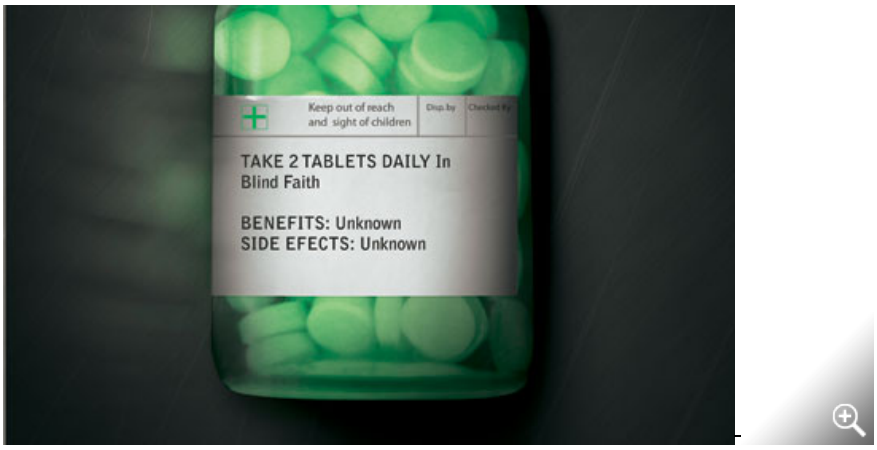
theguardian

The drugs don't work: a modern medical scandal

The doctors prescribing the drugs don't know they don't do what they're meant to. Nor do their patients. The manufacturers know full well, but they're not telling.

Ben Goldacre
The Guardian, Friday 21 September 2012 18.00 EDT



Drugs are tested by their manufacturers, in poorly designed trials, on hopelessly small numbers of weird, unrepresentative patients, and analysed using techniques that exaggerate the benefits. Photograph: Photograph: Getty Images. Digital manipulation: Phil Partridge for GNL Imaging

Reboxetine is a drug I have prescribed. Other drugs had done nothing for my patient, so we wanted to try something new. I'd read the trial data before I wrote the prescription, and found only well-designed, fair tests, with overwhelmingly positive results. Reboxetine was better than a placebo, and as good as any other antidepressant in head-to-head comparisons. It's approved for use by the Medicines and Healthcare products Regulatory Agency (the MHRA), which governs all drugs in the UK. Millions of doses are prescribed every year, around the world. Reboxetine was clearly a safe and effective treatment. The patient and I discussed the evidence briefly, and agreed it was the right treatment to try next. I signed a prescription.

Bad Pharma: How drug companies mislead doctors and harm patients
by Ben Goldacre

But we had both been misled. In October 2010, a group of researchers was finally able to bring together all the data that had ever been collected on reboxetine, both from trials that were published and from those that had never appeared in academic papers. When all this trial data was put together, it produced a shocking picture. Seven trials had been conducted comparing reboxetine against a placebo. Only one, conducted in 254 patients, had a neat, positive result, and that one was published

in an academic journal, for doctors and researchers to read. But six more trials were conducted, in almost 10 times as many patients. All of them showed that reboxetine was no better than a dummy sugar pill. None of these trials was published. I had no idea they existed.

It got worse. The trials comparing reboxetine against other drugs showed exactly the same picture: three small studies, 507 patients in total, showed that reboxetine was just as good as any other drug. They were all published. But 1,657 patients' worth of data was left unpublished, and this unpublished data showed that patients on reboxetine did worse than those on other drugs. If all this wasn't bad enough, there was also the side-effects data. The drug looked fine in the trials that appeared in the academic literature; but when we saw the unpublished studies, it turned out that patients were more likely to have side-effects, more likely to drop out of taking the drug and more likely to withdraw from the trial because of side-effects, if they were taking reboxetine rather than one of its competitors.

I did everything a doctor is supposed to do. I read all the papers, I critically appraised them, I understood them, I discussed them with the patient and we made a decision together, based on the evidence. In the published data, reboxetine was a safe and effective drug. In reality, it was no better than a sugar pill and, worse, it does more harm than good. As a doctor, I did something that, on the balance of all the evidence, harmed my patient, simply because unflattering data was left unpublished.

Nobody broke any law in that situation, reboxetine is still on the market and the system that allowed all this to happen is still in play, for all drugs, in all countries in the world. Negative data goes missing, for all treatments, in all areas of science. The regulators and professional bodies we would reasonably expect to stamp out such practices have failed us. These problems have been protected from public scrutiny because they're too complex to capture in a soundbite. This is why they've gone unfixed by politicians, at least to some extent; but it's also why it takes detail to explain. The people you should have been able to trust to fix these problems have failed you, and because you have to understand a problem properly in order to fix it, there are some things you need to know.

Drugs are tested by the people who manufacture them, in poorly designed trials, on hopelessly small numbers of weird, unrepresentative patients, and analysed using techniques that are flawed by design, in such a way that they exaggerate the benefits of treatments. Unsurprisingly, these trials tend to produce results that favour the manufacturer. When trials throw up results that companies don't like, they are perfectly entitled to hide them from doctors and patients, so we only ever see a distorted picture of any drug's true effects. Regulators see most of the trial data, but only from early on in a drug's life, and even then they don't give this data to doctors or patients, or even to other parts of government. This distorted evidence is then communicated and applied in a distorted fashion.

In their 40 years of practice after leaving medical school, doctors hear about what works ad hoc, from sales reps, colleagues and journals. But those colleagues can be in the pay of drug companies – often undisclosed – and the journals are, too. And so are the patient groups. And finally, academic papers, which everyone thinks of as objective, are

often covertly planned and written by people who work directly for the companies, without disclosure. Sometimes whole academic journals are owned outright by one drug company. Aside from all this, for several of the most important and enduring problems in medicine, we have no idea what the best treatment is, because it's not in anyone's financial interest to conduct any trials at all.

Now, on to the details.

In 2010, researchers from Harvard and Toronto found all the trials looking at five major classes of drug – antidepressants, ulcer drugs and so on – then measured two key features: were they positive, and were they funded by industry? They found more than 500 trials in total: 85% of the industry-funded studies were positive, but only 50% of the government-funded trials were. In 2007, researchers looked at every published trial that set out to explore the benefits of a statin. These cholesterol-lowering drugs reduce your risk of having a heart attack and are prescribed in very large quantities. This study found 192 trials in total, either comparing one statin against another, or comparing a statin against a different kind of treatment. They found that industry-funded trials were 20 times more likely to give results favouring the test drug.

These are frightening results, but they come from individual studies. So let's consider systematic reviews into this area. In 2003, two were published. They took all the studies ever published that looked at whether industry funding is associated with pro-industry results, and both found that industry-funded trials were, overall, about four times more likely to report positive results. A further review in 2007 looked at the new studies in the intervening four years: it found 20 more pieces of work, and all but two showed that industry-sponsored trials were more likely to report flattering results.

It turns out that this pattern persists even when you move away from published academic papers and look instead at trial reports from academic conferences. James Fries and Eswar Krishnan, at the Stanford University School of Medicine in California, studied all the research abstracts presented at the 2001 American College of Rheumatology meetings which reported any kind of trial and acknowledged industry sponsorship, in order to find out what proportion had results that favoured the sponsor's drug.

In general, the results section of an academic paper is extensive: the raw numbers are given for each outcome, and for each possible causal factor, but not just as raw figures. The "ranges" are given, subgroups are explored, statistical tests conducted, and each detail is described in table form, and in shorter narrative form in the text. This lengthy process is usually spread over several pages. In Fries and Krishnan (2004), this level of detail was unnecessary. The results section is a single, simple and – I like to imagine – fairly passive-aggressive sentence:

"The results from every randomised controlled trial (45 out of 45) favoured the drug of the sponsor."

How does this happen? How do industry-sponsored trials almost always manage to get a positive result? Sometimes trials are flawed by design. You can compare your new drug with something you know to be rubbish – an existing drug at an inadequate dose, perhaps, or a placebo sugar pill that does almost nothing. You can choose your patients very carefully, so they are more likely to get better on your treatment. You can peek at the results halfway through, and stop your trial early if they look good. But after all these methodological quirks comes one very simple insult to the integrity of the data. Sometimes, drug companies conduct lots of trials, and when they see that the results are

unflattering, they simply fail to publish them.

Because researchers are free to bury any result they please, patients are exposed to harm on a staggering scale throughout the whole of medicine. Doctors can have no idea about the true effects of the treatments they give. Does this drug really work best, or have I simply been deprived of half the data? No one can tell. Is this expensive drug worth the money, or has the data simply been massaged? No one can tell. Will this drug kill patients? Is there any evidence that it's dangerous? No one can tell. This is a bizarre situation to arise in medicine, a discipline in which everything is supposed to be based on evidence.

And this data is withheld from everyone in medicine, from top to bottom. Nice, for example, is the National Institute for Health and Clinical Excellence, created by the British government to conduct careful, unbiased summaries of all the evidence on new treatments. It is unable either to identify or to access data on a drug's effectiveness that's been withheld by researchers or companies: Nice has no more legal right to that data than you or I do, even though it is making decisions about effectiveness, and cost-effectiveness, on behalf of the NHS, for millions of people.

In any sensible world, when researchers are conducting trials on a new tablet for a drug company, for example, we'd expect universal contracts, making it clear that all researchers are obliged to publish their results, and that industry sponsors – which have a huge interest in positive results – must have no control over the data. But, despite everything we know about industry-funded research being systematically biased, this does not happen. In fact, the opposite is true: it is entirely normal for researchers and academics conducting industry-funded trials to sign contracts subjecting them to gagging clauses that forbid them to publish, discuss or analyse data from their trials without the permission of the funder.

This is such a secretive and shameful situation that even trying to document it in public can be a fraught business. In 2006, a paper was published in the Journal of the American Medical Association (Jama), one of the biggest medical journals in the world, describing how common it was for researchers doing industry-funded trials to have these kinds of constraints placed on their right to publish the results. The study was conducted by the Nordic Cochrane Centre and it looked at all the trials given approval to go ahead in Copenhagen and Frederiksberg. (If you're wondering why these two cities were chosen, it was simply a matter of practicality: the researchers applied elsewhere without success, and were specifically refused access to data in the UK.) These trials were overwhelmingly sponsored by the pharmaceutical industry (98%) and the rules governing the management of the results tell a story that walks the now familiar line between frightening and absurd.

For 16 of the 44 trials, the sponsoring company got to see the data as it accumulated, and in a further 16 it had the right to stop the trial at any time, for any reason. This means that a company can see if a trial is going against it, and can interfere as it progresses, distorting the results. Even if the study was allowed to finish, the data could still be suppressed: there were constraints on publication rights in 40 of the 44 trials, and in half of them the contracts specifically stated that the sponsor either owned the data outright (what about the patients, you might say?), or needed to approve the final publication, or both. None of these restrictions was mentioned in any of the published papers.

When the paper describing this situation was published in Jama, Lif, the Danish pharmaceutical industry association, responded by announcing, in the Journal of the

Danish Medical Association, that it was "both shaken and enraged about the criticism, that could not be recognised". It demanded an investigation of the scientists, though it failed to say by whom or of what. Lif then wrote to the Danish Committee on Scientific Dishonesty, accusing the Cochrane researchers of scientific misconduct. We can't see the letter, but the researchers say the allegations were extremely serious – they were accused of deliberately distorting the data – but vague, and without documents or evidence to back them up.

Nonetheless, the investigation went on for a year. Peter Gøtzsche, director of the Cochrane Centre, told the British Medical Journal that only Lif's third letter, 10 months into this process, made specific allegations that could be investigated by the committee. Two months after that, the charges were dismissed. The Cochrane researchers had done nothing wrong. But before they were cleared, Lif copied the letters alleging scientific dishonesty to the hospital where four of them worked, and to the management organisation running that hospital, and sent similar letters to the Danish medical association, the ministry of health, the ministry of science and so on. Gøtzsche and his colleagues felt "intimidated and harassed" by Lif's behaviour. Lif continued to insist that the researchers were guilty of misconduct even after the investigation was completed.

Paroxetine is a commonly used antidepressant, from the class of drugs known as selective serotonin reuptake inhibitors or SSRIs. It's also a good example of how companies have exploited our long-standing permissiveness about missing trials, and found loopholes in our inadequate regulations on trial disclosure.

To understand why, we first need to go through a quirk of the licensing process. Drugs do not simply come on to the market for use in all medical conditions: for any specific use of any drug, in any specific disease, you need a separate marketing authorisation. So a drug might be licensed to treat ovarian cancer, for example, but not breast cancer. That doesn't mean the drug doesn't work in breast cancer. There might well be some evidence that it's great for treating that disease, too, but maybe the company hasn't gone to the trouble and expense of getting a formal marketing authorisation for that specific use. Doctors can still go ahead and prescribe it for breast cancer, if they want, because the drug is available for prescription, it probably works, and there are boxes of it sitting in pharmacies waiting to go out. In this situation, the doctor will be prescribing the drug legally, but "off-label".

Now, it turns out that the use of a drug in children is treated as a separate marketing authorisation from its use in adults. This makes sense in many cases, because children can respond to drugs in very different ways and so research needs to be done in children separately. But getting a licence for a specific use is an arduous business, requiring lots of paperwork and some specific studies. Often, this will be so expensive that companies will not bother to get a licence specifically to market a drug for use in children, because that market is usually much smaller.

So it is not unusual for a drug to be licensed for use in adults but then prescribed for children. Regulators have recognised that this is a problem, so recently they have started to offer incentives for companies to conduct more research and formally seek these licences.

When GlaxoSmithKline applied for a marketing authorisation in children for paroxetine, an extraordinary situation came to light, triggering the longest investigation in the history of UK drugs regulation. Between 1994 and 2002, GSK conducted nine trials of paroxetine in children. The first two failed to show any benefit, but the company made no attempt to inform anyone of this by changing the "drug label" that is sent to all

doctors and patients. In fact, after these trials were completed, an internal company management document stated: "It would be commercially unacceptable to include a statement that efficacy had not been demonstrated, as this would undermine the profile of paroxetine." In the year after this secret internal memo, 32,000 prescriptions were issued to children for paroxetine in the UK alone: so, while the company knew the drug didn't work in children, it was in no hurry to tell doctors that, despite knowing that large numbers of children were taking it. More trials were conducted over the coming years – nine in total – and none showed that the drug was effective at treating depression in children.

It gets much worse than that. These children weren't simply receiving a drug that the company knew to be ineffective for them; they were also being exposed to side-effects. This should be self-evident, since any effective treatment will have some side-effects, and doctors factor this in, alongside the benefits (which in this case were nonexistent). But nobody knew how bad these side-effects were, because the company didn't tell doctors, or patients, or even the regulator about the worrying safety data from its trials. This was because of a loophole: you have to tell the regulator only about side-effects reported in studies looking at the specific uses for which the drug has a marketing authorisation. Because the use of paroxetine in children was "off-label", GSK had no legal obligation to tell anyone about what it had found.

People had worried for a long time that paroxetine might increase the risk of suicide, though that is quite a difficult side-effect to detect in an antidepressant. In February 2003, GSK spontaneously sent the MHRA a package of information on the risk of suicide on paroxetine, containing some analyses done in 2002 from adverse-event data in trials the company had held, going back a decade. This analysis showed that there was no increased risk of suicide. But it was misleading: although it was unclear at the time, data from trials in children had been mixed in with data from trials in adults, which had vastly greater numbers of participants. As a result, any sign of increased suicide risk among children on paroxetine had been completely diluted away.

Later in 2003, GSK had a meeting with the MHRA to discuss another issue involving paroxetine. At the end of this meeting, the GSK representatives gave out a briefing document, explaining that the company was planning to apply later that year for a specific marketing authorisation to use paroxetine in children. They mentioned, while handing out the document, that the MHRA might wish to bear in mind a safety concern the company had noted: an increased risk of suicide among children with depression who received paroxetine, compared with those on dummy placebo pills.

This was vitally important side-effect data, being presented, after an astonishing delay, casually, through an entirely inappropriate and unofficial channel. Although the data was given to completely the wrong team, the MHRA staff present at this meeting had the wit to spot that this was an important new problem. A flurry of activity followed: analyses were done, and within one month a letter was sent to all doctors advising them not to prescribe paroxetine to patients under the age of 18.

How is it possible that our systems for getting data from companies are so poor, they can simply withhold vitally important information showing that a drug is not only ineffective, but actively dangerous? Because the regulations contain ridiculous loopholes, and it's dismal to see how GSK cheerfully exploited them: when the investigation was published in 2008, it concluded that what the company had done – withholding important data about safety and effectiveness that doctors and patients clearly needed to see – was plainly unethical, and put children around the world at risk;

but our laws are so weak that GSK could not be charged with any crime.

After this episode, the MHRA and EU changed some of their regulations, though not adequately. They created an obligation for companies to hand over safety data for uses of a drug outside its marketing authorisation; but ridiculously, for example, trials conducted outside the EU were still exempt. Some of the trials GSK conducted were published in part, but that is obviously not enough: we already know that if we see only a biased sample of the data, we are misled. But we also need all the data for the more simple reason that we need lots of data: safety signals are often weak, subtle and difficult to detect. In the case of paroxetine, the dangers became apparent only when the adverse events from all of the trials were pooled and analysed together.

That leads us to the second obvious flaw in the current system: the results of these trials are given in secret to the regulator, which then sits and quietly makes a decision. This is the opposite of science, which is reliable only because everyone shows their working, explains how they know that something is effective or safe, shares their methods and results, and allows others to decide if they agree with the way in which the data was processed and analysed. Yet for the safety and efficacy of drugs, we allow it to happen behind closed doors, because drug companies have decided that they want to share their trial results discretely with the regulators. So the most important job in evidence-based medicine is carried out alone and in secret. And regulators are not infallible, as we shall see.

Rosiglitazone was first marketed in 1999. In that first year, Dr John Buse from the University of North Carolina discussed an increased risk of heart problems at a pair of academic meetings. The drug's manufacturer, GSK, made direct contact in an attempt to silence him, then moved on to his head of department. Buse felt pressured to sign various legal documents. To cut a long story short, after wading through documents for several months, in 2007 the US Senate committee on finance released a report describing the treatment of Buse as "intimidation".

But we are more concerned with the safety and efficacy data. In 2003 the Uppsala drug monitoring group of the World Health Organisation contacted GSK about an unusually large number of spontaneous reports associating rosiglitazone with heart problems. GSK conducted two internal meta-analyses of its own data on this, in 2005 and 2006. These showed that the risk was real, but although both GSK and the FDA had these results, neither made any public statement about them, and they were not published until 2008.

During this delay, vast numbers of patients were exposed to the drug, but doctors and patients learned about this serious problem only in 2007, when cardiologist Professor Steve Nissen and colleagues published a landmark meta-analysis. This showed a 43% increase in the risk of heart problems in patients on rosiglitazone. Since people with diabetes are already at increased risk of heart problems, and the whole point of treating diabetes is to reduce this risk, that finding was big potatoes. Nissen's findings were confirmed in later work, and in 2010 the drug was either taken off the market or restricted, all around the world.

Now, my argument is not that this drug should have been banned sooner because, as perverse as it sounds, doctors do often need inferior drugs for use as a last resort. For example, a patient may develop idiosyncratic side-effects on the most effective pills and be unable to take them any longer. Once this has happened, it may be worth trying a less effective drug if it is at least better than nothing.

The concern is that these discussions happened with the data locked behind closed doors, visible only to regulators. In fact, Nissen's analysis could only be done at all because of a very unusual court judgment. In 2004, when GSK was caught out withholding data showing evidence of serious side-effects from paroxetine in children, their bad behaviour resulted in a US court case over allegations of fraud, the settlement of which, alongside a significant payout, required GSK to commit to posting clinical trial results on a public website.

Nissen used the rosiglitazone data, when it became available, and found worrying signs of harm, which they then published to doctors – something the regulators had never done, despite having the information years earlier. If this information had all been freely available from the start, regulators might have felt a little more anxious about their decisions but, crucially, doctors and patients could have disagreed with them and made informed choices. This is why we need wider access to all trial reports, for all medicines.

Missing data poisons the well for everybody. If proper trials are never done, if trials with negative results are withheld, then we simply cannot know the true effects of the treatments we use. Evidence in medicine is not an abstract academic preoccupation. When we are fed bad data, we make the wrong decisions, inflicting unnecessary pain and suffering, and death, on people just like us.

• This is an edited extract from Bad Pharma, by Ben Goldacre, published next week by Fourth Estate at £13.99. To order a copy for £11.19, including UK mainland p&p, call 0330 333 6846, or go to guardian.co.uk/bookshop.

Comments

621 comments, displaying Oldest first

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xyzzy
21 September 2012 11:44PM

Good to have you back in the Guardian, Ben.

Recommend (1256)
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sugarymetal
21 September 2012 11:46PM

Thank God for Ben Goldacre!

Recommend (459)
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sugarymetal
21 September 2012 11:47PM

ps: that was meant as a turn of phrase before anyone wants to get engulfed in a theological debate ahem

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alloomis
22 September 2012 12:03AM

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many people see no benefit in a socialist democracy, but here is one: drugs have to pass through a state testing agency. the technicians involved can be isolated from manufacturers. if the manufacturers find a way to bribe the techs, all involved can do time.

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epinoa
22 September 2012 12:05AM

Recommend (209)
Responses (2)
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At least homeopathic remedies are just water and won't harm them (except in their wallet :D)

cloudgroover
22 September 2012 12:16AM

Recommend (535)
Responses (0)
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An incredibly frank admission highlighting what many of us already suspected. Some prescribed drugs do more harm than good.

myfellowprisoners
22 September 2012 12:20AM

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Welcome back, Ben.

Looking up Reboxitine on the internets, I was surprised to see this from Scientific American:

What the study did find is that reboxetine produced more side effects (noted as "adverse events") than placebo (as might be expected), but with no positive effects at all. While many antidepressants on the market today are not great, most are effective in around 60% of patients; reboxetine turns out to be even worse than that.

http://blogs.scientificamerican.com/guest-blog/2010/11/30/the-antidepressant-reboxetine-a-headdesk-moment-in-science/

Looking further, on a NetDoctor article, The most common side effects are:

Very common (affect more than 1 in 10 people) Difficulty sleeping (insomnia). Dry mouth. Constipation. Sweating. Common (affect between 1 in 10 and 1 in 100 people) Headache. Blurred vision. Dizziness or sensation of spinning (vertigo). Loss of appetite. Awareness of your heart beat (palpitations). Increased heart rate (tachycardia). A drop in blood pressure that occurs when moving from a lying down or sitting position to sitting or standing, which results in dizziness and

lightheadedness (postural hypotension). Flushing. Difficulty passing urine, or a sensation that the bladder has not fully emptied (more common in men). Urinary tract infection. Impotence, pain on ejaculation, delayed ejaculation, or pain in the testicles in men. Chills.

http://www.netdoctor.co.uk/depression/medicines/edronax.html

Now, I appreciate that listed side effects are often a legal arse covering, featuring nearly every symptom that ails mankind and that they can be substantially outweighed by the benefits (think chemotherapy) but I

a) can't think that any of the above would be good for a clinical depressive (pains in the testicles!?) and
b) the drug appears to have no, or very little positive effects at all.

In which case, you are taking what is effectively an expensive, 'unpleasant side-effect generator'. Why not try a small, daily dose of Poison Ivy? At least it's cheaper.

The world of Big Pharma seriously needs, to use the quaint expression, to have its comb cut. What with the recent criminal fines levelled against Glaxo for fraud (why is it always a fine, why never a prison sentence for the boardroom suits?), these people are seriously out of control. And obviously taking advantage of lax scrutiny of studies, biased studies and good, old-fashioned payola to get their products in the surgeries of doctors across the world.

Once again, the perfect illustration of what happens when you let light-touch regulatory and 'self-regulation' regimes police our noble, dynamic 'wealth creators'. The latter use every opportunity they can to deceive us, poison us and bilk as much out of us as they they think they can get away with.
Which, sadly, is a lot.

Shan Morgain
22 September 2012 12:39AM

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COMPLAINT TO THE GUARDIAN

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I am now all too well aware of the name of the product which is now associated with a nasty experience.
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MrsaMrsa
22 September 2012 12:41AM

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This is a good article. The crux of the issue is about research, and the drivers towards only publishing certain results - positive results. The impetus for this is widespread, but espescially so for pharmaceutical companies. It is a source of much frustration to myself when trials are completed for drugs but not published - presumably because of a lack of a 'good' finding. Something has to change

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SkookumNT
22 September 2012 12:43AM

Recommend (317)
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It really is a scandal, but what's worse is that many people basically know that drug companies are prepared to lie and cheat for profit. If the problem is so well documented (thanks Ben) and is killing people, what needs to happen to change the situation?

In my little bubble world I would tell drug companies that trials have to be carried out by independent research institutes (universities?) funded by government by charging a licensing fee to cover costs. If not, no sale in the UK, or Europe.

Vedant
22 September 2012 12:56AM

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This is just the tip of the iceberg...the whole system is rotten to the core. Wait till you get into other areas like vaccinations...which are devious beyond belief...second and third generation offspring suffering devastating life destroying complications....oh and I just cannot accept that doctors don't know...there may be one or two naive doctors out there but believe me a lot of them are culpable.

cloudgroover
22 September 2012 12:59AM

Recommend (165)
Responses (0)
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Pharmageddon.....is "the prospect of a world in which medicines and medicine produce more ill-health than health, and when medical progress does more harm than good" -- and it is no longer a prospect but fully upon us.

RememberGiap
22 September 2012 1:11AM

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Excellent well researched article.....journalism at its best .

Lalongcarabine
22 September 2012 1:38AM

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Some years ago a Canadian gentleman died of old age. His GP, who had treated him for the last 25 years of his life, was surprised to learn he had been left something in his will. The bequest came in the form of a large trunk. On opening it, he found every medicine he had prescribed his patient for the last 25 years. Unused!

GreenKnighht
22 September 2012 1:40AM

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Ethical approval for medical research is a tough vigorous thing currently.

The risks of the experiment have to be small and they have to be outweighed by the potential benefits.

So why is it not considered unethical to put patients at risk from an unproven medication and then not publish the results?

It should be unethical because it is putting people at risk from a medication for no benefit, no good reason.

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icerat
22 September 2012 1:44AM

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icerat
22 September 2012 1:47AM

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"Some years ago a Canadian gentleman died of old age. His GP, who had treated him for the last 25 years of his life, was surprised to learn he had been left something in his will. The bequest came in the form of a large trunk. On opening it, he found every medicine he had prescribed his patient for the last 25 years. Unused!"

That's why the man lived so long! He didn't take the drugs! You should try it! You would live a long life too! Because drugs are bad!

Gripemeister
22 September 2012 1:57AM

Recommend (84)
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So, something like Thalidomide, could quite easily happen again.

This is, I think, a serious problem. But who will take a stand against extremely powerful companies and tell them that the X amount of cash they've spent on development of a drug has been wasted because the drug is useless?

That in itself causes problems about development. This isn't a simple problem, all the more complex due to vested interest and perhaps even corruption.

cbarr
22 September 2012 2:00AM

Recommend (180)
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Just red that article one thing jumped into my brain the EU nations collectively have to be one of the biggest markets for drugs if not the biggest in the world change the contracts force any drug being released in Europe to have trials that all 1. have to be reported and 2. Don't contain gagging orders. 2 things and suddenly the issues raised in the above article dissapear. The EU as a body collectively has both the market power to do this and also has the legal strength to enforce coorporate law. So why not use the EU in one of the few clear examples of bennefits as Europe in a common market to do this? Answers on a postcard...

LeeRudolph
22 September 2012 2:06AM

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Responses (0)
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> But it was misleading: although it was unclear at the time, data from trials in children had been mixed in with data from trials in adults, which had vastly greater numbers of participants. As a result, any sign of increased suicide risk among children on paroxetine had been completely diluted away.

A ground-breaking application of homeopathy in statistics!

LoopyTunes
22 September 2012 2:09AM

Response to Shan Morgain, 22 September 2012 12:39AM

This comment was removed by a moderator because it didn't abide by our community standards. Replies may also be deleted. For more detail see our FAQs.

EatsShootsLeaves
22 September 2012 2:36AM

Recommend (183)
Responses (0)

Doctors and the pharmaceutical industry need people to be sick. So, you know, do the maths.....

Report
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headtheball
22 September 2012 3:01AM

Pharmaceutical companies exist to make money, not to make people better.

Recommend (493)
Responses (1)
Report
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makedo
22 September 2012 3:36AM

I've been prescribed Reboxetine and I'm happy to report that I had the pleasure of lots of side effects and none of the supposed benefits. Why thank you Mr. N. H. S. Psychiatrist with no bedside manner whatsoever, thank you.
It's a good piece of work, as we've come to expect from Ben Goldacre, but, unfortunately, none of it is surprising, is it?

Recommend (313)
Responses (1)
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Novelist
22 September 2012 3:48AM

My favourite saying is in Hindi/Urdu, phonetically:
charasee kadina ma'see. Roughly translated as, charas smokers don't die (they just fade away)

Recommend (36)
Responses (0)
Report
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ws2001
22 September 2012 3:54AM

Thank you! Excellent article. I will definitely be buying the book.

Recommend (39)
Responses (0)
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knowanddo
22 September 2012 4:18AM

And any number of people should go straight to the crowbar hotel.....where their prescriptions will be chosen for them.....whether they need them or not. They couldn't be more deserving.

Recommend (5)
Responses (0)
Report
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David91
22 September 2012 4:32AM

As a matter of editorial policy, why are these individual stories not headlined as and when they first come to light? Just as the Guardian claims credit for harassing relevant authorities into action over the hacking scandal, why are you not pursuing the pharmaceutical industry and its supposed regulators?

Recommend (260)
Responses (1)
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PenTan
22 September 2012 5:27AM

Recommend (52)
Responses (0)
Report
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Response to icerat, 22 September 2012 1:44AM

Get the ABP pop up blocker for your browser - ads are a thing of the past.

Fahrettin
22 September 2012 6:53AM

Recommend (19)
Responses (0)
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Dr. Richard Kimble, we need you!

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bbano
22 September 2012 7:08AM

Recommend (102)
Responses (0)
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Response to Shan Morgain, 22 September 2012 12:39AM

Didn't see the advert because I use a browser that can blocks out Ads/Pop-ups, etc. (Firefox in my case but others do that as well).

WolfieKate
22 September 2012 7:10AM

Recommend (98)
Responses (1)
Report
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I'm recovering from a week on Pregabalin for my anxiety. What foul stuff. Neither me nor my GP knew whether it would work or not and now a week after I stopped taking it I still feel very uncomfortable. The thing is for some people a medication can be a life saver but with someone else's unique chemistry it can be a horrible experience. GPs just don't know. And with mental health services stretched to only dealing with psychoses the rest of the patient population have to try a pill with an unknown outcome or pay for private counselling/therapy. I'm opting for hypnotherapy now but at £60 a visit it's not surprising that people with mental illness are seduced by the idea that an NHS provided pill can cure.

Abertawe
22 September 2012 7:23AM

Recommend (118)
Responses (1)
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> Just block everything on the site that you don't want to see. That's what browser add-ons are for. While you're at it, you can remove all the tracking. If you're getting what I'm blocking, there are seven trackers on this page.

Only seven?

Ghostery is reporting - and blocking - 13 trackers on this page. The Guardian is by far the worst website I visit regularly for third-party crap.

Dortmunder2
22 September 2012 7:24AM

Recommend (32)
Responses (0)
Report
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Shan Morgain
Please download an adblocker for your particular browser,this will remove the annoying ads.This remedy works,see you all at the Medicine Show.

ohgollygolly
22 September 2012 7:33AM

Recommend (63)
Responses (1)
Report
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A doctor can bury his mistakes.

Those of us who are not in the medical profession have to face our errors.

Soarer
22 September 2012 7:37AM

Recommend (83)
Responses (1)
Report
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Great article, as always, from Dr Goldacre.

The problem is clearly regulation. But actually, regulations for drug introduction are complex and expensive. It is a prime example of the tick-box culture, and has been for decades. It costs the drug companies a fortune to get a drug authorised and, as pointed out in this article, this often deters those companies from seeking authorisation where the costs could not be covered by the sales.

Yes, drug companies do bad things. That much is obvious. But it is regulation which has failed, by focusing on things that don't matter, and having them endlessly documented, and ignoring the things that do matter, like whether it works and is not harmful.

Regulation done badly, allows useless drugs to be authorised, but also prevents drugs which would be useful being available. The answer is not *more* regulation, but *better* regulation.

retarius
22 September 2012 7:40AM

Recommend (290)
Responses (0)
Report
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Great article and totally true...the industry is corrupt beyond belief (look at the recent marketing fines of billions of dollars). BTW I worked in the industry for 30 years and finally escaped...it's rotten to the core.

heyjoni
22 September 2012 7:51AM

Recommend (48)
Responses (3)
Report
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I often wonder why the GPs themselves as a whole don't run their own trial on newly released drugs. They have the data at

their fingertips. They could send the trial data of patients who have been put on a course of the new drug to some central unit which can process the statistics. It may not be randomised, but any serious issues will still soon become obvious. But some independent trial really must be put in place.

TonyChinnery
22 September 2012 7:53AM

Recommend (9)
Responses (0)
Report
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I remember reading a report into a trial in which it was shown that Prozac is no more effective than a placebo. The interesting thing is that the participants must have known they were in a trial, and that there was a 50% chance that the pills they were taking were just chalk.

bobskiT
22 September 2012 7:58AM

Recommend (17)
Responses (0)
Report
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Woolworths had the best approach - pick and mix (sponsored by the league of philanthropic dentists)

BaronGrovelville
22 September 2012 8:00AM

Recommend (102)
Responses (0)
Report
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Can't be explained in a sound bite?

They lie, we die.

peterainbow
22 September 2012 8:04AM

Recommend (105)
Responses (1)
Report
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> I did everything a doctor is supposed to do. I read all the papers, I critically appraised them, I understood them, I discussed them with the patient and we made a decision together, based on the evidence

wow are you looking for new patients, my experience over the last few years is of a GP who not only didn't do any due diligence on what she was prescribing to me, but also didn't care or know.

so it was i was not told of any side effects from taking SSRIs and also told that they weren't addictive and that there were no withdrawal symptoms, i could just stop whenever i liked.

she also switched my prescription to save money against what my psych had said, again with no knowledge or care about the risks, the side effects of doing this were truly terrible

---

peterainbow
22 September 2012 8:06AM

Recommend (57)
Responses (4)
Report

Response to WolfieKate, 22 September 2012 7:10AM

> I'm opting for hypnotherapy now but at £60 a visit it's not surprising that people with mental illness are seduced by the idea that an NHS provided pill can cure.

i have always liked the idea of doing hypnotherapy, but cannot afford it, i have only been offered CBT and drugs

as it turns out i have aspergers and my depression/anxiety are co morbid symptoms for which drugs is not a solution

why doesn't the NHS offer hypnotherapy, i'm certain it would be helpful for my anxiety and sleep problems which can quickly lead me to disaster...

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zenithmaster
22 September 2012 8:07AM

Recommend (92)
Responses (1)
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Response to Shan Morgain, 22 September 2012 12:39AM

First, you could use any number of ad-blocking extensions for your browser. Second, when even its short-term future is at stake due to an exponential drop in advertising revenue, complaining that The Guardian has adverts is frankly silly.

peterainbow
22 September 2012 8:12AM

Recommend (49)
Responses (0)
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Response to heyjoni, 22 September 2012 7:51AM

> I often wonder why the GPs themselves as a whole don't run their own trial

i suspect many don't care, especially when it's for a mental illness

fyi there are many forums by patients using medication which i have found to be most useful, obviously like anything online needs to be used carefully, but when i was suffering from serious side effects and my GP denied knowledge of the drugs having any, when i looked online i found many people with the same problems which at the very least made me feel that i wasn't mad and in the end helped me come off the drugs

i find it very hard being a socialist in a country where in my time of need i have been left to fend for myself and my family pretty much alone, with little or no support from both from the NHS and the DWP.

the one bright light was the maudsley hospital, the doctors there were very helpful, but so naive about the help/service i would get from barnet mental health, still nothing...

buddednip
22 September 2012 8:18AM

Recommend (29)
Responses (1)
Report

Pharmaceutical drug companies have learned how marketing is

the best way of outgunning the competition, indeed they were amongst the pioneers of sharp practice. Now the same techniques are used to sell branded cosmetics claiming all kinds of exotic effects upon our skins and upon our apparent ages.

As a profoundly deaf person who uses powerful hearing aids I have suffered incessant ear infections, inflammation and irritation simply from constant use of my aids in poor working atmosphere, usually inadequate temperature and ventilation control (of which air conditioning is one of the worse offenders). My GP has prescribed several ear "drops" with anti-bacterial effect but each and every one has failed to secure a lasting remedy. These are very expensive medicines with short shelf lives and yet they are less effective than olive oil or seawater in containing my ear infections.

The hearing aids themselves can be criticised for not addressing the age old problem of earmould design which allows conveyance of an amplified audio signal without constricting the outer ear canal and causing perspiration to build a perfect environment for bugs. Not everyone will use a hearing aid and very few will need to use them permanently as I do. And that is the reason why there is little money in finding a suitable control for ear infections. Perhaps I should find a GP who will prescribe the bark of a willow for most anything.

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FrogStar
22 September 2012 8:20AM

Recommend (23)
Responses (1)
Report
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> reading a report into a trial in which it was shown that Prozac is no more effective than a placebo.

which does not imply that either was ineffective.

FrogStar
22 September 2012 8:22AM

Recommend (32)
Responses (0)
Report
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Haven't you got a more recent photo, Ben ?

maldonglass
22 September 2012 8:24AM

Recommend (44)
Responses (2)
Report
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There should be a simple system for all patients to record the side effects of the drugs they are prescribed - this would provide valuable data on potential problems at an early stage - however the drug companies would oppose this
The drugs used to treat mental illnesses seem particularly pernicious - these patients are in many cases very vulnerable because they may not be able to accurately assess the effects of their medicatgion and it almost seems as if they are used as guinea pigs

The testing systems often concentrate on a small group of people and are not tested on the whole range of age groups and human types - everyone is different and the impact of drugs varies enormously
The costs of drugs are a huge drain on the NHS
It should be unlawful for doctors to prescibe drugs as a result of receiving 'free holidays' from drug companies
I personally try to avoid any medication

Giorock
22 September 2012 8:29AM

Response to Shan Morgain, 22 September 2012 12:39AM

Use an iPad.....the ads don't show up.....!

Recommend (6)
Responses (0)
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