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FEATURE

INTERVIEW

Andrew Witty: the acceptable face of big pharma?

Following GlaxoSmithKline's announcement that it will open up its research data, **Rebecca Coombes** spoke to the company's chief executive, Andrew Witty, about how he is trying to change the company

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Drug company bosses have a tough time getting positive headlines. As reputations go, they usually have to be content to rub shoulders with bankers and oil executives. So it was surprising that a member of this tribe was recently singled out for praise by one of the industry's harshest critics.

In a spectacular public relations coup last month, Andrew Witty, chief executive officer of Britain's biggest drug company, GlaxoSmithKline, announced the company was to make huge swathes of its research data public.[1] By signing GSK up to AllTrials, the campaign that urges drug companies to disclose detailed clinical study reports as well as the results of all drug trials—not just the ones with favourable results—Witty seemed to be ushering in a glorious new era of openness.

Ben Goldacre, doctor, AllTrials campaign leader, and author of *Bad Pharma*, which fiercely critiques the industry, called it "a cartwheel moment."

Back in October, Witty had also committed GSK to make anonymised patient level data from clinical trials available to researchers.

GSK badly needs this shot of good publicity: last year it was fined $3bn (£2bn; €2.3bn) in the United States for selling antidepressant drug paroxetine (Paxil) for unapproved use in children, concealing safety evidence from the Food and Drink Administration (FDA) on its leading diabetes product, and offering doctors lavish incentives to promote its medicines.[2] More of this later, but the fine stands as the largest in US history for a drug company.

Fresh approach

At 48, Witty is on the young side to lead a multinational company, one with nearly 100 000 employees in more than 100 countries. He's part of a new breed of company bosses, comfortable talking about his ideals, his love of Asia and Africa, and the need for corporate openness. He's even, whisper it, said the word "sorry" for some of his company's past misdemeanours. Could Witty be the acceptable face of "big pharma"?

An economics graduate from Nottingham University, Witty has spent his entire career at GSK. He shrugs off the charge that he's a chief executive bred in captivity, lacking the long range perspective to reform such a mammoth organisation. On the contrary, says Witty, his strength comes from spending most of his career at arm's length from GSK's polished glass headquarters in London.

"I'm what business school would call an 'outsider insider.'" By this he means he's always been on the edges of GSK's empire. "I was never really in the centre. I spent a lot of my career in Africa, in Asia, and that more than anything really influenced the way I think about the world.

"When you're in charge of an organisation, you're not just in charge of delivering the next bit of output or the next quarter. You're in charge of trying to set its culture and the philosophy. When I was told I had the job, I took a very deliberate look in the mirror around, 'What do I want to do with this job?' And the answer in my mind was to change the way we operate—and try as a consequence to change the industry, although I can't control that."

Witty wants to reform GSK in three areas; data transparency, access to medicines, and intellectual property. On the last two, he can point to inroads in developing countries—for example, changing the drug pricing structure that blighted GSK's anti-AIDS treatment in Africa. The company is trialling the first child malaria vaccine, one that when approved Witty decrees will not be sold for profit. "In some situations we develop medicines and we need to get a strong economic return, and in others we develop a vaccine like malaria where we're not looking for an economic return and it's part of our global contribution." Witty also set up a patent pool for neglected diseases to stimulate drug development in this field.

Transparency

The costs of these initiatives won't trouble GSK's balance sheet. The business is in pretty good shape under Witty—in 2012, GSK reported pre-tax profits of £6.7bn. However, Witty's drive

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towards transparency is not without risk. If GSK is truly opening up the data vaults—and the proof is still very much in the pudding—this means the release of potentially unflattering trial data to doctors and patients that could threaten the reputation of its highly profitable blockbuster drugs. Will shareholders tolerate the CEO sharing research data on a drug in the middle of a 10 year cycle of sales?

Of course, the jury is still out on whether GSK will make good on this new transparency pledge. When the *BMJ* met Witty last month, the company was about to undergo its first real test of this commitment. Buoyed by GSK's announcements, independent researchers from the Cochrane Collaboration reignited a three year long campaign to extract research data on the company's leading influenza drug zanamivir (Relenza). A full analysis of trial reports would allow Cochrane's independent academics to answer questions about the benefits of zanamivir. A similar review of Roche's oseltamivir (Tamiflu) is planned for this year. There are long standing concerns that these drugs have been overhyped. True to its word, GSK has now sent Cochrane clinical study reports—some 15 000 pages of data—on zanamivir. However, the team was dismayed to find the data heavily redacted in parts—including the removal of all patient identifier numbers—and is assessing if these omissions make the data impossible to interpret.

Nevertheless, Witty is adamant he wants to change the way GSK operates and that transparency is a key element of this reform. This month the company opens a web portal through which researchers can access the research data once they're given the green light from a GSK panel, whose members are due to be announced.

"The panel will be arm's length and will have people in there who are not GSK insiders," says Witty, adding that all researchers with a legitimate trial question and protocol, who also commit to publishing their results, will gain access to the data they request. Yes, some patient identifiable information will be redacted, he says, but nothing else. The same goes for clinical study reports, including the appendices, which researchers say contain information that is vital for a full analysis to be done. GSK plans to create a specialist team of 15 scientists, including some retired staff equipped with a long corporate memory, to deal with requests going back to the company's formation in 2000.

"Our intent is to be comprehensive and not partial, right? We are going to try and have as much [as possible] out there in the public domain. And absolutely judge us, but we are going to do it.

"We are going to create a dedicated organisation with the sole job of going back and finding all these documents, putting them together so that you can go to one trial and say, here's everything you need. The priority will be the most heavily prescribed drugs first, so we can get the data out there for the things that are affecting the most people."

Witty says he's not afraid of new adverse effects in any of these drugs coming to light as the result of independent scrutiny of trial data.

"My absolute view is if we've missed something in our analysis it's got to be better for everybody for it to be spotted. I don't believe for a second there is any malintent in any part of GSK. But I can't rule out that we sometimes get things wrong, make mistakes, or just look at the data in a different way to other people," he says.

Of course, GSK may be just the first company to see the writing on the wall. Governments and Europe are waking up to the costs of hidden data and research misconduct: British MPs are planning an inquiry into clinical trials, and data disclosure and there are calls for the powerful Public Accounts Committee to investigate the cost to the NHS of missing data relating to the £500m spent on oseltamivir.

Will GSK's actions live up to the fanfare of its various recent announcements? And will its actions put pressure on others to follow suit? "I think they will," says Witty. "We hear through the ether that others are moving in this direction. But of course there is a spectrum of view; there are some people who are probably closer to our position and some maybe less close."

Past problems

Whether data transparency is a matter of honour for Witty, or a canny way to reverse GSK's reputational misfortunes, we can't tell. The company's reputation certainly hit the doldrums in July 2012, with its record £3bn US fine for marketing breaches, including withholding safety data on rosiglitazone (Avandia), the company's best selling diabetes drug. These shocking transgressions were in Witty's in-tray when he took over as chief executive officer in 2008—Frenchman Jean-Pierre Garnier had led the company during the period covered by the fine. The final settlement last year was, says Witty, "the full stop mark on an end of a lot of historic activity."

"We were determined to make sure it never happens again." These humble words are tempered with a touch of bullishness: he wants to be "precise" about where GSK erred over Avandia. It wasn't that GSK deliberately withheld safety data from the Food and Drug Administration in the US, he says, but that some data were not submitted in the regular reporting systems. "It was an absolute error, and we should have been slapped for it and we were. But all the safety information was submitted to the agency in other systems. I'm not proud of it, but it's not the same as deliberately not presenting data."

He says GSK has since been audited by the FDA and "I think we've absolutely nailed that issue."

But aren't companies like GSK willing to pay billions in penalties as long as their rule breaking generates enough profits? Rosiglitazone, for example, has generated at least $10bn worth of sales and paroxetine, another drug named in the settlement, $11bn.

Witty displays a flash of anger: "I completely disagree with this. I've seen absolutely no evidence at any level that people make that kind of calibration or that kind of trade-off. I can tell you the money is the least important part of these things. These sorts of challenges from regulators are the most traumatising thing you could imagine for a company. They are deeply distressing for me, for large numbers of people down through the company. Although [corporate malfeasance cases] end up looking very big, they often have their origin in just one or two things that went wrong, or one or two people who didn't quite do the right thing. It's not about the big piece. The 100 000 people who work for GSK are just like you, right? I'm sure everybody who reads the *BMJ* has friends who work for drug companies. They're normal people. This is not a special subset of the population. Many of them are doctors."

If rotten apples and not endemic corporate malfeasance is to blame, how does Witty propose to root out bad behaviour? "We discipline; we either reduce pay or we terminate employment of people who break the rules. We've very aggressive, much more so than we were historically on that kind of thing."

Only last November was a GSK representative slapped on the wrist at the Prescription Medicines Code of Practice Authority

for off-label promotion of eltrombopag (Revolade). How can Witty be sure his representatives are engaged in honest selling?

"Training is obviously really important. Compliance and enforcement are really important. In the last five years, we've increased by about fivefold the number of compliance investigators in the company. We have 50 000 people meeting with doctors and health professionals every day. We've created compliance hotlines so if an employee says look, a doctor has asked me this, I'm not sure I can answer, [they can ring for advice,] they have to be thoughtful about how they react because the answer might be off-label and they need to be very, very careful. We've seen huge spike-ups in the number of people who ask for advice."

In the US, the company has dropped bonuses for drug representatives based on their individual sales; instead staff get incentives for the quality of service they provide—if they score higher in their scientific knowledge tests, for example, or if they receive positive doctor feedback from one of GSK's customer surveys.

I ask Witty if CEOs shouldn't carry the can for corporate malfeasance? It's the only time he falters. "Well I think ultimately that's the question for regulators and governments to decide. I also think there's a balance to be struck around something that was done deliberately or was it an honest error," he says.

He's against the "tokenism" of "we don't really care who was responsible, let's just have a head on a stake," and, "the kind of liability through proxy that you happen to be in the building therefore everybody is in trouble."

But, ultimately, "if someone has done something deliberately, with intent, which is a break of the rules, they ought to be subject to whatever are the sanctions of their society; it differs [according to] the jurisdiction you are in."

So what does it take to be a 21st century CEO in the pharmaceutical industry? "I don't think you want to be a CEO unless you have an agenda. I think having a point of view is much more important today than it was in the old days. And you've got to have the energy and resilience to be able to stick at it. Of course we need to develop new medicines and technologies, and, of course, we need to get a decent return on them. That's what shareholders need. But we need to be in step with society— not against society. People say to me, what did you shareholders say when you cut your prices in Africa by 75%. But the shareholders understand it's all part of the blend. Where I was helped enormously on this is I grew up inside GSK and I knew the vast majority of people agreed with me. I just knew it."

Competing interests: I have read and understood the BMJ Group policy on declaration of interests and have no relevant interests to declare.

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1 Kmietowicz Z. GSK backs campaign for disclosure of trial data. *BMJ* 2013;346:f819.
2 Jack A. Mea culpa: are multibillion dollar fines forcing drug companies to clean up their act? *BMJ* 2012;345:e4865.

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GSK's drug pipeline

In a challenging corporate environment, and with talk of the drug industry falling off a "patent cliff," Witty talks of tough research and development choices the company has made. For example, it has pulled out of research on depression and several neurological disorders.

"It's a tough needle to thread because scientifically, biologically, there aren't great targets; it's a poorly understood set of mechanisms [with] not brilliant non-human models to develop drugs. As a result you end up with very expensive development programmes which fail at the end—almost the worse situation. You end up with drugs which might, might jump the regulatory hurdle but then have a very high chance of being rejected by NICE and others," he says.

"We've terminated a number of very, very good drugs because we didn't think they would be any better than what's out there. And will people pay for it? Because at the end of all this we can only continue if we get rewarded for the innovation."

Instead the focus is on respiratory medicine, oncology, and vaccines. There are also interesting exceptions like Parkinson's and Alzheimer's, "because we believe there are better targets, we have better theories, and we think we can make better progress."

GSK has around 150 drugs in the pipeline, says Witty, and the biggest barrier to development is finding new biological targets.

"We have a very simple paradigm—we will focus where we think there is significant unmet need, and where we think there is significant bedrock of biological targets for us to develop molecules against. Super obvious, super simple, but that's why you don't go into depression because there are no new biological targets. It's why we withdrew from areas like overactive bladder: big unmet need but no new targets."

He thinks the UK government could do more to stimulate and support innovation and takes a swipe at NICE's quality adjusted life year (QALY) threshold. "It's inappropriately low. The QALY is the same in absolute points as it was in 1999, when it was first adopted. And there's no question that if the QALY had been inflated over the last 14 years as everything else has, well, for sure more medicines would be being made available in Britain. I'm not saying there should be unfettered access—that everybody should be given every new drug. But I think there should be greater focus on adoption of innovation once it's been deemed to be safe and effective and all the rest of it."

Some Witty facts

- Witty is 48 years old
- He joined Glaxo UK in 1985 as a management trainee, straight from Nottingham University, where he read economics
- In 2011, Witty's base salary was £1m (€1.2bn; $1.5m) and his bonus was £2m
- Since Witty became CEO in 2008, GSK's share price has increased by 25%
- In 2012, GSK's pre-tax profits were £6.7bn
- Witty was knighted in the 2012 New Year honours list