Innovation Breakdown: How the FDA and Wall Street Cripple Medical Advances by Joseph V. Gulfo

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, “It was like watching Gladiator!” The only difference is that this really happened. Sometimes life is more dramatic and unbelievable than fiction; the courtroom-like trial in front of FDA’s medical Advisory Panel is certainly one of those times. A second was the “declaration of war” – 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 Street’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 “see one, do one, and teach one” as the means to master a procedure and to complete the “circle of education.” With respect to biotech and medtech companies that have been severely compromised by an untenable system, having “seen one, done one, and taught one” he now seeks to “prevent a hundred” similar unfortunate examples. Continued advancement of our national health depends on it.

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