You will come under pressure to 'bend' the law. Common examples when I was in practice included:

- 'Doc, the chemist said that if you just add "SP" to the script, I'll get the tablets much cheaper' or 'Doc, I'm told that if you ring to get a special authority…'
- 'My mother overseas can't afford to buy the tablets she needs over there. Give me a script in my name and I'll get it filled here and send them to her.'
- 'My mum's/dad's on Repat. Write the script in her/his name and I'll get the medicine cheaper.'

To agree to such requests is not compassionately 'bending' the law, it is fraud. It is criminal fraud, because it would satisfy the test of *mens rea* (literally, guilty mind). You clearly knew that you were issuing a document which would enable a Commonwealth benefit to be obtained improperly. Penalties can be heavy. Section 128B of the *Health Insurance Act 1973* [Commonwealth] states that the penalty for such offences is a fine of up to $10 000 or five years in prison, or both.

You should also be aware that section 128A of that same Act says that it is an offence even if, without intent (that is, without *mens rea*), you:

> make, or authorise the making of, a statement (whether oral or in writing) that is:
>
> (a) false or misleading in a material particular; and
>
> (b) capable of being used in connection with a claim for a benefit or payment under this Act.

The penalty for a breach of section 128A is a fine of up to $2000. That's called a 'strict liability' offence, meaning that there is no need to prove *mens rea*. In other words, if you wish to prescribe under the PBS the burden is on you to learn how the Scheme works.

A prospective study[1] has described how latent conditions interact with error-producing conditions leading to active failures and then prescribing errors:

- 'Latent conditions' – organisational sloppiness, such as the boss saying to the intern, 'Put Mr X on digoxin' without checking that the intern knew the correct dose, frequency, route of administration, and duration of treatment.
- 'Error-producing conditions' – such as overwork, poor team communication, inadequate protocols, H.A.L.T. doctors (Hungry, Angry, Late or Tired), and unhelpful patients with perhaps both complex medical problems and language or other communication difficulties.
- 'Active failures' – these can be subdivided into:
  - 'errors', such as slips (thinking of one name but when distracted writing another), lapses (such as failing to delete the previous drug from a medication chart when substituting it with another) and frank mistakes (such as co-prescribing drugs known to interact)
  - 'violations' (such as consciously ignoring clearly stated protocols, for example checking procedures).

This research points the way to avoiding treatment errors:

- When delegating treatment, always give clear, detailed (preferably written) instructions.
- Slow down and concentrate even more than usual when H.A.L.T. (Of course, it is better to HALT when H.A.L.T.!)
- Concentrate when writing prescriptions – do not try to write them while the rest of your brain is attending to another task. (How often do you attend to the list of requested repeat scripts when also returning that day's phone calls?)
- If the computer prescribing system is down, and you have come to rely on it, slow down and check, check, check.

One way or another, general practitioners probably use their signatures about 50 times a day. That means that over the average professional lifetime, you will sign your name about half a million times. It is frightening to think that any one of those signatures applied carelessly could land you in medicolegal hot water.

Reference

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Conflict of interest: none declared

Letters

Letters, which may not necessarily be published in full, should be restricted to not more than 250 words. When relevant, comment on the letter is sought from the author. Due to production schedules, it is normally not possible to publish letters received in response to material appearing in a particular issue earlier than the second or third subsequent issue.

Withdrawal of temazepam gelcaps

Editor, – I was disappointed to read certain advice and factual inaccuracies in the article regarding issues relating to the use/misuse of temazepam capsules (Aust Prescr 2004;27:58-9). The withdrawal by Sigma of its temazepam capsules from the market has not led to a complete lack of this drug in Australia and temazepam gelcap injection still continues to be a problem.

Furthermore, I am concerned about the comment, 'in this instance they have a duty of care not to prescribe benzodiazepines'. While doctors should not respond to coercion, as alluded to in the article, appropriate

management of benzodiazepine abuse/dependence might include notification to the relevant government department and an appropriate prescription for benzodiazepines (usually diazepam) in controlled amounts; such as by daily, or alternate daily, pick-up from a nominated chemist. Such an approach, conducted as part of a planned strategy to attempt to gradually wean the patient off benzodiazepines, is a more appropriate, caring and responsible response to a request for benzodiazepines than an outright refusal. It will ensure that the individual will not suffer the possibility of withdrawal seizures as well as diminishing the possibility of ever-increasing demands on other healthcare providers further down the track as the individual becomes ever more desperate in their attempt to obtain such drugs.

Martyn Lloyd-Jones
Director, Drug and Alcohol Services
Delmont Private Hospital
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Dr H. Wilce, the author of the article, comments:

I am not sure what factual inaccuracies Dr Lloyd-Jones is referring to as nowhere in the article does it state that the removal of temazepam gelcaps has led to a complete lack of this drug in Australia. The article states that front-line services are seeing a reduction in problems since the removal of gelcaps from the market. Unfortunately we will continue to see problems with this medication until stockpiles have been depleted. Gelcaps may also continue to be available via the internet or via overseas imports. It is possible that we will continue to see the physical sequelae of past injecting misuse for years to come.

Dr Lloyd-Jones has misinterpreted the advice that 'doctors have a duty of care not to prescribe benzodiazepines'. This statement was made in the context of coercion. While the article does not attempt to discuss the vexed issue of benzodiazepine reduction regimens, there is little good evidence that such regimens are effective and in fact they may be associated with an escalation rather than reduction in use. This problem is one that is likely to continue while the ongoing supply of benzodiazepines is difficult to control. However, it is clear that these regimens have the greatest chance of success if there is an effective therapeutic relationship between the doctor and patient. This is very unlikely to be the case if the doctor is coerced into providing scripts for benzodiazepines.

Inside the isomers: the tale of chiral switches

Editor, – Reference is made to the article 'Inside the isomers: the tale of chiral switches' (Aust Prescr 2004;27:47–9). In this article it is asserted that 'in overdose, there is a concern about the potential for sudden death, possibly related to QT prolongation due to a secondary metabolite formed from (R)-citalopram. (S)-citalopram (escitalopram) was therefore developed with the aim of a better harm:benefit ratio compared to (R)-citalopram'.

Significantly, the authors of this article have not referenced any of the statements in this paragraph. I would like to advise that the statement regarding the propensity of a metabolite of the (R)-enantiomer of citalopram to cause sudden death as a result of QT prolongation is completely unfounded.

A survey has investigated the effects of citalopram, at therapeutic doses, on ECG parameters.[1] The authors concluded that citalopram has no significant effects on PQ, QRS or QTc intervals, during short- or long-term treatment. Nor were there any deaths or clinically significant arrhythmias reported among all pure citalopram intoxications (n=108 with doses up to 5.2 g) over a two-year period in Sweden.[2]

Since there is absolutely no basis to the assertion that a metabolite of (R)-citalopram is associated with sudden death as a result of QT prolongation, the reason given for the development of (S)-citalopram is also purely speculative and quite simply, untrue.

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Associate Professor Andrew Somogyi, one of the authors of the article, comments:

There is evidence that the didesmethyl metabolite of (R)-citalopram prolongs the QT interval in animals and therefore might contribute to those rare instances of cardiac arrhythmia after very high doses of citalopram in a suicidal setting.[1,2,3,4]

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Pharmaceutical free trade – will it be fair?

Editor, – What has happened to your HONcode? Your editorial (Aust Prescr 2004;27:54–5) on the US Free Trade Agreement fails to meet the requirement of honest informed reliable advice that your magazine purports to hold dear. Your editorial is not only a farrago of unsubstantiated and false claims on what is a contentious political issue, it reveals an abysmal lack of knowledge of the agreement itself. It is insulting to your professional colleagues in the Department of Health whose fully-informed public statements correcting the falsehoods you have regurgitated have been ignored by you – if you ever bothered to inform yourself of them.

It is now possible for you to discover reality, and inform your readers of it, by reading the 18 recommendations in the recent report on the FTA of the Joint Standing Committee on Treaties, chaired by your professional colleague, Dr Andrew Southcott MP. All but one of these 18 were supported by the three Labor members of the committee; this report demolishes your stand.

As a former federal Shadow Minister for Health and subsequently Consul-General in New York, I have closely studied the US Free Trade Agreement. I challenge you to point to any section of the agreement that supports the thrust of your claims. You appear to have confused the terms of the agreement which are clear and self-evident with the inevitable uncertainty of the exact nature of the Australian government's measures to implement it – measures that are entirely up to an elected Australian government and subject to the democratic political process – and which could be introduced whether there was an FTA or not. The US has no power to require action otherwise than in the strict wording of the agreement and attached side letters, reflecting the same right we have at their end. In no instance does that right establish a US position that justifies your scare-mongering.

This is how your nonsensical claims fall down:

- There is nothing in the agreement that empowers the Medicines Working Group, which has a specified advisory-only role (giving us access to the world's most dynamic innovative pharmaceutical knowledge) to determine 'details of the agreement'. You are just plain wrong in claiming it 'probably' will do so; you cannot provide any evidence to support this.
- It does not 'remain to be seen' whether an Australian decision not to approve a drug or not to list it on the PBS 'could be construed as a breach' of the FTA; the agreement guarantees the basic architecture of the PBS and you cannot point to any section of it that leaves this issue otherwise than totally in the hands of the Australian government; even the nature of the independent review process for PBS listing is entirely up to the Australian government.
- There is nothing in the agreement that requires or empowers the independent review process to overturn a listing decision; the Minister remains the only instrument of approval and can only act on the recommendation of the PBAC. The FTA does nothing to change this and the government has already said it has no intention to do so.
- No trade deal can dictate how much the Australian government spends on medicines or what they cost and you cannot point to anything in the US FTA that has the capacity to do so.
- The FTA specifies that any marketing and advertising to consumers must comply with Australian laws (such as prohibiting industry advertising direct to consumers) and there is nothing in the agreement requiring the government to change them.
- The agreement reinforces Australia's existing intellectual property protection of pharmaceuticals, ensuring that generics cannot enter the market until a patent has expired. What on earth is your objection to that – or do you favour us joining the patent-pirates and getting excluded from western commerce?
- Most rational people think greater transparency of governmental agency decisions (and a formal appeal mechanism) represents a more democratic approach. Why don't you?

Your editorial demeans you and your journal. Like most quack medicines, it should be marked 'harmful if swallowed'.

Michael Baume
Mosman, NSW

The Editorial Executive Committee comments:

The controversy surrounding the editorial is ironic, as the Editorial Executive Committee's intention was to bring to readers' attention some of the issues that have been raised concerning the pharmaceutical part of the Free Trade Agreement. As pharmaceutical policy influences prescribing it was appropriate for *Australian Prescriber* to comment.

While the wording of parts of the agreement seemed ambiguous this may have been to allow flexibility in implementing the agreement.[1] Although the Editorial Executive Committee is grateful for Mr Baume's insight into the arcane language of international treaties, some questions remain. They will only be answered with the passage of time. It is therefore appropriate that the first of the 23 recommendations made by the Joint Standing Committee on Treaties was to have a review of the impact of the agreement after five years.

Reference

1. The Australia-United States Free Trade Agreement. Report 61. Canberra: Commonwealth of Australia; 2004. http://www.aph.gov.au/house/committee/jsct/usafta/report/fullreport.pdf [cited 2004 Sept 6]

New drug – teriparatide

Editor, – Your recent comment on our product Fortéo (teriparatide) (Aust Prescr 2004;27:22–3) was an informative and well-rounded review, however, I would like to address a couple of points.

Your final paragraph states: 'Until more data are available teriparatide should only be prescribed for patients who have a high risk of fractures and cannot take other treatments for osteoporosis'.

In fact, the product information approved by the Therapeutic Goods Administration for the use of teriparatide states:

> Fortéo is indicated for the treatment of osteoporosis in postmenopausal women and the treatment of primary osteoporosis in men when other agents are considered unsuitable and when there is a high risk of fractures.

While this may seem like a small change in wording, it is actually a significant consideration for those prescribing Fortéo.

A published paper helps to place the rat osteosarcoma issue in context. It concluded that: 'in adult humans … it is unlikely that the risk of bone neoplasia would be increased by daily treatment with PTH (1-34) for a relatively small fraction of the normal life span'.[1]

Troels Wolthers
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Reference

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MedSafety – www.medsafety.net

Editor, – Medication errors occur regularly in Australian and overseas health systems[1,2,3,4], and their incidence may be increasing.[5] There is therefore a need to improve medication use and to educate health professionals in the rational and safe use of medicinal drugs.[3] The recent rapid development in safety and quality improvement in overseas and Australian healthcare systems has made it difficult for undergraduate courses to adapt quickly enough and incorporate appropriate content. It is also difficult for health professionals working at the coalface to keep up to date with the latest developments.

The Tasmanian Schools of Pharmacy and Medicine have produced an on-line learning resource for medication error prevention. Modules have been developed around actual clinical problems or cases involving a medication error. There are supporting electronic resources so that the modules may be used for self-directed learning, or as a basis for teacher-led discussion on medication safety issues.

There are currently six modules:

- how to disclose errors to patients
- patient communication skills
- system improvement methods
- the role of information technology in reducing error
- intravenous therapy and error
- high-risk medications.

Each module takes approximately one hour to complete. In addition there are topics covering incidence of medication error, causes, root cause analysis, the 'systems approach' to understanding error, and many case examples of medication error with suggestions for prevention. The site also features a full text search, extensive links to on-line medication safety information, quizzes and a discussion forum. A facility to report personal experiences of medication incidents is also available.

The web site should be of interest to hospitals and healthcare institutions, within and outside Australia. Flyers for doctors, nurses and pharmacists have been developed to introduce the first module. These are available on-line at www.medsafety.net

Professor Gregory Peterson
Professor of Pharmacy, Tasmanian School of Pharmacy

Mr James Reeve
PhD candidate, Tasmanian School of Pharmacy

Associate Professor Janet Vial
Associate Head, Tasmanian School of Medicine
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Glucosamine for osteoarthritis of the knee

Editor, –The article on glucosamine (Aust Prescr 2004;27:61–3) understated a couple of points. Firstly, that 'both trials were sponsored by the Rotta Research Laboratorium and used that company's formulation of glucosamine sulphate'. Surely this implies some considerable bias. Secondly, because no glucosamine product in Australia has an AUST R rating by the Therapeutic Goods Administration, does this not also imply that the products in Australia may be subject to qualitative and quantitative variations to the product studied and therefore may not produce the same or any therapeutic effect? This point is implied by the author who states 'this formulation may differ from those available in Australia'.

While glucosamine may have a unique mechanism of action, is this not thrown into doubt by the 'poor correlation between structural and symptomatic responses'? Regardless, where are the well-designed comparative trials necessary to show that glucosamine is better than standard therapy? Previous comparative trials were poorly designed, of short duration and involved small numbers.

Derek Grubb
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Associate Professor G. McColl, the author of the article, comments:

Both of the major randomised controlled studies were sponsored by the Rotta Research Laboratorium and this may have introduced bias into the studies. This notion, of course, would also have to apply to the majority of medications available on the Pharmaceutical Benefits Scheme, as the studies supporting their listing would also have been supported by their manufacturers.

The issue of 'qualitative and quantitative' variation in glucosamine products available in Australia is a significant one. In the purest view of evidence-based medicine we should only use the preparation that was tested in the study. As the Rotta glucosamine product is difficult to access in Australia this creates a problem. In practical terms, however, it is reasonable to extrapolate the data from these studies to 'reputable' glucosamine products in Australia, particularly if a therapeutic trial of three months is recommended.

No high quality trial has compared routine therapies such as paracetamol or non-steroidal anti-inflammatory drugs to glucosamine. I agree that this is a deficiency and will hopefully be addressed by a current study sponsored by the National Institutes of Health in the USA.

Book review

Australian Medicines Handbook 2004

Adelaide: Australian Medicines Handbook; 2004.

788 pages. Price $152; students $99; plus postage

Tracy Soh, General practitioner, Canberra

The Australian Medicines Handbook was developed jointly by the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists, the Pharmaceutical Society of Australia and the Royal Australian College of General Practitioners. It was designed as a national formulary that would provide concise, up-to-date, independent drug information to facilitate better prescribing and dispensing practice. The contributors to the handbook represent all disciplines and all parts of Australia.

The latest edition is a well presented and simple to use, practical formulary of most of the drugs currently marketed in Australia. As with previous editions, the information is well researched and reflects current and reliable sources. The new edition provides several new sections including HIV, hepatitis B, hepatitis C, tinnitus, macular degeneration, functional dyspepsia and prostatitis.

The handbook is organised broadly according to organ systems and clinical presentations. Each section provides an overview of the clinical problem and the general considerations involved in treatment, including a brief summary of the available classes of medication. It subsequently presents a monograph of each class of medication which includes comparative information between medications within that class and specific practice points. The handbook then details the key features particular to each of the drugs within that class including specific indications and dosage.

The presentation of the information makes the handbook a useful tool for quick reference during clinical practice. The logic and consistency of the format of each section makes the relevant information easy to find and quick to read.

The Preface suggests that the handbook may be used as a learning tool for students – the clinical approach would provide a good structure for students to base their learning upon. However, the information has been well summarised and medical students are likely to need more detailed references.

I found this book to be a useful and practical addition to the available information resources for general practice. Its compact size makes it portable enough to carry to home visits and on the ward. It is a well designed tool to support the practice of evidence-based medicine.