Book Review

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Free to Choose Medicine (3rd ed.)
by: Bartley J. Madden
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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 reconceptualise 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 each necessarily describes this must-read book. Rich in depth, cogent in analysis, yet only 89 pages (including 11 pages of notes and references). 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 utilised, easily accessible to the novice, yet resonating to the specialist.

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 decentralised decision-making. The US Food and Drug Administration (FDA)[1], 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 life-saving drugs. If we as a society demand effective drugs[2], 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.

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;[3] its excessive focus on attenuating potential

negative publicity, while neglecting the urgency to get cheaper drugs to those who need it most.

Madden has done his homework, peppering his text with numerous quotes from doctors, professors, 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 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)

The FTC bypasses the randomised control trial (RCT), which perhaps more than any other factor has significantly increased the time for bringing a new drug to market by 40% since the mid-1960s [Folland et al., (2013), p.349]. 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:

1 The unnecessarily long testing process ignores the demands of the living who could immediately benefit.

2 Why should a segmented sample receive a placebo when they knowingly could have received the drug itself?

3 In order to randomise, the FTC homogenises the sample of patients receiving the new drug, ignoring groups at the fringe, the very population that needs access.

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 healthcare costs. At just 3% of GDP in 1965 (just prior to passage of Medicaid/Medicare), healthcare costs will approximate 19% of GDP – the highest of any nation – by 2026 (Cuckler et al., 2018). Madden's FTC can reduce health costs by reducing the cost of drugs and the length of hospitalisation.

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. This decentralised and democractised database is already transforming medicine into a:

> "Distributed, laterally scaled, peer-to-peer relationship in which patients, doctors, researchers and other health care providers collaborate in open-networked commons to advance patient care and the health of society." [Rifkin, (2014), p.241]

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 monopolised.

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 recognises 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 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 galvanise 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)

Alfred Marshall (1920 [1946], p.v) wrote in the preface to his best-selling *Principles of Economics*, "economic 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 conceptualisations 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 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 a disconnect between technology, democracy and efficacy (perhaps higher education?). We need your passion, your voice and your erudition.

References

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Notes

1 The current FDA traces its roots to the Pure Food and Drug Act (1906), the first of many consumer protection laws passed in the 20th century, and precipitated by the uproar created the publication of Upton Sinclair's *The Jungle*. In 1936, the Roosevelt Administration revamped the FDA, creating the current structure. In 1962, the act was significantly reformed, greatly expanding the monopoly and authority of the FDA, especially pertaining to the introduction of new drugs.

2 For a wonderfully entertaining, concise and illuminating history of pharmacology and pharmaceuticals, see Duffin (2010, pp.98–128).

3 For an expanded discussion, see Phelps (2010, pp.507–527).