the FDA approval process. Kudos, Dr. Gulfo!

Rarely have I read a book by someone with so much passion and fight. Dr. Joseph V. Gulfo details the difficult, cumbersome and lengthy FDA approval process that almost didn't allow his breakthrough product, MelaFind-a melanoma screening device-to get approved. He is the Rocky of medical innovation! Highly recommended.

What a great personal story as well as a super primer for those thinking of taking the plunge into biomedical start-ups. I have recommended it to many of my friends who are interested in what it takes to lead a new company with smart science in the wild world of Wall Street and the FDA

A good read about the battles of one company with the FDA. It lives the reader baffled about the FDAs actions and how difficult it is to move a new medical device to market. Unfortunately, we don't have the government's side of this venture but the tale is worth reading about.

A compelling read - this is a gripping and honest telling of the experience of dealing with regulators and Wall Street in the quest to bring to market a device that helps to save lives. The author provides a fascinating glimpse of what it takes to be successful as an entrepreneur in the medical device industry. The honesty is a refreshing change from the typical hagiographies of CEOs. Remarkable and this should be read by every aspiring biotech and medical device professional!

Dr. Gulfo recounts the TRUE and UNVARNISHED FDA approval experience in a manner that does NOT point fingers, and weep openly, but rather seeks to educate on the pitfalls and challenges in gaining marketing approval. It is a MUST read for any Angel, Investor, Analyst, or I daresay, C-level exec in the biotech sector. There is a great divide in the perception and the actuality of innovative medical product development and approval, and this book seeks to illustrate how innovation is currently a cruel taskmaster, and the ways in which this may be addressed.

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