

Doctors as lapdogs to drug firms: Independence may be most cost effective way to improve health care

Peter R Mansfield

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Notes

Letters

How doctors' anonymity in family courts is under threat

Gornall is way out of date

EDITOR-Gornall is embarrassingly out of date in his detailed analysis of the B case (which was dealt with by the family courts nearly three years ago), and its relevance to proposed changes in the law to make the English family court system more transparent.1

Since then, notwithstanding the ever increasingly exaggerated claims from some quarters that opening the family courts would harm children and deter court experts, the courts themselves are acknowledging the need for English family courts to do their business in the more transparent way that courts in Canada, Australia, and of course Scotland have done without apparent difficulty for years, Several High Court judgments have recorded judicial support for more openness to increase public confidence, and Gornall fails to mention that the president and many of his senior judges are in favour of change in this direction.

In a landmark case which was decided on 3 November, Munby J agreed that an ongoing case where parents dispute expert evidence that they injured their child should be open to the media. The local authority concerned issued a "position statement" to the press and the reporting in the Times, Guardian, and the Mail on Sunday set out both sides' cases, as did the broadcasting media. A BBC "Real Story" programme on the case allowed a senior official from the local authority ample time to put their case. No vilification of any experts involved was reported.

It is likely that more judges will follow Munby J's example and more public interest cases will be opened to the media pending any change in the law.

Will the skies fall in? I doubt it, but your readers can judge for themselves. Hopefully they will understand that in complex childcare cases where expert evidence may



be tenuous and the stakes for children are very high, public debate can stimulate awareness of the problems faced by all professionals involved in child protection. It's difficult getting the balance right, but doing it in secret doesn't help.

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Competing interests: SH is the subject of the article.

1 Gornall I. How doctors' anonymity in family courts is under threat. BMJ 2006;333:1024-5. (11 November.)

Author's reply

EDITOR-Despite her enthusiasm for openness, Sarah Harman still seems unwilling to disclose the names of the journalists she has recruited to her campaigning organisation FACTO (Families Action for Court Transparency and Openness). Will she now do so? Perhaps readers might be better equipped to evaluate the many newspaper articles purporting to expose alleged wrongdoings of the family court if the allegiances and agendas of the journalists behind them were a little more transparent.

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Competing interests: JG is the author of the

Doctors as lapdogs to drug firms

The beast is ourselves

EDITOR-Fugh-Berman is correct that we need to bite something tender and to get out of that lap.1 But we are fighting the wrong beast. The beast is not the pharmaceutical industry-it is ourselves.

Pharmaceutical companies sell products under the banner of science. But their only raison d'être is to make money. Industry has to balance genuine hypothesis testing and transparency against commercial interests and the financial consequences of dishonesty. This is not in itself a criticism-it is a simple fact.

It is also of course true that the industry provides products which are often beneficial to our patients. It is equally evident that many actions of industry have not resulted

in benefit, and have instead caused harm. More importantly, we are often completely unable to assess the degree of harm, because information is hidden by gag clauses, the threat of litigation, and cosy commercial arrangements between the regulators and

We, as doctors, have created the atmosphere which has allowed companies to malfunction. We have allowed industry to subvert the rules of science.3 We have watched quietly as governments and academics have colluded with industry to hide information critical to our patients. We have remained silent as our medical schools have churned out graduates who have no knowledge of the dilemmas and scandals of medicine. We have allowed many of our medical journals to become corrupted and timid. The soft parts that need biting may well be our own.

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Competing interests: AB is involved in a dispute with Procter and Gamble Pharmaceuticals over hiding of research data and research integrity. www.slate.com/id/2133061/

- 1 Fugh-Berman A. Doctors must not be lapdogs to drug
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Independence may be most cost effective way to improve health care

EDITOR—I hope Fugh-Berman's talk is effective in prompting drug companies to cease their involvement in medical education.1 If so, stopping such talks could be the most cost effective way to improve health care because exposure to drug promotion correlates with suboptimal health care.2 That includes the subtle promotion in disguise that makes involvement in medical education profitable for drug companies.

The main barrier to progress is doctors' denial that we are often adversely influenced by drug promotion. This denial arises partly from ignorance of the evidence about drug promotion,^{3 4} partly from overconfidence,2 and partly from refusal to believe that evidence because it is seen as insulting our self esteem.5 We need to move from the illusion that being misled is unlikely or shameful to accepting that it is normal for humans to be vulnerable to misleading promotional techniques.⁵ There is no proved method for obtaining more good than harm from exposure to drug promotion¹ so we should all follow Fugh-Berman's

call to stop being lapdogs to the pharmaceutical industry.

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Competing interests: I am the Director of Healthy Skepticism Inc. www.healthyskepticism.org

- 1 Fugh-Berman A. Doctors must not be lapdogs to drug firms. *BMJ* 2006;333:1027. (11 November.)
- 2 Mansfield PR, Lexchin J, Wen LS, Grandori L, McCoy CP, Hoffman JR, et al. Educating health professionals about drug and device promotion: advocates' recommendations. PLoS Med 2006;3(11):e451. medicine.plosjournals.org/perlserv/request=get-document&doi=10.1371%2Fjournal.pmed.0030451
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Not lapdogs, not pit bulls

EDITOR—In response to Fugh-Berman, ¹ first of all, for ethical reasons, let me declare my conflict of interests: I am a medical marketing consultant for the pharmaceutical industry in Brazil. As an American trained physician, after my return to my homeland back in the 70s, I could feel the size of ignorance of the poorly informed Brazilian doctors, who are by no means more or less ignorant than doctors from other underdeveloped (or developing, if you wish) countries. Even in well developed countries the quality and the level of information held by doctors is variable and "not all doctors are educated equally."

My specialty is the development of continuing medical education projects for the pharmaceutical companies, which share with me the basic concept of intelligent medical marketing: promote the global understanding of the pathology first and then let the doctors know about your products in a balanced and ethical way. But, like drinking and driving, never mix medical information with product promotion.

Is this an easy task? Obviously not. Most of the drug companies behave just like you said, trying to turn doctors into lapdogs and being very successful on it. How can we transform this promiscuous relationship into an ethical and reliable source of medical information? The answer is strict regulation and intelligent control of educational materials produced by the pharmaceutical industry.

As a member of the National Health Council of the Brazilian Ministry of Health, I am working on a proposal based on the concepts described above for the implementation of regulatory legislation that would allow freedom with responsibility for the pharmaceutical industry to promote continuing medical education projects.

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1 Fugh-Berman A. Doctors must not be lapdogs to drug firms. *BMJ* 2006;333:1027. (11 November.)

Knee pain interventions show no net gain

EDITOR—The conclusions of the study by Hay et al¹ can be paraphrased as, firstly, physiotherapy plus medication advice provides perceived benefit in patients with knee pain for up to three months and then there is no benefit. Secondly, inappropriate prescriptions of anti-inflammatory drugs can be reduced if the prescriber adheres to good practice. Thirdly, some people who are enrolled in a study and told they will be followed up for 12 months consult their general practitioners less often in the first six months than a control group.

It follows from the above that after three months, patients with knee pain receiving this treatment package are no better in terms of pain levels or functional measures than patients untreated—so why provide this treatment? If general practitioners can be encouraged to prescribe appropriately, the role of the pharmacist in this context is redundant. After six to 12 months, patients either retain or resume their old habits in terms of visits to their general practitioner.

Bottom line? There is no net gain.

I fully support the profession of physiotherapy and admire the high levels of skill demonstrated by my colleagues from this profession. However, in my opinion, the profession is done no favours by presenting these findings as "evidence" of anything. Certainly there would be no grounds to commission a service based on these findings.

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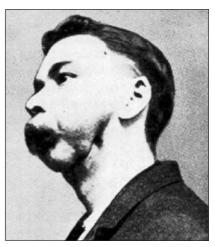
Competing interests: None declared.

1 Hay EM, Foster NE, Thomas E, Peat G, Phelan M, Yates HE, et al. Effectiveness of community physiotherapy and enhanced pharmacy review for knee pain in people aged over 55 presenting to primary care; pragmatic randomised trial. BMJ 2006;333:995-8. (11 November.)

Osteonecrosis of the jaw and bisphosphonates

Editorial was confusing

EDITOR—The recent editorial by Landis et al has added confusion rather than clarity to the issue of osteonecrosis of the jaw (ONJ) in association with the use of bisphosphonates.¹ They do not distinguish between the use of very high doses of intravenous bisphosphonates (monthly pamidronate or zoledronate) to treat patients with malignancy, and the use of much lower doses of bisphosphonates (approximately 1/12 of the oncology dose)



Phossy jaw

in the treatment of Paget's disease or osteoporosis. These two different uses of bisphosphonates have been associated with different risks for ONJ. The authors quote an incidence of 1-10% for ONJ in association with bisphosphonates.¹ However, they fail to indicate that this estimate relates to people with malignancy treated with high dose intravenous bisphosphonates. They also refer to ONJ as "avascular osteonecrosis of the jaw".¹ ONJ is not usually termed "avascular" since reduced vascularity has not been proved to be an aetiological factor in ONJ associated with bisphosphonate treatment.

Most patients who receive bisphosphonates are prescribed them for osteoporosis or Paget's disease. By March 2006, about 170 cases worldwide of ONJ in association with alendronate had been reported to the manufacturer (Merck).2 There are few clinical details available for most of these cases. In 2004, it was estimated that there had been about 20 million patient-years of alendronate treatment for osteoporosis or Paget's disease.3 While it is possible that under-reporting of cases of ONI has occurred, this would have to be very substantial to significantly alter the very low incidence. No cases of ONI were reported in randomised controlled trials of alendronate, risedronate, zoledronate, and ibandronate in non-malignant skeletal disease that collectively included more than 60 000 patients treated for at least two years.4 In the recently completed three year trial of annual zoledronate in >7000 postmenopausal women with osteoporosis, there was one case of ONJ in the zoledronate group, and one in the placebo group-interestingly the latter patient had never received any bisphosphonate treatment.5 Therefore, while the incidence of ONJ in patients treated with bisphosphonate for Paget's disease and osteoporosis is difficult to determine, it is very likely to be less than one in 60 000.

The authors recommend that all people have a specialist dental review before starting bisphosphonate treatment, in agreement with other dental authorities, even though they acknowledge that this approach has not been proved to prevent

ONJ. For patients with osteoporosis and Paget's disease, who appear to have an extremely low risk of ONJ, this intervention (even if it was 100% effective) is not likely to be cost effective, and may lead to unnecessary invasive dental procedures, with attendant morbidity.

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Competing interests: None declared.

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Historical lesson from occupational

EDITOR-100 years ago the manufacture of matches using yellow phosphorus was subject to an International Convention in Berne (1906), which resulted in substitution of yellow phosphorus for phosphorus sesquisulphide and the control of a disease "phossy jaw." This was an extensive necrosis, usually of the mandible, which developed after a latent period of anything up to five years after first exposure in those who manufactured matches. Those affected became disfigured, and secondary infection was a common cause of death with a 20% case mortality.1 The first case was described in 1845,2 but it took 60 years to ratify an international convention and introduce laws to control the problem.

It is of interest that the same problem has resurfaced with the use of bisphosphonates.3 The addition of antibiotics and preventive dental care may reduce the severity of the condition but it is likely that the re-emergence of this condition may be controlled only by restriction of the use of biphosphonates in future.

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Competing interests: None declared.

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- 2 Hamilton A. Exploring the dangerous trades. Beverly, MA: OEM Press, 1995.
 3 Landis BN, Richter M, Dojcinovic I, Hugentobler M.
- Osteonecrosis of the jaw after treatment with bisphosphonates: is irreversible, so the focus must be on prevention. BMJ 2006;333:982-3. (11 November.)

Predicting mental illness in soldiers

Pre-deployment screening for vulnerability to post-traumatic stress disorder

Editor-Rona et al have conducted an important study of UK military personnel with a large, statistically powerful cohort. Hyams points out the confounding "healthy warrior" effect.2 This, together with the marked differences between conscripted and volunteer groups, makes it difficult to extrapolate findings from the first and second world wars to the modern era. Nevertheless, there is a powermessage that posttraumatic stress disorder (and

other mental disorders) are difficult to predict, with the implication that ex-service personnel are likely to present to civilian mental health services with such conditions. As a substance misuse service, we have seen post-traumatic stress disorder with drug and alcohol misuse as the index symptom in several such people and have found Combat Stress (based in Leatherhead, Surrey) a very useful organisation, not least because of the ability to tap into the "healthy warrior" effect through group and individual therapies, allowing us to treat the addictive behaviours in context.

Predicting mental

illness in soldiers

Post-trauma debriefing is possibly harmful,3 so service personnel need vigilant monitoring for mental disorder after the fact. This is particularly important when they leave the protective group environment provided by military life. More attention should be paid to the transitional and demobilised phases to allow early detection of post-traumatic stress disorder emerging from a dormant phase. Often, on discharge, ex-service personnel feel abandoned, adding to the sense of anomie experienced by those with post-traumatic stress disorder. There is a case for all mental health services to receive training in helping them accept generic treatment and access more specialised input, where indicated.

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Competing interests: None declared.

- 1 Rona RJ, Hooper R, Jones M, Hull L, Browne T, Horn O, et al. Mental health screening in armed forces before the Iraq at. Mentai neatin screening in armed forces before the trad war and prevention of subsequent psychological morbidity; follow-up study. *BMJ* 2006;333:991-4. (11 November.)
 2 Hyams KC. Mental health screening before troop deployment. *BMJ* 2006;333:979-80. (11 November.)
 3 Rose S, Bisson J, Churchill R, Wessely S. Psychological
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Too broad a conclusion

EDITOR—We read with interest the article by Rona et al on mental health screening in the

armed forces before the Iraq war and prevention of subsequent psychological morbidity.1 We disagree with the conclusion that pre-deployment screening would not have reduced morbidity from common mental illnesses. This is too broad a conclu-

sion. All that may be concluded is that the screening tools employed by the researchers did not predict morbidity.

When looking at the three main scores used (GHQ-12, SF-36, and PCL-C), it is clear that these tools were designed for a "snapshot screen" in time. None was designed as a predictor of future mental illness.2-Military deployment occupies a unique position in that it will almost invariably expose individuals to signifi-

cant psychological insult. The concept of predeployment screening therefore poses the unique question: what predisposes an individual to mental illness given an imminent, predictable insult? To our knowledge, there is no assessment tool that is designed to answer this question.

We share the authors' disappointment that the commonly used mental health screening tools have not proved useful in predicting illness. However, we advise caution against a broad statement that screening for common mental disorders before deployment does not reduce morbidity. We must not discourage future researchers from devising more appropriate predictive tests for these debilitating diseases in this unique group of

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Competing interests: None declared.

- 1 Rona RJ, Hooper R, Jones M, Hull L, Browne T, Horn O, et al. Mental health screening in armed forces before the Iraq
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Statins and outcomes in patients with pneumonia

Not only healthy user bias

EDITOR—We read with interest the article on the use of statins for patients with pneumonia.1 Although an important addition to the literature, several issues limit this article's usefulness.

The choice of an outcome measure combining in-hospital mortality and admission to intensive care is curious for a



prospective study with such a rich clinical database. Previous research shows that 30 day mortality is largely pneumonia related,2 and from our recent study,3 33% of deaths were after discharge and before 30 days. A preferred way to examine the impact of statins on sepsis would be to examine sepsis-related outcomes (vasopressor use, incidence of severe sepsis, or mortality

The findings that age >65 years, ischaemic heart disease, and using levofloxacin are protective, or that PSI4 class III has an odds ratio of 2.45, have not been previously reported and seem implausible. Inclusion of younger subjects who are less often prescribed statins, and are at much lower risk for mortality, reduces the ability to see an effect. A specific list of variables entered into the final model would be informative to assess potential multicollinearity.

We also believe it is inappropriate to label the odds ratios as "potential harm" or "potential benefit" as all of the 95% confidence intervals include 1.0. These odds ratios and 95% confidence intervals show no association, not potential "harm" or "benefit."

Overall, the study suffers from faults in the study analyses, notably a failure to assess interactions and multicollinearity in the face of counterintuitive results, undermining the contention that previous findings may be attributable to healthy user bias. Future research needs to adjust for factors associated with healthy user bias, patient frailty, and other forms of potential confounding. Only well designed randomised controlled trials will be able to determine finally whether statins have a role in the management of serious infectious diseases.

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Competing interests: None declared.

- 1 Majumdar SR, McAlister FA, Eurich DT, Padwal RS, Marrie TJ. Statins and outcomes in patients admitted to hospital with community acquired pneumonia: population based prospective cohort study. *BMJ* 2006;333:999-1001. (11 November.)
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Not the best combination

EDITOR-Majumdar et al have highlighted in their paper that the use of statins did not reduce in-hospital mortality and the need for intensive care intervention.1 Other studies, such as that reported by Mortensen et al, showed in their study that statins can lead to a reduction in mortality at 30 days in patients with community acquired pneumonia.2

In the UK British Thoracic Society (BTS) guidelines,3 the empirical antibiotics choice for hospitalised patients with severe and non-severe community acquired pneumonias includes macrolides-that is, clarithromycin or erythromycin.

The combination of macrolides and statins is not advisable and can lead to debilitating myopathy. Warnings can be seen in the British National Formulary.4 From our department's experience, patients can be left with prolonged mobility complications. Therefore, the use of statins in these patients should be carefully monitored and adjusted accordingly

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Competing interests: None declared.

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- Majumdar SR, McAlister FA, Eurich DT, Padwal RS, Marrie TJ. Statins and outcomes in patients admitted to hospital with community acquired pneumonia: population based prospective cohort study. *BMJ* 2006;333:999-1001. (11 November) November.)
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- 4 British National Formulary 52. September 2006. Appendix

Appreciating bias and precision in study

EDITOR-The work by Majumdar et al is a major step forwards in dealing with confounding of uncertain direction and magnitude in studying pleiotropic effects of statins.1 However, we believe that despite the limited statistical power of the study, the investigators should have planned subgroup analyses for institutionalised and noninstitutionalised patients separately as, for example, in influenza vaccine studies. When examining table 1 it becomes clear that 20% of the non-statin users and only 8% of the statin users were nursing home residents (P < 0.001).

Nursing home residents have other risk profiles than community dwelling people, and uptake of medication is determined by many factors other than their absolute risk of outcome. Importantly, in-hospital treatment may also be different for the separate groups. Including such a subgroup of study subjects may therefore distort the association under study in such a way that confounding cannot be effectively controlled for or, even worse, more unobserved bias

through external interventions may be introduced. Apart from statistical control for observed confounders, it is of importance to note that increasing the numbers of covariates in the model will decrease precision of the adjusted estimate of association. We are, however, currently not aware of any formal power calculation for nonrandomised studies including the number of

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1 Majumdar SR, McAlister FA, Eurich DT, Padwal RS, Marrie TJ. Statins and outcomes in patients admitted to hospital with community acquired pneumonia: population based prospective cohort study. *BMJ* 2006;333:999-1001. (11 November.)

Doctors leading climate change is self delusion

EDITOR-It is both egotistical and unwarranted to presume that doctors are more, or indeed less, caring for the planet than individuals with similar disposable incomes.1 When I attended my hospital this morning there were three other cars in the on-call car park-all huge gas guzzling monstrosities: Land Rover, Mercedes, and Volvo.

Consultants generally have huge or ridiculous cars such as Porsches, four wheel drives, and so on, and only the ones deemed terminally eccentric or anaesthetists are seen (God forbid!) cycling to work. I suspect general practitioners are similarly inclined, particularly following the new contract, and I think doctors in particular and the NHS in general are in no position to lecture others on "carbon footprints."

Hospitals are almost all electric company financial directors' dreams, with unheeded lights lit all weekend, radiators jammed on next to open windows, and all the other ecovandalisms we have been familiar with for decades. The NHS says "Sod the planet, Jack, I'm all right", and it's right. For a few years at least. Cease this self delusion.

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Competing interests: None declared.

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