

■ MEDICAL REGULATION

A proper and principled concern for fairness

From Mr F. Scott

There is a danger of equating a proper and principled concern for fairness with "professional self-protectionism" (*PJ*, 16 September, p324).

The issue of standard of proof is not straightforward and it is helpful to look at the decisions of the UK's most senior judges, including the law lords sitting as the Judicial Committee of the Privy Council. In the case of *Campbell versus Hamlet [2005] UKPC 19*, which concerned a finding of misconduct by an attorney, Lord Brown of Eaton-under-Heywood stated that their lordships entertained no doubt that the criminal standard was the correct standard to apply to such proceedings.

Similarly, Lord Justice Richards, in the Court of Appeal judgment in *re: AN [2005] EWHC 587 (Admin)*, stated: "Although there remains a distinction in principle between the civil standard and the criminal standard, the practical application of the flexible approach demonstrated in the authorities means that they are likely in certain contexts to produce the same or similar results. Indeed, there are exceptional situations in which, for reasons of policy or pragmatism, the actual criminal standard is used in civil proceedings, as in . . . certain disciplinary contexts (Campbell)."

The General Medical Council does not shirk from vigorous and effective action to enhance and promote patient safety and this year will spend over £40m on investigation and adjudication of complaints against doctors.

We are committed to processes and procedures that are fair, objective, transparent and free from unfair discrimination. Erasure from the register has profound implications for doctors. Sir Graeme Catto's key point, expressed in ordinary language, is that we should be sure of the facts when erasure is being contemplated. This is wholly compatible with protecting patients and the public interest.

As the national regulator, the General Medical Council must command the confidence and support of all the main interests — patients and the public, doctors, the NHS and other health care providers, and medical schools and royal colleges. That is why, for example, Sir Graeme has announced the GMC's commitment to a balanced composition for the council, reflective of those four main constituencies.

Finlay Scott
Chief Executive
General Medical Council

■ PSNC

Independent pharmacy is heading towards a bleak future

From Mr D. R. Kent,
MRPharmS

May I, through your columns, congratulate the Pharmaceutical Services Negotiating Committee on achieving an increase of £89m to the global sum paid to pharmacies in 2006/07?

Might I then expect that the PSNC would use a relatively insignificant part of this, £7.4m or

less, to fund the low dispensing volume pharmacies back to the position they had before the implementation of the iniquitous new pharmacy contractual framework? I think not. Although the PSNC has not yet stated how the increased funds will be disbursed, we can be confident that the larger, stronger players will get the lion's share of the cash.

Why do I think this when the new payment schedule has not yet been issued? Because the PSNC has also indicated a rise of 3 per cent, to 2,060 items, in the threshold for payment of the establishment fee when the period of protection runs out in April 2008. Please bear in mind that this will equate to almost 2,200 at that date. If the PSNC were going to demonstrate a social conscience indexing would not have been necessary.

The PSNC tells these disadvantaged pharmacists to go out, offer new services and poach prescriptions from their colleagues, and then moves the threshold for achieving the base figure even higher, making it harder — as it indicated it would in the original new contractual framework document.

I have been banging the drum on this subject since the iniquitous vote in 2004 which the multiples and bigger players could not lose.

When will my colleagues wake up to the serious implications of the removal of a complete layer of pharmaceutical provision? Where will the new, young, aspirational independent contractor pharmacists purchase their first pharmacies when affordable smaller pharmacies cease to exist?

I will not even mention the impact on those members of the public who find it difficult to access the high street.

Wake up! The PSNC is forcing the community sector of our profession into an arm of big business where profits and share value take prime place.

The future of independent pharmacy is bleak and that bleakness must be placed at the feet of the PSNC.

This is a personal view and not necessarily that of Camden and Islington Local Pharmaceutical Committee.

David Kent
Secretary
Camden and Islington Local
Pharmaceutical Committee

Advertisement

Letters for publication can be posted, faxed, or sent by e-mail to letters@pharmj.org.uk and should not normally be of more than 400 words and should cover one topic only. *The Journal* reserves the right to abridge letters and to edit them for clarity and style. Pharmacist correspondents should supply their membership numbers and a contact telephone number should always be given. Women correspondents should specify a preferred title otherwise "Ms" will be used.

Letters are accepted for publication on the understanding that they have not appeared anywhere, including electronic media, previously. If the issue is of such significance that the correspondent has simultaneously submitted the letter elsewhere, it is the responsibility of the correspondent to inform *The Journal* at the time.

Letters that are critical of individuals, organisations or companies may be sent to the person or body concerned so that they are given a simultaneous right of reply. In these instances, the authors' identities will not be disclosed until publication, and publication will usually be delayed.

Anonymity will only be accepted in exceptional circumstances. These circumstances will be at the discretion of the editor and the decision made in consultation with the correspondent.

■ DRUG INTERACTIONS

A different view

From Dr I. H. Stockley, FRPharmS,
and Miss K. C. Baxter, MRPharmS

It is good that pharmacists like Sue Howshall are on the alert for interactions while doing medicines use reviews (*PJ*, 2 September, p276). However, we take a slightly different view on some of the interactions she mentions.

Although the manufacturers of omeprazole recommend that patients taking warfarin should have their international normalised ratio measured if they are given warfarin, the evidence we have found suggests that any interaction is rare. Also, although some monitoring may be appropriate with large doses of fish oils, we have yet to see any evidence to suggest that concurrent use needs to be avoided.¹ Mrs Howshall also makes the comment that one litre of ice cream can interact with warfarin, but so far there are only two cases on record, so its general importance is almost certainly small.¹

Maybe we misunderstood the reasons behind these comments

and recommendations but perhaps this patient has been denied some of these medicines which are probably safe, provided regular tests to ascertain the INR are being carried out, as well as any necessary dosage adjustments made.

We believe that we should take the opportunity to emphasise the fact that rare case reports do not, in isolation, confirm an interaction and patients should not be denied potentially beneficial treatment because of these rare occurrences.

Ivan Stockley
Karen Baxter
Stockley's Drug Interactions

Reference

1. Baxter K, editor. *Stockley's Drug Interactions*, 7th ed. London: Pharmaceutical Press; 2005, pp281–2, p307.

Broad spectrum

The Broad Spectrum feature is open to any reader. Contributions of around 1,100 words commenting on topical issues should be sent to graeme.smith@pharmj.org.uk for consideration

■ NUTRACEUTICALS

Use of nutraceuticals in cancer

From Dr M. de Lemos, MRPharmS

Hill *et al* have provided an extensive review of nutraceuticals that may have some anti-cancer activities (*PJ*, 2 September, pp277–84). From my experience of advising cancer patients on natural health products, there are several points I would like to emphasise.

First, prevention and treatment of cancer are two different things. A substance that may help to prevent cancer is not necessarily useful for the treatment of the disease, and vice versa. For example, oestrogen alone can promote the continuing growth of oestrogen-receptor positive breast cancer. Hence anti-oestrogen therapy like tamoxifen may arrest the progress of this disease. However, oestrogen alone is not sufficient to cause *de novo* development of breast cancer, otherwise many more women would have developed breast cancer.

Second, a randomised, controlled trial has shown that 25g of flaxseed in muffins may reduce

the proliferation of breast tumour cell growth in women with breast cancer.¹ Another issue with flaxseed is that, like other phytoestrogens, one needs to consider the implication of its oestrogenic effect on women with breast cancer, particularly if it is oestrogen-receptor positive. For example, can it interfere with the efficacy of antioestrogen therapy like tamoxifen? Animal studies do not seem to suggest that.^{2,3} However, given that the oestrogenic lignans need to be converted by the gut bacteria, one needs to be careful in extrapolating rodent studies to humans, each with their own microflora. Interestingly, flaxseed oil has been shown to increase breast tumour growth in transgenic mice at certain doses.⁴

Finally, Lissoni *et al* produced nearly all the randomised studies on melatonin versus observation in cancer patients^{5–12} and few have duplicated their findings.¹³ There are several limitations to their studies. It is unclear if assessment was blinded, which may be important when the endpoints included reduction in toxicity. It is unclear if some patients were included in more than one

Advertisement

report,^{5,6,10} as few details on the patients and cross-references with previous studies were provided. Also missing were details on the methods of randomisation, prognostic factors, chemotherapy regimens, etc.^{7,10} In some cases, the survival data presented were unclear. For the advanced disease study, less than 50 per cent of the events had occurred at one year. Hence, the apparent increase in survival may be premature.⁷ In contrast, the survival curves for the lung cancer study were presented as five-year ones, although most patients already died within the first year.¹⁰

Mário de Lemos
Vancouver, Canada

References

1. Thompson LU, Chen JM, Li T, et al. Dietary flaxseed alters tumor biological markers in postmenopausal breast cancer. *Clinical Cancer Research* 2005;11:3828–35.
2. Chen J, Hui E, Ip T, et al. Dietary flaxseed enhances the inhibitory effect of tamoxifen on the growth of estrogen-dependent human breast cancer (mcf-7) in nude mice. *Clinical Cancer Research* 2004;10:7703–11.
3. Chen JM, Mann J, Thompson LU. Dietary flaxseed dose dependently enhances the inhibitory effect of tamoxifen on the growth of human breast cancer (MCF-7) xenografts in nude mice. *FASEB Journal* 2005;19(Part 2 Suppl S):A993 (abstract 583.6).
4. Rao GN, Ney E, Herbert RA. Effect of melatonin and linolenic acid on mammary cancer in transgenic mice with c-neu breast cancer oncogene. *Breast Cancer Research and Treatment* 2000;64:287–96.
5. Lissoni P, Paolorossi F, Ardizzoia A, et al. A randomized study of chemotherapy with cisplatin plus etoposide versus chemoendocrine therapy with cisplatin, etoposide and the pineal hormone melatonin as a first-line treatment of advanced non-small cell lung cancer patients in a poor clinical state. *Journal of Pineal Research* 1997;23:15–19.
6. Lissoni P, Barni S, Ardizzoia A, et al. Randomized study with the pineal hormone melatonin versus supportive care alone in advanced nonsmall cell lung cancer resistant to a first-line chemotherapy containing cisplatin. *Oncology* 1992;49:336–9.
7. Lissoni P. Is there a role for melatonin in supportive care? *Support Care Cancer* 2002;10:110–16.
8. Lissoni P, Barni S, Mandala M, et al. Decreased toxicity and increased efficacy of cancer chemotherapy using the pineal hormone melatonin in metastatic solid tumour patients with poor clinical status. *European Journal of Cancer* 1999;35:1688–92.
9. Lissoni P, Tancini G, Barni S, et al. Treatment of cancer chemotherapy-induced toxicity with the pineal hormone melatonin. *Support Care Cancer* 1997;5:126–9.
10. Lissoni P, Chieffelli M, Villa S, et al. Five years survival in metastatic non-small cell lung cancer patients treated with chemotherapy alone or chemotherapy and melatonin: a randomized trial. *Journal of Pineal Research* 2003;35:12–15.
11. Lissoni P, Meregalli S, Nosetto L, et al. Increased survival time in brain glioblastomas by a radioneuroendocrine strategy with radiotherapy plus melatonin compared to radiotherapy alone. *Oncology* 1996;53:43–6.
12. Lissoni P, Barni S, Ardizzoia A, et al. A randomized study with the pineal hormone melatonin versus supportive care alone in patients with brain metastases due to solid neoplasms. *Cancer* 1994;73:699–701.
13. Cerea G, Vaghi M, Ardizzoia A, et al. Biomodulation of cancer chemotherapy for metastatic colorectal cancer: a randomized study of weekly low-dose irinotecan alone versus irinotecan plus the oncostatic pineal hormone melatonin in metastatic colorectal cancer patients progressing on 5-fluorouracil-containing combinations. *Anticancer Research* 2003;23(2C):1951–4.

COMMUNITY PHARMACY

Work breaks

From Mr G. C. B. Smallwood,
MRPharmS

I refer to my earlier letter (*PJ*, 12 August, p188) and Stan Wheatley's letter (*PJ*, 16 September, p334) regarding the report from the European Court of Justice that the requirements of the European Working Time Directive must be applied to the UK. My interpretation of the directive is that employees must have a 20-minute break during, not after, every six hours of work, thus giving the Department of Trade and Industry guidelines issued in 1998 real teeth. I hope that this directive will be embedded in the Royal Pharmaceutical Society's revised Code of Ethics.

Charles Smallwood
Croydon, Surrey

CPA

Pharmacists can become personal members of the Commonwealth Pharmaceutical Association, the fee for which is £10 a calendar year. The CPA has been strongly supported since its foundation by the Royal Pharmaceutical Society.

Applications should be sent to Mrs Betty Falconbridge, Administrator, Commonwealth Pharmaceutical Association, 1 Lambeth High Street, London SE1 7JN