

Big pharma often commits corporate crime, and this must be stopped

Tougher sanctions are needed, says **Peter C Gøtzsche**

When a drug company commits a serious crime, the standard response from the industry is that there are bad apples in any enterprise. Sure, but the interesting question is whether drug companies routinely break the law.

I did an internet search of the names of the 10 largest drug companies in combination with the term “fraud” and looked for offences on the first page for each company. The most common recent crimes were illegal marketing by recommending drugs for non-approved (off-label) uses, misrepresentation of research results, hiding data on harms, and Medicaid and Medicare fraud.¹ All cases were related to the United States and involved huge settlements or fines, exceeding \$1bn (£620.6m; €769m) each for four companies.

It was easy to find additional crimes committed by these same companies and committed outside the US.¹ As the crimes were widespread and repetitive, they are probably committed deliberately—because crime pays. Pfizer, for example, agreed in 2009 to pay \$430m to resolve charges related to illegal marketing of gabapentin (Neurontin), but as sales were \$2.7bn in 2003 alone, and as about 90% was for off-label use, such fines are far too small to have any deterrent effect. When Pfizer was fined \$2.3bn for off-label use of four other

drugs, also in 2009, the company entered into a corporate integrity agreement with the US Department of Health and Human Services to detect and avoid such problems in future. Pfizer had previously entered into three such agreements in the past decade.²

Of the top 10 drug companies, in July 2012 only Roche was not bound by such an agreement. However, over 10 years in the 1990s high level executives in Roche had previously led a vitamin cartel that, according to the US Justice Department, was the most pervasive and harmful criminal antitrust conspiracy ever uncovered.³ Roche agreed to pay \$500m to settle charges, equivalent to about one year’s revenue from its US vitamin business.

Doctors are often complicit in these crimes, as kickbacks and other forms of corruption were common; they were induced to use expensive drugs and paid to lend their names to ghostwritten articles purporting to show that a drug works for unapproved conditions.¹

The disconnect between the drug industry’s proclamations—of the “highest ethical standards,” of “following . . . all legal requirements,” and providing “most accurate information available regarding prescription medicines”^{4,5}—and the reality of the conduct of big pharma is vast. These proclamations are not shared by the companies’ employees or experienced by the public.

Many crimes would be impossible to carry out if doctors weren’t willing to participate in them

An internal survey of Pfizer employees in 2001 showed that about 30% didn’t agree with the statement, “Senior management demonstrates honest, ethical behavior.”⁶ When 5000 Danes ranked 51 industries in terms of the confidence they had in them, the drug industry came second to bottom, beaten only by automobile repair companies. A US poll also ranked the drug industry at the bottom, together with oil and tobacco companies.

The consequences of these crimes are huge, including the unnecessary deaths of thousands of people and many billions in losses for our national economies every year.⁷ As doctors have access only to selected and manipulated information, they believe that drugs are far more effective and safe than they really are. Thus, both legal and illegal marketing leads to massive overtreatment of the population. In the US, the most sold class of drugs in 2009 (in US dollars) was antipsychotics. Antidepressants came fourth, after lipid lowering drugs and proton pump inhibitors. It is hard to imagine that so many Americans can be so mentally disturbed that these sales reflect genuine needs.

It is time to introduce tougher sanctions, as the number of crimes, not the detection rate, seems to be increasing.⁸ Fines need to be so large that companies risk going bankrupt. Top executives should be held personally accountable so that they would need to think of the risk of imprisonment when they consider performing or acquiescing in crimes. To bring the crimes to light also outside the US, we need laws that protect whistleblowers and ensure they get a fair proportion of the fines. We also need to avoid the situation that, by settling accusations of crimes, drug companies can pretend they are innocent, which they often do.

We also need laws requiring firms to disclose all knowledge about their drugs and research data,⁷ and laws that not only allow but require drug agencies to publish what they know, without hiding under some absurd “proprietary nature of companies’ trial results” clause, as happened with rosiglitazone⁹—with the consequence that the public was not informed that the drug causes myocardial infarction.

Last but not least, doctors and their organisations should recognise that it is unethical to receive money that has been earned in part through crimes that have harmed those people whose interests doctors are expected to take care of. Many crimes would be impossible to carry out if doctors weren’t willing to participate in them.^{1 10 13}

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A fuller account is at <http://bit.ly/VLH8A>.
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● Feature: Letting the sunshine in on doctor-pharma relationships (*BMJ* 2011;343:d6459)

● Views and reviews: Don’t just blame big pharma (*BMJ* 2012;345:e4825)

● EDITORIAL, p 7



BELLE MELLOR

FROM THE FRONTLINE **Des Spence**

Imagine all the people

“What do you see?” he breathed down my neck. I squinted down the microscope. All I saw was a collection of stained circular blobs where pancreas cells should be. We were supposed to sketch this in drawing books. “Elephants,” I exclaimed—for the exercise was rubbish as far as I was concerned, but histology was no place for the flippancy. Next week, a friend winked at me and furtively pulled out a histology atlas. I beamed in appreciation. We traced round the photos of cell structures and then coloured them in. This is not cheating, just showing initiative.

Medicine is about pattern recognition, with images branded into the memory (many I wish I had never seen). Indeed an image is worth a thousand words. In the past there was a real poverty of clinical images. Many textbooks had pictures that were either black and white, small, ancient, or hospital based, showing gross examples of disease. These



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images were hopelessly misleading because disease presents in many different ways. Classic medical images were like classic textbook descriptions of disease—largely useless. But access to knowledge through the internet has changed medicine forever; it is just that the profession has not realised this yet.

The prison of the NHS blocks most internet content. But liberate yourself with a mobile phone or a 3G enabled tablet to see the extent of the information revolution. Google Images has a vast array of clinical pictures of illness, rashes, parasites, drugs, devices, and just about any other conceivable medical image that we might desire. YouTube has coughs, wheeze, demonstrations of inhaler technique, discussion of diseases, and the rest. These are useful aids in teaching and useful in the consultation too. And modern imagery cuts both ways, with patients often bringing in photos taken

on smartphones. Real time video links such as FaceTime and Skype offer a type of medical triage once only dreamed of. The possibilities for electronic imagery are endless.

The procurement record for information technology in the NHS makes the Ministry of Defence's inept unaccountable officials look positively entrepreneurial. All central NHS attempts at telemedicine should be abandoned. They are snared in medicolegal confidentiality neuroticism, overcomplicated, always attempting to reinvent the wheel, and so security obsessed as to make them functionless. Much NHS information technology is defunct on the day of commissioning. Healthcare professionals at a local level should be freed to use the current technology, to explore, and to imagine the range of possibilities to improve healthcare.

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STARTING OUT **Kinesh Patel**

End the silence on animal products in drugs

“I am sorry, Mr Goldstein, but you are just going to have to eat your bacon for breakfast. The same goes for you, Mr Khan. Just pretend it's something else. If you don't eat it you'll never get better, will you?”

It sounds ridiculous, doesn't it? We would never dream of being that insensitive to religious preferences—or other personal choices. So it strikes me as really quite odd that when it comes to drugs we actually are that insensitive. We avoid the issue of giving people products that they would refuse to put in their mouths if they knew what was in them, by simply not telling them what is in them.

As Jerome K Jerome notes in *Three Men in a Boat*, after inadvertently drinking water from the River Thames without harm: “What the eye does not see, the stomach does not get

upset over.” In this case it's “What the eye does not see, the sensibilities don't get upset over.”

One culprit is Gelofusine—or, as I like to think of it, boiled beef bones in a bag. I can't think of a scenario when it has been essential to give this to a patient, because there are plenty of alternatives that are acceptable to vegetarians. Yet we never consider this. “Just squeeze in the Gelo,” is the familiar command echoing around emergency departments and anaesthetic rooms.

Drug capsules are another problem because they are principally made from gelatine derived from pork or beef. Even though drug packaging has plentiful information about allergies and so on, it makes no mention of animal products used. In the current climate, where beefburger manufacturers use our equine friends



Where beefburger manufacturers use our equine friends and bovine prey interchangeably, is not our duty even clearer to check what is in the tablets we prescribe?

and bovine prey interchangeably, is not our duty even clearer to check what is actually in the tablets we prescribe?

About 10% of the adult UK population is vegetarian.¹ Hindus, Jains, Muslims, Jews, and Buddhists might also object to some of these products. A first step to consider these patients' interests would be to mark every drug in the *British National Formulary* that contains animal byproducts. Alternatively, hospitals should wean themselves off the non-vegetarian items they buy, just as they have largely done for latex. The current silence and ignorance is not defensible in a modern multicultural NHS.

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