

BOOK REVIEW

Author Offers Revolutionary New Approach to Drug Approval Process

By Jack Reardon

Technology is rapidly changing how we produce and consume resources and how we provision. No longer is the world neatly divided into consumer and producer, buyer and seller, markets and commons; but each is morphing into something quite different, requiring a new lens and a new vision to understand our changing world.

This new modus operandi is already emerging in energy, education, and medicine, giving us fruitful pause (but certainly not long-lasting) to reconceptualize the firm, the industry, the role of the government, and how we adequately provision for all.

Enter Bart Madden's wonderfully pithy, cogent, thoughtful, and revolutionary book.

Excuse the excessive modifiers, but

Bartley J. Madden, Free to Choose Medicine, 3rd ed. (Arlington Heights, IL: The Heartland Institute, 2018), ISBN 978-1-934791-67-7

each necessarily describes this must-read book, which is rich in depth, cogent in analysis, yet only 89 pages (including 11 pages of notes and references) in length. Madden, a former financial entrepreneur turned independent (and pluralist) thinker, is passionate to make the world a better place. He draws from a broad background of economics, finance, management, and psychology; and writes with an easy flair, every word efficiently utilized, easily accessible to the novice, yet resonating to the specialist.

Simple and Revolutionary

His thesis is narrowly simple, but pregnant with revolutionary overtones: Technology is changing how we practice medicine, disrupting and toppling traditional monopolies while bringing doctor and patient closer together in a nexus of decentralized decision-making.

The U.S. Food and Drug Administration (FDA), however, is stuck in an earlier mindset, excessively and myopically focused on the risk of adverse publicity while ignoring the invisible graveyard of people silently suffering without access to lifesaving drugs. If we as a society demand effective drugs, quickly, timely, and at lower cost, why does a new drug take 12 years for FDA testing and approval at an average cost of \$2.5 billion dollars? Should not we be outraged? Absolutely, argues Madden.

Pinpointing the Problems

The book is divided into six chapters. The first two introduce us to the invisible graveyard and to systems thinking (which, by the way, is intrinsically pluralist), allowing us to see the big picture while pinpointing problems and bottlenecks.

The preponderant bottleneck preventing our society from producing drugs quickly and cheaply is the FDA, with its unnecessarily long testing process and its excessive focus on attenuating potential negative publicity while neglecting the urgency to get cheaper drugs to those who need them most.

Madden has done his homework, peppering his text with numerous quotes from doctors, professors, and former and current FDA officials, letting the actors speak for themselves. He is not proposing the abolition of the FDA, only its demise as a monopoly. He proposes an alternative, secondary track in which patients and their doctors can obtain a drug in half the time (and at half the cost). Madden explains the nuts and bolts of Free to Choose (FTC) in the book's second two chapters, and



specifically:

“The way to solve the FDA bottleneck is to preserve the current conventional track for new drug approval which includes sequentially phased clinical trials, [and] create a second new track, called Free to Choose, that patients and their doctors could use to access a drug that has successfully passed both Phase I safety trials and one or more Phase II efficacy trials. Instead of the current one-size fits-all regulatory straightjacket that assumes everyone is equally risk-averse, patients could express their own unique preferences for risk versus the opportunity for health improvement” (pp. 44–45).

Bypassing RCT

The FTC bypasses the randomized control trial (RCT), which perhaps more than any other factor has significantly increased the time for bringing a new drug to market by 40 percent since the mid-1960s. Wait a second, you might ask, is not the clinical trial the bedrock of science, in which we select volunteers who, not knowingly, are either given the drug itself or a placebo? And is not the RCT the only way to protect the health of future users, who might otherwise suffer a calamity? How does science progress if not by the RCT?

The RCT itself, argues Madden, has several ethical problems, or dilemmas, if you will. The unnecessarily long testing process ignores the demands



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BOOK REVIEW CONTINUED

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of the living who could immediately benefit. Why should a segmented sample receive a placebo when they could knowingly have received the drug itself? In order to randomize, the FTC homogenizes the sample of patients receiving the new drug, ignoring groups at the fringe, the very population that needs access.

Confronting Ethical Problems

But no matter the system used to distribute drugs to the public, ethical decisions abound, and Madden’s book puts them squarely on the table.

The FTC will reduce escalating health care costs. At just 3 percent of GDP in 1965 (just prior to passage of Medicaid and Medicare), health care costs will approximate 19 percent of GDP—the highest of any nation—by 2026, according to *Health Affairs* (“National health expenditure projections, 2017–2026: despite uncertainty, fundamentals primarily drive spending growth,” March 2018). Madden’s FTC can reduce health care costs by reducing the cost of drugs and the length of hospitalization.

Another FTC benefit is the rapid development of a national database on which drugs work and which drugs do not, exhibiting economies of scale as more people use the information.

Empowering Patients and Doctors

But like the provision of big data elsewhere, democratic institutions need to be established to guarantee that the data is readily available for all and does not become monopolized. Is it ethical to offer drugs to ready and eager patients? Are they being exploited? Are they guinea pigs, sacrificed for the future benefit? No: Denying all patients a choice, which they and their doctors should make, is unethical.

The penultimate chapter recognizes the myriad obstacles intrinsic to a steadfast bureaucracy set in its ways; after delineating them, Madden proffers effective solutions. The last chapter is a call to action. This is a book about empowerment and democracy. Madden ends with the clarion call to the reader, “it really is in your hands” (p. 78). And it is. Large bureaucratic institutions do not change themselves.

This book reminded me of Thomas Paine’s *Common Sense*. Of course, the



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two books speak to a different time, a different age, and a different set of problems; yet, each author writes with perspicacity and is able to gauge the mood of the country and galvanize with sharp, cogent, and pithy writing. Indeed for Madden, “Passage of a FTC Medicine Act would be a defining moment for America—a directional change from today’s trend of increasing litigation and regulation as well as a stake in the ground anchoring the undeniable truth that control of medical decisions belongs, first and foremost with individual patients and doctors, not the government.” (p. 75)

Counting Blessings, Curses

In the preface to his best-selling *Principles of Economics* (1920), Alfred Marshall wrote, “[E]conomic conditions are constantly changing, and each generation looks at its own problems in its own way.” While a good argument can be made that our problems are indeed most formidable, we are blessed and cursed with rapidly changing technology. Blessed because it can enable new conceptualizations to solve problems and cursed because it can ossify the old.

Nobel laureate Vernon Smith wrote in the foreword to Madden’s *Free to Choose*, “this book is fundamentally bipartisan and should be read in that spirit” (p. 8). But *Free to Choose* is more than bipartisan; it is a book for all society to read, hopefully expanding dialogue by touching on common ground. Medicine is one of the few issues that directly affects everyone. And how we provide for the sick, indigent, elderly; and how we plan and provide for better health defines who we are as a nation.

This is a great book for economics courses and especially microeconomics. Not only is it cogent and concise, but

it discusses issues of central concern to economics: power, pricing, competition, regulation, the role of the government, and changing technology.

I highly recommend this book to all and look forward to future work from this versatile and erudite thinker. Bart Madden, please survey our economy and find other areas with disconnects

between technology, democracy, and efficacy (perhaps higher education?). We need your passion, your voice, and your erudition.

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Welfare’s Worst Failure

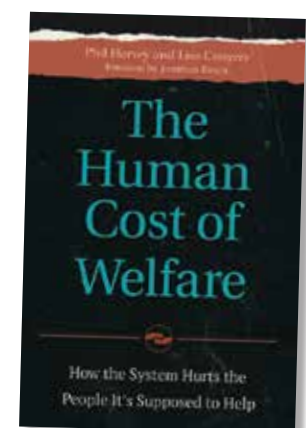
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