

reviews

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Big Pharma: How the World's Biggest Drug Companies Control Illness

Jacky Law



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Rating: ★★★☆

The pharmaceutical industry is a business. This banal and obvious fact needs emphasising because it is often forgotten or overlooked by both supporters and critics of the industry's ethos and activities. And the industry itself is happy to downplay its true motivations where this suits the circumstances. It can, for example, pose instead as educator, charity supporter, health service provider, and even patient advocate.

While such roles hardly mask the underlying commercial imperative, observers may be reluctant to consider them primarily in business terms. This would be a mistake, not least because, when viewed in this way, there is much to admire about the pharmaceutical industry. Other industries could perhaps learn from its energy, professionalism, flexibility, and ability to ensure that its interests are well represented wherever key healthcare decisions are taken. What is more, a focus on the pharmaceutical industry as a business need not deny the great advances the industry has provided and continues to offer, or the good intentions of many who work in it.

Indeed, the difference between the interests of industry and the public good is not necessarily a problem. Where medicines are affordable and scrupulously regulated, and offer genuine therapeutic benefits, the overlap between public health and the legitimate business interests of industry can be self evident. There is a danger, however, in taking such overlap for granted. Multinational pharmaceutical companies grew big through producing and promoting innovative medicines for major diseases. But it becomes ever more difficult and expensive to repeat such successes. Increasingly, therefore, the companies stay big by identifying and promoting diseases for their

major medicines and refashioning and repackaging old products as "innovations." Also, they commonly operate under regulatory and other statutory arrangements that appear to assume that what industry produces is inevitably worth having—an approach that is more patent focused than patient focused. In this environment, assuming or pretending that there is a direct relationship between industry's efforts and improvements in public health is, at best, naive.

These issues form the core of Jacky Law's excellent treatise on how major pharmaceutical companies dictate which healthcare problems are researched, publicised, and provided for. This concept is not novel. But what Law adds is a highly readable synthesis of evidence and commentary to argue how and why the pharmaceutical industry fails to address healthcare issues that really bother people.

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The author is clearly no great fan of the industry. But, refreshingly, she avoids the sort of lazy polemic that casts major pharmaceutical companies as an evil empire that continually foists its products on unwilling and unsuspecting healthcare professionals and patients. Nor does she shy away from criticising those outside the pharmaceutical industry—government, regulators, doctors and patients—who have encouraged or acquiesced in the industry's way of doing things.

Tracing the development of the modern pharmaceutical industry, Law correctly cites the failure of what she calls "the deal"—a regulatory framework broadly based on the idea that pharmaceutical companies always produce worthwhile products that society will automatically buy. In hindsight, of course, this settlement seems woefully optimistic. But it is important to remember that it came about at a time when companies really were producing innovative medicines relatively easily; when such development was affordable; when patients were passive and trusted doctors; and when doctors trusted the medicines. And even now, as the book makes clear, the guiding principles of the deal remain in place, despite being increasingly unfit for purpose.

A key example in the UK is the Pharmaceutical Price Regulation Scheme, the unique, grotesquely brilliant arrangement that dictates how much overall profit a major pharmaceutical company can make through sales of its brand-name products to the NHS. The scheme helps to control the national drugs bill. However, it also deliberately uncouples the price set, and the profit made on, an individual product from the costs incurred in developing, testing, and promoting that product.

The "deal" was bound to fail through the spiralling costs and increasing difficulty involved in producing genuinely innovative medicines, and society's mounting disinclination to pay, particularly for products of questionable value. These economic realities have been compounded by recent high-profile instances of regulatory failure, in particular, the problems surrounding the use of rofecoxib (Vioxx) and selective serotonin reuptake inhibitors. The book concisely reviews the evidence indicating that in these cases regulators repeatedly favoured the interests of pharmaceutical companies above those of patients.

Such information forms a key part of Law's championing of active and representative involvement in individual and societal decision making about health care. This view is compelling given the lack of trust patients and the general public have for regulators and the wider medical establishment. However, much less convincing is the book's suggestion that the UK government should have addressed parents' scepticism about official advice on the MMR (measles, mumps, and rubella) vaccine by making alternative single vaccines available on the NHS. This highly questionable proposal seems a rare lapse in an otherwise tightly argued text.

The final third of the book highlights how moves to strengthen and ensure more balance in the doctor-patient relationship could help lessen the often distorting influence of the pharmaceutical industry. This suggestion may seem wildly hopeful, particularly given the industry's proved adaptability. But as Law herself concludes, it would be a good start.

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Items reviewed are rated on a 4 star scale (4=excellent)



Miracle Workers

Weekly in the United States on ABC, Mondays at 10 pm Eastern time, 9 pm Central time
<http://abc.go.com/primetime/miraclegworkers>

Rating: ★★☆☆

Each episode of this reality television show, which began last week, tells the story of two people whose serious medical problems have not so far been helped by the high tech US medical system. Guided by two attractive doctors and two extremely attractive nurses, and sponsored by a chain of drug stores, the “contestants” are given “cutting edge” care—cutting edge as in surgery, the programme often reminds viewers. In each episode we follow the patients from the initial consultation with the medical team that will treat them to the treatment itself—“state-of-the-art special effects” will take viewers inside the patients’ bodies—and the results.

One of the two patients in the first episode is Todd Heritage, a 34 year old hospital assistant who has been blind for the past 22 years because of a Stevens-Johnson reaction to penicillin. Three times he has major surgery to repair his scarred corneas, apparently involving several corneal transplants, but in each case the transplant has become scarred. “It’s like trying to see through a potato chip [crisp],” his surgeon says later, as he holds up the opaque yellowish cornea he has just removed.

The programme often reminds us that Todd has never seen his wife or his children and that his sister is risking her eyesight to help him. And reminds us again.

The surgeon, Edward Holland of the Cincinnati Eye Institute, plans to restore Todd’s sight by using stem cell implants taken from the edge of his sister’s cornea and from a cadaver donor, as well as a cornea from a cadaver.

The second patient is Vanessa Slaughter, a 47 year old woman who cannot get out of her wheelchair because degenerative disease of her spine has compressed vertebrae so that they pinch nerves and cause extreme pain. She has had several operations, without success. Her sister says it’s like seeing her die emotionally.

Her surgeon, Stanley Gertzbein of Christus St Joseph Hospital in Houston, Texas, plans to implant titanium disks filled with bone chips from her hips between her damaged vertebrae. She’ll be a bit more stiff, he says, but she should have no pain.

There’s an edge of the seat moment when Todd opens his eyes after receiving his sister’s corneal stem cells and a corneal transplant. Alas, he can’t see. But Dr Holland assures him that the new corneal stem cells

may grow into his cornea and provide support for another corneal transplant.

A potentially similar tense moment for Vanessa is that she could bleed to death if her surgeon injures a major blood vessel in his approach through her abdomen to her spine. But Vanessa’s treatment goes well from the start, although it is clearly major surgery. Later we see her with her supportive sister. Vanessa is walking, bending, and what she hoped to do: working in her own flower store.

And, yes, Todd’s second procedure works. The “miracle worker” removes the “potato chip” cornea and implants a clear one. Todd sees! Sees his wife and children, hugs them, and goes to look at the ocean that he’s always wanted to see.

How did these people get these treatments, and who is paying for them?

The programme never explains why Todd and Vanessa weren’t able to get these treatments as part of their regular medical care. Have their insurance companies given up on them? Has their insurance run out? Are these treatments not covered?

Although both the surgeons in this episode say that their methods are approved and offer cure rates of around 90%, sometimes US health insurance companies don’t cover treatments they consider experimental.

On the other hand, maybe health insurers are right to consider these treatments as too experimental to pay for and as not having a high enough success rate. In which case Todd and Vanessa are lucky to be the ones whose treatment worked. As a professional sceptic I wonder whether the programme tells only the success stories. (My calls to the programme makers weren’t returned.)

The *New York Times*, reviewing the programme (6 Mar: sect E, p 10), managed to extract some information that most documentaries would include:

Who’s paying for all this, and how much is it costing? If you guessed ABC for the first (except for those families that have insurance), you’d be right, but no one in need of these operations probably could stand to hear the answer to the second. The closest we get to a hard number is a shameful plug at the program’s end in which the CVS pharmacy [the sponsoring company] gives Mr Heritage a \$25 000 [£14 440; €20 930] gift card for his medications.

Apparently it’s not easy to get on this programme and have your medical care paid for. *Miracle Workers* is a soap opera that exploits vulnerable people. The blessing is that it may help those who pass the auditions. Like various medical dramas, it plays to the public’s interest in high tech medicine—“cutting edge,” as the announcer says.

I hope the series will make some viewers ask important questions. Why are other people who need this care not getting it? Do these treatments really help most of the people who receive them? And why don’t Americans have a healthcare system that works?

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NETLINES

- For serious information on neuromuscular diseases, you will find a substantial source at www.neuro.wustl.edu/neuromuscular/index.html. The home page offers signposts to get you started, and the site also has search facilities and an alphabetical index. The database is helpfully divided into major headings such as myopathy, neuropathy, and laboratory tests.

- The practice based website of an ear, nose, and throat specialist in Houston, Texas, offers an excellent collection of pictures relating to the specialty (www.ghorayeb.com/Pictures.html). You can choose to list the topics alphabetically or by anatomical site. The collection comprises clinical pictures and radiology images but also labelled diagrams, sometimes accompanied by descriptive text. The site contains plenty of common and not so common scenarios in the specialty.

- Medicine is littered with conditions named after the people who first described them. If you are interested in such ophthalmic conditions and want to know who Argyll Robertson, Goldmann, and Sjögren were, check out www.mrcophth.com/ophthalmology/halloffame/mainpage.html. The notables in this collection are represented by a portrait of them linking to a short biography.

- Many readers will know of the excellent Wikipedia—an online, open access encyclopaedia whose entries can be edited by anyone (<http://en.wikipedia.org/>). Now there is a medical equivalent, Ganfyd, that is based on the same principles (<http://ganfyd.org/>)—although in this case only suitably qualified people can edit and update the database. This is a hugely ambitious project and deserves to succeed, though it is far from finished and is by no means comprehensive. However, the skeleton is laid for others to contribute.

- Websites for hospital departments and general practices are now fairly common, and overall there has been a step up in quality from the past practice of simply publishing a brochure online. Many such websites are much more interactive, and one good example of an interactive component is www.littlewickmedicalcentre.co.uk/score.htm. This “score yourself” facility on health related scales is part of one UK general practice’s well produced website and includes questionnaires assessing cardiac risk, depression rating, alcohol use, weight, and need for antibiotics if you have a sore throat.

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We welcome suggestions for websites to be included in future Netlines. Readers should contact Harry Brown at the above email address

PERSONAL VIEWS

On being downstream from faked scientific reports

For some time the US writer David Rorvik held the dubious distinction of being history's greatest hoaxer when it came to human cloning. In the 1970s Rorvik wrote *In His Image: The Cloning of a Man*, the story of how he helped convene a research team somewhere on a Pacific Ocean island in order to clone a US millionaire (www.museumofhoaxes.com/cloning.html). It wasn't true, of course, but enough people believed this former medical reporter to keep the story afloat. Rorvik was eventually found out, and both author and book faded away, although the idea that people could copy themselves lingered on.

In late 2005 fraud charges starting bubbling around another claimant to success in human cloning. The South Korean researcher Hwang Woo-Suk and colleagues had reported earlier that year that they had used cloning techniques to create stem cell lines of 11 people. The report followed up a 2004 report indicating success in using nuclear transfer techniques to produce an early stage human embryo. Both reports appeared in one of the most eminent scientific journals in the world, *Science*. Even so, it was not long before critics began to call the findings into question, and a hastily convened review panel found that—contrary to the 2005 report—no human stem cell lines had been produced as described (*BMJ* 2006;332:67). Professor Hwang murmured that it was all a misunderstanding and asked for time to vindicate himself (*Financial Times* 13 Jan: 2).

Before Professor Hwang's work was debunked, it seemed that the dawn of customised human stem cell lines was at hand. Commentators around the world had taken up the report, if not for the science then for the ethics. For lectures and public presentations about the ethics of human embryonic research in general, and stem cell technology in particular, I turned to Professor Hwang's report. The report did in fact stir the already morally choppy waters of human embryo research. Some commentators hailed the report as evidence that clinical therapies were imminent; but others wasted no time in condemning the "disaggregation" of embryos involved in this research.

Strictly speaking, simply because it is possible to create individualised stem cell lines through cloning does not mean that we should do that. On this point the critics of stem cell research have it exactly right: the possibility of the research is never its own justification. For that, we should weigh the

benefits of the research against its risks and costs. In their moral calculations many people are prepared to accept these risks and costs, even if one of the outcomes is the destruction of a number of human embryos. Moreover, the research may have a political edge too: emerging medical benefits might persuade some people to reassess their moral objection to government support for this kind of research. In any case, these were the kinds of issues I discussed in public: the meaning of the findings for moral debate. I turned to Professor Hwang's study because it was no incidental report. One way or another, medicine and society would have to come to grips with the powers he appeared to be putting into the hands of researchers and clinicians alike.

As a philosopher of medicine I don't have the expertise to detect the flaws in Professor Hwang's 2005 report. Yet I still feel a degree of remorse and even humiliation for uncritically treating the report as true, treating it as the starting point from which moral discussion should proceed. What makes matters worse is that there is no way to go back to all the people with whom I talked and to recant, to tell them that it was all a mistake, that personalised stem cell lines are still in the future, if at all. We were all taken in.

There is more than one cautionary tale here. There has been so much talk about human cloning and such swift progress in the field that researchers and academics on both sides of the moral debate stand ready to believe that someone somewhere will succeed in creating cloned embryos and individual stem cell lines to order. That receptivity is also the very first step toward gullibility. Science may uncover its own errors, but it will do so only over time and not before false reports inflict collateral damage. Professor Hwang's fraud did not go undetected for very long, but it went on long enough to produce a domino effect of false expectations among policy makers, politicians, bioethicists, and disease therapy advocates. The time spent discussing this report was time wasted for everyone.

Because of the way researchers rely on one another, knowing misrepresentations are among the worst transgressions of ethics in science. But whether we are scientists or not, we are all downstream from research projects with profound implications for the way we live—from genetics to cloning to neurology to global warming. Falsified science is not just a betrayal of the research community; it is also a betrayal of the public.

The time spent discussing Professor Hwang's report was time wasted for everyone



LEE HOON-KOO/AP/GETTY IMAGES

Tiers of a clone: Professor Hwang's fraud produced a domino effect of false expectations

Without an expectation of trust, the fields of bioethics, the law, education, theology—and all the other disciplines that discuss scientific findings in one way or another—cannot do their own work with any confidence.

No error exists in isolation in science, especially science that plays a role in key social debates. Most scientists do police themselves when it comes to fraud and misconduct. Only greater vigilance will protect us from the rogue opportunists and liars who do not. Towards that end scientific journals must have stringent evaluation practices in place, and all scientists must do their share of analysis, testing, and replication. Ethics courses for young scientists will certainly help too. But we must also look to our own willingness to believe as a factor that makes some fraud possible. A very healthy dose of scepticism—even towards eminent scientific authorities—can do its part in guarding against complicity in extending the tendrils of fraud across the social fabric.

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Competing interests: TFM is the author of *Case Studies in Biomedical Research Ethics*.

Online selection of junior doctors: a student's view

See *News* p 625

With finals looming, you would expect students in their last year of medical school to be revising hard and meeting up for the occasional last orders at the hospital social club. The one thing at the forefront of our minds should, as in previous years, be the exams that we have been working towards all our academic lives. However, the subject most talked about at attachments is jobs. Not surprising, you may think. But what is surprising is that not only do we talk, we also speculate and repeat rumours that we have heard while wondering if we will be able to work in England.

Final year students must apply for jobs through the Multi-Deanery Application Process (MDAP). Online, they must answer a series of questions on topics ranging from academic performance and personal achievements to the qualities of a good doctor. But each question must be answered in just 75 words. Students are not called to interview, but ranked depending on their application form score (out of 48). In this year's first round, thousands of students applied, each selecting their top 40 jobs. Many obtained identical scores, leaving some students who applied for the more popular jobs unplaced.

Understandably, most students apply for jobs at the deanery where they have trained—so it's bad luck if you trained in London. Jobs in the capital are oversubscribed now with equal opportunity laws giving any European Union applicant the same chance of employment. Royal Free and University College Medical School (RUMS) students seemed to come out the worst, making up 87 of the approximately 600 students without jobs. This has been put down to "RUMS-centric jobs" being among the most highly prized, such as those at the newly opened and publicity friendly University College Hospital.

In a letter to the *Times* newspaper on 4 March a group of leading medical professors protested against the application method. An adjoining article focused on how a few doctors allocated by this system last year were not able to fulfil their duties, detracting from the amazing achievement of those students who did obtain a job through this ridiculous system.

Last year, when a similar system was in place, some less popular hospitals had burnt fingers after employing large numbers of overseas graduates, who tended to have

lower application form scores. As a result, some doctors fell below required language and clinical experience requirements and hospitals had to employ locums to supervise their work. Consequently, many UK students with impeccable medical school records now face further interviews to check their ability to speak English as well as their commitment to working in the United Kingdom, as a result of a poor score on their forms. Surely this further assessment is not required of a student who has trained in the UK and passed their finals?

It was recently discovered that if you simply added the word "admin" to the MDAP web address you could access the internal administration pages. Word spread rapidly about this, until it was realised that the website offered a way in to every student's application form as well as his or her references—easily accessible, changeable, and not even requiring a password to do so. And now, as some of my fellow students talk to employment lawyers about the validity of the application process, others speak to the press, in the hope that public embarrassment will push MDAP to improve its system.

I never thought I'd say this, but at this point in the year I'd rather be revising pathology than reapplying. But it is difficult for students to focus on revision when we have lost all faith in MDAP. We are taught communication skills and told to respect patients, yet we are shown little respect ourselves when it comes to obtaining information about our futures. On some of my attachments, not a single student has a job. What if we do not get a job in round two? What will happen in the clearing process that follows this stage? We can ask the administration, but the fact is, no one knows. This is not something that has yet been decided.

You can find numerous faults with the system, most of which we are resigned to accept. For example, we can't find out about the jobs that we are applying to, meet the teams we will be working with at interview, or, in many cases, visit the hospitals or even areas that we are now choosing to live and work in for a year. The noble aim behind MDAP—to move medicine away from its image as an old boys' network—has created a completely new set of tribulations for medical students.

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SOUNDINGS

A sporting chance

When the United Kingdom's heavy industries began closing in the 1970s and 1980s, working class boys received their redundancy notices. What future was there for them? Nowadays many working class boys are out of control, disruptive, depressed, violent, self harming, and addicted to drugs, and we lock them up in record numbers.

Doctors—either seduced by intellectual vanity or naivety—have stepped in to "treat" these troubled youngsters. Estimates suggest that 1 in 10 of them has a diagnosis of attention-deficit hyperactivity disorder (ADHD). A pupil from an inner city academy can expect a school exclusion order, a psychologist, and amphetamines, and to graduate with a first class ASBO (antisocial behaviour order). Our school system is a construct of middle class values, where academic qualifications are the only measure of a success. Consequently, many working class boys are in, and are, trouble.

When I was at secondary school, I was tall and poorly coordinated, last picked at games and shoved in goal. The physical education teacher shouted at us constantly: "Concentrate," "Work together," "Stay in position," "Think, you idiot," and "Team work!" Then it was round and round the pitches, sprints, press ups, and squat thrusts until our lungs burnt with pain. Then more shouting: "Support him," "Shut up, Spence," "Cool it," "You're off if you do that again," "Do as I tell you," "Heads up," and "Show some respect." The teacher denigrated us one and all, and we hated him and the game. We cursed him behind his back and told that joke about games teachers wearing their IQ scores on their shirts. But competitive team sports were compulsory, and no number of drippy letters from daddy was going to get you off.

I have my own children now and I stand on the touchline every Sunday. I couldn't care less if they win or lose, nor even if they enjoy sports, because that's not the point. I figure that competitive team sports are the child psychologist and stimulant drug of much of humanity. These games for life provide some balance between the individual and the group, between winning and losing, and between aggression and control and the power of belonging.

The 1970s are back in fashion, so time for the can-shout-will-shout, polyester-tracksuit brigade to make a come back.

Des Spence *general practitioner, Glasgow*