

TAMING THE BIG PHARMA MONSTER:
by Speaking Truth to Power

HEDLEY REES

For PEDRO HERNANDEZ, in memoriam.

Evangelist, pioneer of quality by design (QbD) and process analytical
technology (PAT)

Man of integrity and passion for doing the right thing; educator, learner and
developer of people

Sadly, no longer with us in body, his spirit lives on

True friend of modernisation in the medicines industry

Thank you for your groundbreaking work, Pedro

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PREFACE

I almost didn't write this book. My maiden and two subsequent attempts, despite receiving great reviews, were disappointing in terms of sales. I had been certain the world was hungry to hear the messages within, not just to inform and educate on my speciality subject—strategic management of the supply chain—but also to help catalyse change for the better in the medicines (pharmaceutical) industry, with tongue-in-cheek accounts of what's been going on, and wrong.

As I think back, the important messages were about as popular as the Conservative Club in Moscow to a world believing there was no better, more patient-centred way.

Undeterred, I have continued to preach the messages at conferences, in professional journals, and through webcasts and podcasts. The presentation I give is purposefully provocative. I've resorted to giving the drug development and commercialisation process a funny name, find it, file it, flog it, and semi-ridiculing the notion of scientists discovering blockbuster drugs in the dead of night, surrounded by test tubes, Bunsen burners and other apparatus involved in deep chemistry.

The audiences are mainly polite. People tend not to challenge me on what I say, although there must be a lot of skepticism underneath. Only once have I been taken to task, at a conference, by an industry leader who appeared greatly irritated by such frank expression of opinion that was clearly counter to his own. It took me by surprise at the time.

I have recently been toying with the idea of writing something even more direct and explicit than my previous attempts, accessible to an informed patient, industry professionals and other key stakeholders. Something has been stopping me, though. It's one thing shouting at the dark when people aren't listening, but if they do listen, and take it all in, that would place a whole new burden of responsibility on me to follow-through with it.

For reassurance, I recently returned to my copy of *The War of Art* by Steven Pressfield. His view is that creativity is blood, sweat, and tears, and a fight against the fear of creating something at which others will pick, often deeply. It requires a steely determination to keep resisting the knot in your stomach telling you to stop and pursue more tranquil endeavors—to turn up at your desk every morning to write the next installment.

That wasn't the only source of reassurance, as I go on to explain.

Firstly, there is Mrs Madeleine Moon, MP for Bridgend. I sent her a copy of a paper I had previously submitted to a House of Lords inquiry into life sciences in the UK. There was little if any response from the enquiry committee, so I emailed Mrs Moon, as my constituency MP, to ask why this might have been the case. I also sent a copy of the paper. She then asked to meet me and since then, she has been fighting our corner at every opportunity, despite her grueling schedules.

The following is Mrs Moon's account:

I receive many emails each week asking me to support a wide variety of causes ranging from the armed forces to medical and environmental campaigns, so when Mr. Rees wrote to me, asking about a paper he had submitted to the UK House of Lords Committee Inquiry into Life Sciences and Industrial Strategy, I read it and was intrigued by its contents. It seemed to address, head-on, issues of medicines affordability, accessibility, R&D productivity and speed to market. It also appeared to offer up solutions to a politician that seemed eminently sensible.

As one of my constituents, I have duly taken his corner, and have made the Health and Social Care Committees of UK and Welsh Governments aware of the initiative this book is a companion to. I have also sent details to several All-Party Parliamentary Groups (APPGs) with an interest in the topic area.

In the Press Release announcing the inception of this initiative, I was pleased to comment as follows:

“It is time that we explored ways of improving accessibility and reducing the amount of time it takes to bring new medicines to market. It will be interesting to see whether the specialists can teach the pharmaceutical industry new approaches to tackle these challenges. “

So, we wait and see what they come up with. Judging by the weight of skill and experience on the facilitation panel, and the impressive number of patient representatives and healthcare professionals attending, we may be in for a very pleasant treat!

Next inspiration and reinforcement comes from Mark Duman.

I describe Mark to people as a force of nature, mainly because he is. Mark is to networking what Mohamed Ali was to boxing. He floats like a butterfly, stings like a bee, in metaphorical terms of course.

We met in a pub in Paddington, home of every Welshman's train trip over the border into England, on the road to Twickers. It was early in 2016. He had scribbled all over the copy of the FIFIFI book I'd sent him for review. He was enthusiastic about what he had read, and ever since has used his 'bee sting' to get me a hearing with senior UK folk in the medicines industry and politics.

Results have been predictable, if I'm honest. I expect the brush-off now, in the knowledge that those within an established system are rarely disposed towards changing it. Expecting it and accepting it is another matter, however. Being even more honest, I hate it; but the frogs are there to be kissed and someone has to do it. I just wish it wasn't me. Most of what you read in this book, though, luckily, is about the princess and princesses that did the switch along the way, or were never a frog in the first place.

Indirectly though, this led me to the breakthrough I'm describing today. At Mark's suggestion, I penned the paper that Mrs Moon was able to read and digest and get behind.

Next on the list is an organisations not a person. It is LinkedIn (LI). I didn't add Jeff Weiner in the section on industry giants in the name of not overloading readers, but he is squarely in there. You will learn what qualities it needs to qualify later. Suffice to say that the LI product offering is phenomenal value for money, if charging zilch, zippo, didly squat is any measure of value.

For zero smackeroonies, you get to put your full profile out there, available to the world of business and enterprise; and you can view other's minded to do the same thing. For those you take a shine to, the opportunity is there to invite them to connect with you. It might take a politely worded note, drawing attention to your shared interests and plans, but that is more than compensated by the joy of connection with a like-minded soul.

There is no pressure to do any more than that. When the time is ripe, opportunities may arise to speak more on a topic, but no pressure. Over time, as you make more connections and become increasingly visible; others invite you, rather than just vice versa. You start to build a powerful network that can work for you, and you for it.

I should stop here now for the sake of brevity, but I'm only scratching the surface of what you get for free. Guilty conscience has led me to take up the LI premier service of late, but I could still manage well without it.

Next source of inspiration are the facilitation panel members, listed in the appendix. They don't know they are an inspiration, of course, why would they? All they have agreed is to join a list, having no idea what arrangements were in place to make the initiative happen; and if it were to happen, what that participation would involve; but for them, being on a public list, supporting an event like this, is not to be taken lightly. This list has been shared far and wide and not one has asked for their names to be removed. Hopefully, they will tun up on the day!

Now we turn to Janet Woodcock MD. The Wiley Editor for Pharmaceutical Sciences, Jonathan Rose, who commissioned my first book, suggested I seek permission to add Dr Woodcock's name as a contributor, given I had used some of her pronouncements taken from the FDA website. I wasn't quite sure how I would get to such a prominent person, so took a stab at finding her on the FDA website – and there she was, email address staring up at me.

I wasn't getting excited yet, because I still had to ask the question, which I did. The following day, I had the permission.

As the years have gone by, Dr Woodcock has never failed to respond to my occasional emails requesting various snippets of information. Even so, it was not without trepidation that I made the request for her to record the Keynote Address. Before I knew it, my email was forwarded to the FDA digital communications team, headed by Paul Buckman, and the recording was slotted into the schedule.

The Penultimate inspiration is Mike Day and his team at Filament Publishing. They have been a delight to work with and have restored my faith in the publishing industry – no budding author needs to surrender their manuscript to predatory publishers while Filament is around.

As a blatant act of raging self-interest, special mention is made of Liz Sheppard-Jones, who is editing this work and keeping me on the straight and narrow.

The final inspiration is the venue for our conference, and its location. Nestled in the once infamous dock area in Cardiff Bay, transformed by the City into a stunning waterside cultural and entertainment attraction, lay Techniquest. I will leave Lesley Kirkpatrick, CEO, to welcome you to it.

Welcome to Techniquest, Cardiff's leading science discovery centre and home to innovative interactive science experiences in Wales.

At Techniquest, it's our mission to create a STEM (science, technology, engineering and mathematics) literate society across Wales, by making these essential foundational skills accessible to all. Our nation is home to a rich STEM heritage, coupled with smart innovation, and we've pledged to make STEM-related learning exciting for everyone who comes through our doors, as well as inspire the future STEM workforce across Wales.

While we are a beloved local institution, many people are unaware that we are an educational charity and that we deliver nurturing and inspirational educational programmes to over 73,000 school pupils across Wales. Over the next year, we'll be marching forward with our transformational project, *The Science Capital*. This project encompasses a radical transformation of our current building, with an extension set to double our footprint. We hope you'll join us on our journey and come back to visit when we reveal our brand-new interactive science hub in Summer 2020.

We're thrilled to be involved with PharmaFlow's vital exploration into modern medicine, and we're incredibly proud to be setting the stage for the Medicines for the 21st Century conference. With a natural curious eye and passion for the future of STEM-related activities, we're looking forward to hearing from the inspiring panel of experts as they explore the challenges, approaches and sustainability of the pharmaceutical industry.

1. DISRUPTING BIG PHARMA? DO ME A FAVOUR...

PLEASE, SUSPEND JUDGEMENT UNTIL YOU'VE HEARD OUR CASE

There aren't too many people willing to countenance the potential disruption of the pharma (from here on referred to as 'medicines') industry. In fact, there is probably no-one who would give house room to the notion; but it's possible. If this book achieves nothing other than convincing you of that, then we a result on our hands.

So, give your brain a quick swill, wash out your pre-conceived ideas, and sit back for a fascinating few hours.

A UNIQUE INITIATIVE, NOT A MOMENT TOO SOON

This book is pre-reading for a unique initiative, aiming to transform the approach pharmaceutical companies (from here on referred to as pharmacos) take to developing and commercialising medicines—root, branch, twig and leaf.

TBC