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From: **Arthur Schafer** < Arthur. Schafer@ad.umanitoba.ca>

Date: 22 November 2012 18:52

Subject: my rant

To: "David Healy (david.healy54@googlemail.com)" <david.healy54@googlemail.com>

Hi, David,

There was recently some discussion on the Biojest Listserv about your new book (which I thought was wonderful and recommended highly – except when I found it maddening) and Ben Goldacre's new book.

FYI, I posted the following comments on your book (and Ben's).

Since I count you as a valued friend, it didn't seem right that I should criticize your views without alerting you to the posting.

In solidarity, Arthur

Ps: I'm excited about prospects for the Rxisk website but I find it difficult, i.e., quite technical in the way it presents information. I fear that most ordinary folks will find it intimidating. Compared to *Worst Pills*, e.g., it's going to be a tough slog for most non-scientists/non-physicians. [E.g., you mostly use chemicalgeneric names rather than brand names.] Has anyone else responded to the site in this way?

On 2012-11-20, at 8:51 PM, Arthur Schafer < Arthur.Schafer@ad.umanitoba.ca > wrote: Every Biojester who has not already purchased and read Ben Goldacre's book *Bad Pharma* and David Healy's book, *Pharmageddon*, should do so forthwith. Both books are beautifully written (though Goldacre's is more journalistic and will be more accessible to a wide public and Healy's may appeal more to the scientifically literate) and both are packed with insightful analysis and a devastating critique of Big Pharma.

But, as the critique of Goldacre's book (circulated earlier today by Jo Ann Cook) points out, Goldacre's analysis has definite limitations and his reformist conclusions miss (in the words of economist Henry Shutt) "some blindingly obvious inference[s]". Shutt's most telling point against Goldacre is that Pharma could not stay in business if it were not allowed to continue licencing and marketing drugs that are useless at best and harmful at worst. I.e., medical research cannot have integrity and social utility so long as researchers, whose mandate is the pursuit of truth, are "partnered" in a connubial relationship with industry, whose mandate is maximizing shareholder profit. Goldacre's concluding recommendations for reform, in other words, are feeble in comparison to the depth of the problem his analysis uncovers. [That used to be true, btw, of Marcia Angell's writing on this topic. No longer. She's become a tiger. Go, Marcia.]

The same reformist blindness found in *Bad Pharma*, I'm sorry to say, is true of David Healy's *Pharmageddon*. Or, rather, it blights his book's final conclusions.

Healy makes many true and important points but he is maddeningly blind to the importance of conflict of interest in explaining and giving coherence to the various problems he rightly identifies as prime suspects. It's probably unnecessary to say this but I will say it anyway: I count David Healy as a friend as well as a colleague. I have learned much from him, both in personal conversations and when we've shared public platforms together, and from his books. But he has learned nothing from me and, worse, he has learned nothing from the many fine scholars who have explored the seminal role played by biomedical conflicts of interest in generating all the problems which he recognizes but whose genesis he can't see.

Healy thinks that attributing the lack of research integrity (in current Pharma-sponsored research) to COI is "superficial". The real problem, Healy claims, is "deeper", and resides, primarily, in industry's "unwillingness to allow access to the data". [Like Ben Goldacre, David somehow misses the point that if Pharma allowed access to all its raw data and if scientists had the independence to analyse that data honestly then Pharma could not stay in business, creating wealth and employment for its shareholders and jobs for the boys (and girls).]

David's dismissive attitude to the claim that COI is critically important to understanding what's wrong with contemporary medicine and contemporary medical research occupies primarily the last few pages of *Pharmageddon*. But in several of his published articles he proudly announces that he has accepted money from many of the world's leading drug companies. He has consulted for them, he tells us, and his research has been funded by them. Not only that, David admits (proclaims, even) that he has been biased by this funding and these consultancies and other perquisites that have come his way from his financial associations with industry. But, he insists, that it's no big deal because he, like everyone else (including every researcher), is biased anyway. In other words, we shouldn't get our knickers in a twist about the fact that the biomedical literature is produced by (or at least purports to be authored by) researchers who are consultants to industry, funded by industry, hold shares in the companies whose drugs they are investigating, serve on speakers' bureaux, etc. The argument Healy puts forward is that bias is ubiquitous and ineradicable and that we should simply accept it as inevitable.

David points out that there are many sources of bias in addition to financial self-interest. E.g., he proclaims (in his excellent review of Shuchman's book, published in the Monash Law Review, I think it was) that he finds Nancy Olivieri attractive and that this physical attraction biases his judgement in her favour. Somehow, he fails to notice that the many biases, personal prejudices and career self-interest, etc., to which we are all susceptible (as he rightly points out) are highly various and tend to cancel each other out. That is, they point in many different directions. Some people find Nancy irresistible. But perhaps there are people who find Miriam Shuchman attractive. OK, that's not a good example, but you get my point. Individual researchers and research institutions have many competing biases and interests. But what is critically important, in my judgement, is the fact that Pharma funds almost all clinical trials and the fact that when Pharma funds trials they turn out to be marketing exercises rather than science. The bias is all in one direction. On David's analysis, this is unimportant. That is, he fails to see that financial conflicts of interest are hugely powerful and push powerfully in **one** direction only: the marketing of Pharma's products, regardless of the cost in terms of integrity, patient health or health care financing.

If we are to avoid Pharmageddon, David says, we must insist on open access to the raw data of clinical trials. [This is not his only prescription but it's his central panacea.] Somehow, he fails to notice that with all the great drug disasters, past and present, notwithstanding the fact that masses of critical data have been exposed to view by people such as David himself, conflicted Key Opinion Leaders continue to sell their colleagues on dangerous/useless drugs and the medical community continues to listen (over fancy dinners) to their ghost-written pitch and government regulators continue their role as handmaidens to industry and medical faculties and research hospitals continue to fall all over themselves in their oleaginous attempt to attract donations from the likes of Apotex or Ely Lilly or Pfizer. We have access to loads of data on the uselessness of SSRIs for mild to moderate depression. So, how does David explain the fact that these drugs continue to attract millions of prescriptions and billions of dollars annually in profit. There is no shortage of data demonstrating that statins (for primary prevention) may lower cholesterol and may reduce heart attacks and strokes but they don't improve all-cause mortality.

In practice, we will never get **effective** open access to raw data from clinical trials because governments, in the pocket of industry, may pass regulations requiring trial registration and access to data but will never enforce them (for the reason given above) and if, *per impossibile*, we had open access then it wouldn't matter much anyway. We would learn, as we already have learned, that when you look at all the data there is no good evidence to support the massive prescription of anti-depressant drugs, of anti-psychotic drugs, of cholesterol lowering drugs (for primary prevention), of bone density drugs (for pre-osteoporosis), of Celebrex (for arthritic pain), of Avandia (for diabetes), of Herceptin, of ... of... but we will discover that notwithstanding a plethora of available data, analysed often by one or other Cochrane review, the prescriptions continue to be written by the millions and the cash register continues to make its pleasant ka-ching sound.

Sorry for this rant.

Arthur

Arthur

As you know i love you to bits, would greatly appreciate if you could post the following response.

What DH is trying to do - perhaps misguidedly - is say that science does not depend on scientists being moral or saintly. (He certainly isn't and has never pretended to be). It is a group process that has little to do with the integrity of individuals. Individual studies may be flawed by conflicts but the process is self-correcting if there is access to the data so that competing biases can be brought to bear on an analysis - and ultimately those with no vested interests in an issue tip the balance.

Lack of access compromises this process. But access to the data is not all. There are forms of knowledge that can be biased. Controlled trials ipso facto introduce a bias that can be

detrimental to good patient care and making these trials publicly rather than privately funded does not solve the bias.

There is a good case these days to make that anyone who promotes controlled trials even fully publicly funded trials plays into industry hands

I hope to post a lecture on this topic soon - and would welcome a response from all biojesters on the content.

David

Hi, David,

I just posted your response on Biojest and will, if there are responses, pass them along to you.

My own response (not posted on Biojest) is that those who see COI as *the* major factor working to undermine research integrity do not then propose that the solution to the problem is for scientists to become "moral or saintly". The solution is to prohibit research COIs by allowing only arm's length funding.

There is much more to be said but you are safely tucked up in bed by now, (or so I hope), and I am ready for dinner.

Best.

Arthur

Perhaps you could post just what you've said here and then my response which is two-fold. (I pressed send too quickly last night)

Arms' length funding is not the answer. Science needs the biases brought by funding, as well as the bases brought by delusions, passions and all kinds of other conflicts - this is the cauldron out of which insights are borne.

But I am not referring here to policy. In the policy domain we have to take a different approach to conflicts as there is no self-correcting mechanism at play. And then there is clinical practice where we have the huge conflicts introduced by the availability of treatments on prescription only - something you steer clear of.

The paradox is this - we want doctors to be biased by treatments that work and best quality evidence. The only people who are not conflicted in this sense are people with nothing to offer a patient. I go to a medical doctor rather than an alternative practitioner precisely because of their conflicts of interest - but Pharmageddon suggests we may fast be reaching a tipping point where it might not be wise for me to go to a medical doctor.

I recently have given lectures on just this point - under the heading of Professional Suicide. Here attached is a link to the content of these talks that it would be great to get responses to.

http://davidhealy.org/wp-content/uploads/2012/11/2012-medical-partizans.pdf

I don't pretend to know at the end of the day if my conflicts as a prescribing doctor depending on evidence make me a good doctor or not. Nor do I know if your detachment from the corruptions of the clinical domain give you a clearer insight or not. But whatever about learning from you, I do take the issues that you and Carl and others raise with the utmost seriousness.