

**Reducing the paperwork for residential aged-care facility waiting lists**

50 Aine G Greene, Bernadette Kenny, David C Currow

**Commercialism, choice and consumer protection: regulation of complementary medicines in Australia**

50 Nigel A Pollard

51 Antonino Santoro

51 Vicki Kotsirilos

52 C Scott Masters

52 Ken J Harvey, Viola S Korczak, Loretta J Marron, David B Newgreen

**Pregnant women with fetal abnormalities: the forgotten people in the abortion debate**

53 Edward D Watt

54 Simon B Gerber, John T Wenham

54 Lachlan J de Crespigny, Julian Savulescu

**Calcium supplementation does not increase mortality**

55 Mark J Bolland, Andrew B Grey, Ian R Reid

55 Benjamin M P Tang, B E Christopher Nordin

**Apical lung hernia**

56 George R Crowe

## Reducing the paperwork for residential aged-care facility waiting lists

Aine G Greene, Bernadette Kenny and David C Currow

**TO THE EDITOR:** Although there are data on the population needs for residential aged-care facilities (RACFs)<sup>1</sup> and models of engagement by general practitioners once someone is resident in a facility,<sup>2-4</sup> there are ongoing administrative barriers for people trying to secure a place in an RACF. The aim of requesting data before admission is to provide continuity and quality of care, but the burden of paperwork currently falling on family members and GPs is of concern.

We initiated an audit when it became apparent that local acute public and private hospital inpatient units had a policy of insisting that once an inpatient was eligible for RACF residency, he or she was required to be placed on waiting lists for 8–10 different RACFs. As part of a broader project to coordinate better care at times of transition, all RACFs in southern Adelaide (feeder population 400 000) were approached to provide us with the forms that need to be completed before someone can be placed on their waiting list.

All 22 facilities in southern Adelaide provided a copy of the application pack that they normally give to a family member. A median of 4.5 forms had to be completed before a person could be placed on a waiting list (range, 0–13). The most frequently requested forms were an Aged Care Assessment Team form (17 facilities), an application form (15 facilities), a medical history form (12 facilities), and an assets declaration (9 facilities). One RACF required direct

debit payment forms to be filled out before considering an application, and another required documentary evidence of funeral arrangements. By contrast, four RACFs required no forms at all.

GPs were responsible for the medical history form. This form was unique to each RACF, with the result that similar data had to be provided multiple times in different formats. GPs were also potentially required to witness several other forms for each different application.

There is an inherent challenge in balancing the need to run a financially viable RACF and provide best care from the moment a resident arrives with minimising the paperwork that frail spouses or busy family members are often expected to generate or replicate for many facilities simultaneously. These forms, most of which will never be used, create a burden on family members at an already stressful time.

An agreed national industry standard for an Aged Care Assessment Team form, an assets form and a medical history form (to be filled out once by a GP) would ease stress at arguably one of the more difficult transitions any person and his or her family can face.

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<sup>2</sup> Royal Australian College of General Practitioners. Medical care of older persons in residential aged care facilities. Melbourne: RACGP, 2006.

<sup>3</sup> Gadzhanova S, Reed R. Medical services provided by general practitioners in residential aged-care facilities in Australia. *Med J Aust* 2007; 187: 92-94.

<sup>4</sup> O'Halloran J, Britt H, Valenti L. General practitioner consultations at residential aged-care facilities. *Med J Aust* 2007; 187: 88-91. □

## Commercialism, choice and consumer protection: regulation of complementary medicines in Australia

Nigel A Pollard

**TO THE EDITOR:** In the January issue of the Journal, Harvey et al raised some serious concerns about the listing system for complementary medicines.<sup>1</sup> In particular, they suggest scrapping the listing system (AUST L) and requiring complementary medicine (CM) products to be evaluated by the Therapeutic Goods Administration (TGA) for efficacy.

Scrapping the system would be a significant setback for natural medicines, which have an important role to play in the health system. Such a move would be likely to remove products from the market, while the problem outlined by Harvey et al is more about the claims made for products rather than the products themselves. Certain CM products play a valuable role in many chronic diseases, in situations where existing synthetic products are often lacking. The regulatory system should encourage evidence-based CM products, and appropriate sanctions and enforcement should downgrade the claims made on products that don't have a specific evidence base.

CMS, especially herbal medicines, are complex products with numerous biolo-

gically active components. This means that the evidence is specific to the product and cannot be extrapolated. This fact has two important consequences for practitioners and the health system as a whole:

- the “generic” concept of synthetic pharmaceuticals (eg, interchangeability of paracetamol-containing products) is invalid for CM, meaning that a prescription for “St John’s wort” for example is not reliable, as St John’s wort is not one substance; and
- meta-analyses and systematic reviews of a “substance” (eg, a herb, or glucosamine) are easily misinterpreted because the products made from that “substance” are so different, any conclusions drawn can only be applied to the particular products that have been trialled.<sup>2</sup>

While the health system fails to discriminate between products that have specific trial evidence and those that do not, practising evidence-based complementary medicine will remain difficult. Encouraging evidence-based use of CM products, including supporting specifically clinically proven products, will lead to further research and better integration of CM into our health system for the benefit of the Australian public.

**Competing interests:** I am the Managing Director of an Australian complementary medicine company, and own shares in that company. No company product names have been mentioned, and the letter is an industry view on an article which examines issues in relation to complementary medicine products promoted in Australia.

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1 Harvey KJ, Korczak VS, Marron LJ, Newgreen DB. Commercialism, choice and consumer protection: regulation of complementary medicines in Australia. *Med J Aust* 2008; 188: 21-25.

2 Linde K, Mulrow CD, Berner M, Egger M. St John’s wort for depression. *Cochrane Database Syst Rev* 2005; (2): CD000448. □

### Antonino Santoro

**TO THE EDITOR:** I am writing in response to the recent article by Harvey and colleagues about complementary medicines in Australia.<sup>1</sup>

Rottapharm is the developer and manufacturer of DONA glucosamine, a patented form of glucosamine. DONA is a registered medicine in 54 countries, in many on the equivalent of the Pharmaceutical Benefits Scheme. DONA is the leading glucosamine product in the world measured by specific trial evidence, sales and registration approvals.

The fundamental issue is that different products that contain glucosamine and other complementary medicine (CM) products should be considered to be distinct products. Standards of active ingredients and methods of manufacture of finished products are substantially different between companies.

Specific clinical trial evidence for glucosamine is essential because of:

- formulation differences (DONA glucosamine is a patented formulation of crystalline glucosamine sulfate, which is not comparable with glucosamine hydrochloride or other glucosamine sulfate formulations);
- bioavailability of glucosamine sulfate (unlike all other formulations on the Australian market, DONA has proven plasma concentrations and synovial fluid levels consistent with a clinical effect at a dosage of 1500 mg once a day, and is the only glucosamine product available with proven human bioavailability and pharmacokinetics);<sup>2</sup> and
- results of specific clinical trials (studies of non-DONA glucosamine products [unknown formulations] have had mixed results while DONA has shown consistent efficacy across all trials, and has been assigned level 1A evidence by the European League Against Rheumatism).<sup>2-6</sup>

Not requiring sponsors to have evidence to support claims made about their products encourages low quality. For example, the market-leading glucosamine products in Australia have not been subject to independent peer review to establish whether they are effective. As the claims allowed on such products are identical to the claims allowed on DONA, there is no incentive for the industry to source the “real thing” or conduct their own clinical trials.

In the interests of their patients, we believe that health professionals have a right to be able to identify specific products that have been clinically proven. Use of CMs that is not evidence-based is likely to lead to failure to realise significant health benefits of CM for the Australian public.

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1 Harvey KJ, Korczak VS, Marron LJ, Newgreen DB. Commercialism, choice and consumer protection: regulation of complementary medicines in Australia. *Med J Aust* 2008; 188: 21-25.

2 Reginster JY. The efficacy of glucosamine sulfate in osteoarthritis: financial and nonfinancial conflict of interest. *Arthritis Rheum* 2007; 56: 2105-2110.

- 3 Reginster JY, Deroisy R, Rovati LC, et al. Long-term effects of glucosamine sulphate on osteoarthritis progression: a randomised, placebo-controlled clinical trial. *Lancet* 2001; 357: 251-256.
- 4 Herrero-Beaumont G, Ivorra JA, Del Carmen Trabado M, et al. Glucosamine sulfate in the treatment of knee osteoarthritis symptoms: a randomized, double-blind, placebo-controlled study using acetaminophen as a side comparator. *Arthritis Rheum* 2007; 56: 555-567.
- 5 Altman RD, Abramson S, Bruyere O, et al. Commentary: osteoarthritis of the knee and glucosamine. *Osteoarthritis Cartilage* 2006; 14: 963-966.
- 6 Vlad SC, LaValley MP, McAlindon TE, et al. Glucosamine for pain in osteoarthritis: why do trial results differ? *Arthritis Rheum* 2007; 56: 2267-2277. □

### Vicki Kotsirilos

**TO THE EDITOR:** The article by Harvey et al raises important concerns about the complementary medicine (CM) industry, particularly with respect to inappropriate marketing and advertising by some sponsors.<sup>1</sup>

The role of the Therapeutic Goods Administration (TGA) in setting standards and regulation of CMs should not be taken lightly. Australia has one of the highest quality standards for CMs internationally. Many CM products in Australia are assessed by expert authorities within the Office of Complementary Medicines and the Complementary Medicines Evaluation Committee of the TGA for safety and (where appropriate) efficacy relating to claims made for products.<sup>2</sup> This is not fully appreciated by the authors.

While many CMs may lack high-quality research to validate efficacy, this does not necessarily mean they are not clinically effective. Many clinicians and consumers find CMs to be of clinical value in improving health status. By suggesting that “the listing system should be scrapped, and CAMs [complementary and alternative medicines] ... be assessed for efficacy and delisted if evidence is lacking” would be to deny consumers choice of treatment and potential health benefits, and lead to a “black market” or buying products from overseas which may not compare in quality. The authors fail to acknowledge that much of the drive for CM sales is actually coming from consumers through their choice of health care treatment.<sup>3</sup> Consumers have the right to trial CMs. It is our role to ascertain safety issues and encourage clinical trials where they are lacking. For thousands of years, populations have relied on some CMs for health benefits, not having the advantage of any trials, but relying solely on traditional use. If the risk of harm to human health from the use of a CM

outweighs any proven or unproven efficacy, consideration should be given to delisting the product or restricting its use. More research is required to assess safety data and efficacy for CMs.

Australia has come a long way in regulating CMs. To say the "listing system should be scrapped" does not appreciate the tremendous efforts and gains made by the TGA compared with international efforts to enforce good manufacturing practice and various methods to better safeguard consumers.

The authors do raise a valid point in saying that sponsors should provide "key evidence supporting each indication of the ARTG [Australian Register of Therapeutic Goods] . . . [which] should be publicly available on the Internet". This may be useful for consumers and health practitioners, but requires appropriate funding to be viable. Furthermore, codes of conduct and complaints procedures for CMs, such as through the Complaints Resolution Panel, need to be strengthened, particularly with respect to breaches in the advertising code.<sup>4</sup> To date, the Parliamentary Secretary has asked the TGA for advice on the proposals put forward by Harvey and colleagues.<sup>1,5</sup> The government will consider its response to these proposals in the context of taking forward legislative changes that were deferred in anticipation of the establishment of an Australian New Zealand Therapeutic Products Agency (TGA advice, 28 May 2008).

**Competing interests:** I am an expert consultant to the TGA, serving on two committees, the Complementary Medicines Evaluation Committee and the Adverse Drug Reactions Advisory Committee. I am not involved with sponsorship and do not receive monies for any CM products. This letter reflects my personal views, which are not necessarily those of the Complementary Medicines Evaluation Committee or the TGA.

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1 Harvey KJ, Korczak VS, Marron LJ, Newgreen DB. Commercialism, choice and consumer protection: regulation of complementary medicines in Australia. *Med J Aust* 2008; 188: 21-25.

2 Therapeutic Goods Administration. Complementary Medicines Evaluation Committee (CMEC) [website]. <http://www.tga.gov.au/docs/html/cmec/cmec.htm> (accessed Jan 2008).

3 MacLennan AH, Wilson DH, Taylor AW. The escalating cost and prevalence of alternative medicine. *Prev Med* 2002; 35: 166-173.

4 Therapeutic Goods Advertising Code Council (TGACC) [website]. <http://www.tgacc.com.au/index.cfm> (accessed Jan 2008).

5 Cresswell A. Alternative medicines group backs curbs. *The Australian* 2008; 19 Jan. <http://www.theaustralian.news.com.au/story/0,25197,23068700-23289,00.html> (accessed 2 Jun 2008). □

### C Scott Masters

**TO THE EDITOR:** Harvey et al<sup>1</sup> have a right to be concerned about the parlous state of regulation in the billion-dollar complementary medicine (CM) industry. They are not alone, with various leaders from CM doctor groups and other leaders also expressing concern.<sup>2,3</sup>

Predictably, those in the CM industry itself are denying any problems exist, and just repeat their mantra that their products are safe and effective.<sup>3</sup>

As business people, the leaders of the CM industry must be pleased with the unchallenged run they have had over the past 20 years (except for one challenge with the Pan Pharmaceuticals debacle<sup>4</sup>).

Consider one company (Mannatech) whose multilevel marketed products are promoted by their associates (natural drug representatives) as useful for arthritis, diabetes, dementia, attention deficit hyperactivity disorder, Parkinson's disease, asthma, cancer and various other chronic diseases. The associates promoted claims that a product, Ambrotose, would assist with the above conditions using literature that did not carry the company logo, and used the company literature for non-specific claims and testimonials, thus absolving the company of responsibility.

The Therapeutic Goods Administration is helpless in such a situation, and it was only when a medical practitioner started selling Mannatech products, including Ambrotose, from his surgery that the state medical board took an interest.<sup>5</sup> However, the medical board has no jurisdiction over the company, and when the doctor was deregistered, he would have been able to keep marketing the product for the company.

Mannatech launched Ambrotose in Australia, quoting the benefits of their product from a trial conducted and published in the *Journal of the American Nutraceutical Association* by American immunologist Dr See and colleagues.<sup>6</sup> Eighteen months later, the published trial was the subject of much controversy.<sup>7</sup> There was little if any effect on the company from this, in stark contrast with what one would expect in the pharmaceutical industry.

Yes, Harvey and colleagues are just starting to scratch the surface of controversies that are decades old in this unregulated

industry. For the good of the public and for the good of the CM industry, there needs to be a watchdog, similar to Medicines Australia, to regulate CM.

**Competing interests:** I have been paid speaker fees and travel allowances to speak on musculoskeletal medicine topics by Boehringer, Pfizer, Mundipharma and Merck Sharpe & Dohme.

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1 Harvey KJ, Korczak VS, Marron LJ, Newgreen DB. Commercialism, choice and consumer protection: regulation of complementary medicine in Australia. *Med J Aust* 2008; 188: 21-25.

2 Bethell G. Alternative therapy regulation under fire. *Medical Observer* 2008; 18 Jan. <http://www.medicobserver.com.au/displayarticle/index.asp?articleID=8810&templateID=105&url=http://Lock:87%2Fsearch%2Fsearch%2Easp?key-words%3Dalternative%2Btherapy%26x%3D0%26y%3D0> (accessed Feb 2008).

3 Smith P. Experts attack TGA loophole. *Australian Doctor* 2008; 1 Feb.

4 Therapeutic Goods Administration. Pan Pharmaceuticals Limited — regulatory action and product recall information. Canberra: TGA, 2003. <http://www.tga.gov.au/recalls/2003/pan.htm> (accessed Feb 2008).

5 *Medical Board of Queensland v Raddatz*. Health Practitioners Tribunal. File No: D. 2392 of 2000. Delivered 8 Sep 2000. <http://archive.sclqld.org.au/qjudgment/2000/QHPT00-001.pdf> (accessed May 2008).

6 See DM, Gurnee K, LeClair M. An in vitro screening study of 196 natural products for toxicity and efficacy. *JANA* 1999; 2: 25-41.

7 Evans D. Mannatech using disputed study to boost sales of its products. New York: Bloomberg, 1999; 4 Aug. <http://www.ratbags.com/rsoles/comment/mannatech02.htm> (accessed May 2008). □

**Ken J Harvey, Viola S Korczak, Loretta J Marron and David B Newgreen**

**IN REPLY:** We agree with Kotsirilios that the current listing process of the Therapeutic Goods Administration (TGA) provides some protection for consumers by ensuring that complementary medicines (CMs) are manufactured in accordance with good manufacturing practice.

The TGA claims that about 25% of new listings are assessed in detail each year for compliance with requirements, including that sponsors must hold evidence to support promotional claims made.<sup>1</sup> However, we understand that the TGA does not assess this evidence for quality, and that literature searches are not performed to see if more recent evidence<sup>2</sup> contradicts that submitted by the sponsor.<sup>3</sup>

In addition, sponsors can make a conservative claim at the time of listing but then make very different claims in promotional campaigns. An under-resourced, laboriously slow and largely impotent complaint system provides little disincentive to such unethical (but profitable) behaviour.

While the Medicines Australia code of conduct (for prescription medicines) still has room for improvement, we agree with Masters that it currently provides more effective sanctions for breaches (eg, fines up to \$200 000) than the options currently available to the TGA. Medicines Australia also proactively monitors compliance with the code of conduct and provides useful annual reports.<sup>4</sup>

Regardless, claims for CM that cannot be substantiated by appropriate evidence are better dealt with at the time of a marketing application rather than many months after advertisements have been published and when consumers have long been misled. We also recommended that therapeutic equivalence of the product in question should also be assessed at this time; a point reiterated by Santoro and Pollard.

We support the right of consumers to choose from a variety of therapeutic modalities offered in the market place. However, good decision making requires evidence-based information about risks and benefits, regardless of whether the medicine in question requires a prescription, can be obtained over the counter or is a CM. Even if the risks of CMs are relatively low, the financial and opportunity cost for consumers can be significant.

A pragmatic compromise to delisting CMs that lack evidence of effectiveness would be an opt-in system, funded by an additional fee, that would independently evaluate the effectiveness of specific CM products. A product with reasonable evidence of effectiveness could be awarded a symbol similar to the the National Heart Foundation "red tick". Implementing this measure, together with the disclaimer and other recommendations we made in our article,<sup>5</sup> would assist consumer choice and provide a market advantage for the sponsors of evidence-based, ethically promoted CMs.

These proposals have received support from health professional and consumer organisations as well as sections of the CM industry. They have been put to the Parliamentary Secretary who assists the Minister for Health and Ageing.<sup>3</sup>

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1 Australian Government Department of Health and Ageing; Therapeutic Goods Administration. Evidence summary table for listed medicines. <http://www.tga.gov.au/docs/html/tgaccevi.htm#lmtable> (accessed Feb 2008).

2 Bent S, Padula A, Neuhaus J. Safety and efficacy of citrus aurantium for weight loss. *Am J Cardiol* 2004; 94: 1359-1361.

3 Choice. Complementary medicines. <http://www.choice.com.au/viewArticle.aspx?id=105376&catId=100386&tid=100008&p=1&title=Complementary+medicines> (accessed Feb 2008).

4 Medicines Australia. Code of conduct annual report 2006/2007. Sydney. <http://www.medicinesaustralia.com.au/pages/images/Code%20of%20Conduct%20Annual%20Report%202007.pdf> (accessed May 2008).

5 Harvey KJ, Korczak VS, Marron LJ, Newgreen DB. Commercialism, choice and consumer protection: regulation of complementary medicines in Australia. *Med J Aust* 2008; 188: 21-25. □

## Pregnant women with fetal abnormalities: the forgotten people in the abortion debate

Edward D Watt

**TO THE EDITOR:** The recent article by de Crespigny and Savulescu<sup>1</sup> is nominally about the medical care of pregnant women, but its ramifications extend more widely into power relations, law and ethics, and matters of life and death.

The article is entirely adult-centred: its authors never hint that a doctor who is treating a pregnant woman has not one but two patients. There is never the faintest suggestion that the fetus is a separate human being with his or her own medical interests. The "research" reported is a survey of 20 obstetricians, who all agree with the authors on abortion for fetal abnormality. Unsurprisingly, most said they would prefer fewer constraints on such abortions.

Which abnormalities are grounds for termination? The authors never say, although terminations are performed in Victoria for conditions as readily treatable as cleft lip.<sup>2</sup> The authors cite an estimate that where Down syndrome is identified in Victoria, 95% of pregnancies are terminated. Yet people with Down syndrome do not appear to find their lives intolerable: is the misery

we want to put Down syndrome children out of *their* misery, or their parents'?

The authors insist that in Victoria, "uncertain laws compromise good prenatal care". The prenatal care they seem to have in mind can hardly be called care of the child: can it be called care of the mother? In one of the cases cited, a woman at Melbourne's Royal Women's Hospital was threatening suicide unless her pregnancy was terminated after a diagnosis of dwarfism at 31 weeks.<sup>1</sup> Instead of providing her with urgent psychiatric care (had they never encountered a suicidal patient before?), the doctors terminated her pregnancy. If she had demanded the amputation of her left arm, would they have called in the surgeons? The surgical mutilation of an adult patient would not have been considered for a moment, but the surgical killing of a fetal patient was an available and practised routine. This woman was already not well, and the "prenatal care" she received put her further at risk.

This case illustrates how true prenatal care is compromised, not by the few remaining legal limits on child destruction and abortion, but by their ready availability. Readers of the literature on post-abortion syndrome will have encountered many other illustrations of what should be obvious: that you are not likely to help a woman by destroying her child. Experienced and attentive general practitioners and psychiatrists will be able to give their own examples.

Doctors need to pay close attention to the short paragraph on conscientious objection.<sup>1</sup> The authors declare that "a doctor's conscience should not be allowed to interfere with medical care" and that if "some individuals or institutions have moral objections ... those objections cannot compromise patient care". If that does not mean that the authors want to exclude anyone who disagrees with them about what constitutes "medical care" from medical practice, what *does* it mean? There could hardly be a plainer threat to doctors' personal professional judgement.

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1 de Crespigny LJ, Savulescu J. Pregnant women with fetal abnormalities: the forgotten people in the abortion debate. *Med J Aust* 2008; 188: 100-103.

2 Riley M, Halliday J. Birth defects in Victoria 2003-2004. Melbourne: Victorian Perinatal Data Collection Unit, Victorian Government Department of Human Services, 2006. [http://www.health.vic.gov.au/perinatal/downloads/bdr\\_report0304.pdf](http://www.health.vic.gov.au/perinatal/downloads/bdr_report0304.pdf) (accessed May 2008). □

Simon B Gerber and John T Wenham

**TO THE EDITOR:** Superficially, de Crespigny and Savulescu make a compelling case for clarifying late-term abortion law.<sup>1</sup> However, at a deeper level, it is disappointing that alternative points of view were not discussed in their article. The only solution offered in the case of a potentially imperfect child is to abort the pregnancy and try again. Unfortunately, this ignores several important issues.

First, the consequences of abortion for the mother, both physical and psychological, are neglected.<sup>2</sup> Our experience, as general practitioners, is that late-term abortions only lead to heartache and regret, even depression and anxiety, as the mother tries to deal with what has happened to her. Every time she sees either a “normal” or an “abnormal” child, her loss is re-lived. A patient of one of us (SBG) has developed Asherman syndrome as a result of a late-term abortion; she is now infertile.

Second, without a definition of “child”, any discussion regarding abortion law is, at best, futile; at worst, it is emotionally charged and reliant on anecdotes. If a fetus is defined as a child, then that child has a right to live, whatever the disability. If not, then any disability up to the defined age could potentially justify “abortion” (ie, destruction).

Third, the references given to support the assertion that women might “refuse to consider motherhood” without genetic testing described women who carry germline monogenic abnormalities (eg, thalassaemias, Huntington genotypes). These women would be eligible for earlier antenatal screening, such as pre-implantation genetic diagnosis, amniocentesis and chorionic vilus sampling — all of which are available well before the current legal time frames in question.

Fourth, de Crespigny and Savulescu’s premise for allowing late-term abortion is that there is a life-threatening fetal abnormality *and* the mother wishes to have children. However, a consequence of liberalising the law for the benefit of these women would be that women with non-life-threatening fetal abnormalities, and also those who simply did not want a child, could also access late-term abortion more easily. This is obviously a major concern.

Finally, use of the term “child destruction” in the law is important when considering these situations. A helpful definition of the purpose of the law is to prevent injustice.<sup>3</sup> As seen by the ability for women to access

“legal” abortion before 20 weeks’ gestation, any law that protects children needs to stand. The pregnant woman clearly has a voice; unfortunately, the unborn child does not have the same ability to state his or her case before an ethics committee.

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1 de Crespigny LJ, Savulescu J. Pregnant women with fetal abnormalities: the forgotten people in the abortion debate. *Med J Aust* 2008; 188: 100-103.

2 Fergusson DM, Horwood LJ, Ridder EM. Abortion in young women and subsequent mental health. *J Child Psychol Psychiatry* 2006; 47: 16-24.

3 Family Guardian. The purpose of law. <http://familyguardian.org/Subjects/LawAndGovt/Articles/PurposeOfLaw.htm> (accessed May 2008). □

Lachlan J de Crespigny and Julian Savulescu

**IN REPLY:** Watt seems to wish to return to the days of no prenatal testing; we believe today’s women reject this paternalistic view. However, Watt is correct in saying our article is “adult-centred” — it is not self-evident that the fetus is a patient, nor is this view consistent with those of most liberal legal jurisdictions.

It has been found that 81% of Australians,<sup>1</sup> including a majority in all major Australian religious groups,<sup>2</sup> agree with a woman’s right to choose an abortion. Only 4% of Australians consider abortion wrong.<sup>3</sup>

We echo Amnesty International’s call for abortion to be decriminalised globally.<sup>4</sup> Abortion laws should no longer discriminate against pregnant women with fetal abnormalities.

Contrary to Watt’s claims, it is well documented that an experienced psychiatrist was central in managing the pregnant woman who had an abortion at 32 weeks at the Royal Women’s Hospital. In addition, we do not believe abortion has been demonstrated to cause psychiatric “post-abortion syndrome”,<sup>5,6</sup> nor that abortion is analogous to amputating a healthy limb.

We do not challenge doctors’ personal judgements. All individuals must be free to make their own value judgements for their own lives, including doctors. However, doctors have a duty to inform patients of all appropriate treatments. When a patient requests abortion and the doctor has a moral objection to providing it, the doctor must refer the patient to another practitioner.<sup>5</sup>

Contrary to Gerber and Wenham’s claims, we did not suggest that “to abort the preg-

nancy and try again” is the only option for fetal abnormality. Abortion — or continuing the pregnancy — must be the woman’s decision.

One of us (LJdC) has 30 years’ experience of prenatal testing, including treating many women after terminations for fetal abnormality. Such women are sad about the diagnosis and outcome, extremely worried during subsequent pregnancies, and regret having had to make an awful decision. However, none have said that they made the wrong decision.

Regarding Gerber and Wenham’s comments about the definition of “child”, our position is that (before birth) the fetus does not have the rights of a child.<sup>7</sup>

The data we cited show that prenatal testing for Huntington disease “allows” at-risk women, who might otherwise choose not to conceive, to have children. Personal experience (of LJdC) shows that women with a past history of other serious fetal disorders are no different.

We did not suggest that late abortion should be available only in cases of life-threatening fetal abnormality. Indeed, our article clearly related to “pregnant women with fetal abnormalities” (not necessarily life-threatening). The claim that women would request late abortion simply because they don’t want a child demeans women’s integrity.

We need clear abortion laws so that pregnant women and their doctors can know when abortion is lawful. Developing clear laws necessitates removing the crime of child destruction.<sup>8</sup>

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1 Australian Reproductive Health Alliance. Social attitudes towards abortion [fact sheet]. Canberra: ARHA, 2004. <http://www.arha.org.au/factSheets/socialattitudestowardsabortionnew.pdf> (accessed Mar 2008).

2 Betts K. Attitudes to abortion in Australia: 1972 to 2003. *People Place* 2004; 12 (4): 22-28. <http://eicpress.monash.edu.au/pnp/view/abstract/?article=000010218> (accessed Mar 2008).

3 de Vaus D. Diversity and change in Australian families: statistical profiles. Melbourne: Australian Institute of Family Studies, 2004.

4 Zwart B. Amnesty in hot water on abortion. *The Age* (Melbourne) 2007; 28 May. <http://www.theage.com.au/news/national/amnesty-in->

- hot-water-on-abortion/2007/05/27/1180205077430.html (accessed May 2008).
- 5 House of Commons Science and Technology Committee. Scientific developments relating to the Abortion Act 1967. Twelfth Report of Session 2006–07. Vol I. London: The Stationery Office, 2007. <http://www.publications.parliament.uk/pa/cm200607/cmselect/cmsctech/1045/1045i.pdf> (accessed Mar 2008).
  - 6 Royal College of Obstetricians and Gynaecologists. The care of women requesting induced abortion. Evidence-based Clinical Guideline Number 7. London: RCOG, 2004. [http://www.rcog.org.uk/resources/Public/pdf/induced\\_abortionfull.pdf](http://www.rcog.org.uk/resources/Public/pdf/induced_abortionfull.pdf) (accessed Mar 2008).
  - 7 Savulescu J. Is current practice around late termination of pregnancy eugenic and discriminatory? Maternal interests and abortion. *J Med Ethics* 2001; 27: 165–171.
  - 8 de Crespigny LJ, Savulescu J. Abortion: time to clarify Australia's confusing laws. *Med J Aust* 2004; 181: 201–203. □

## Calcium supplementation does not increase mortality

Mark J Bolland, Andrew B Grey and Ian R Reid

**TO THE EDITOR:** We believe that Tang and Nordin<sup>1</sup> misunderstood the findings of our recent study of calcium supplementation.<sup>2</sup>

We disagree with their claim that the increase in the number of women with self- or family-reported myocardial infarction, stroke or sudden death became non-significant after adjustment for covariables. They correctly noted that the increased number of women experiencing the composite endpoint of cardiovascular events (after adjudication of events and inclusion of unreported events from hospital records) was not statistically significant. However, the increased event rate for this composite endpoint with calcium was statistically significant (rate ratio, 1.43; 95% CI, 1.01–2.04;  $P=0.043$ ). Thus, in our study, the number of women needed to treat with calcium for 5 years to cause one cardiovascular event was 29, and the corresponding number to prevent one fracture was 50.<sup>2</sup>

Tang and Nordin then meta-analysed data from five studies of calcium and vitamin D supplementation to conclude that calcium supplementation does not increase mortality.<sup>1</sup> We disagree.

For one of the studies, they classified a subgroup of participants who received annual vitamin D but no calcium supplements as having received “calcium supplementation”.<sup>3</sup> Further, for the RECORD (Randomised Evaluation of Calcium Or vitamin D) study, they compared the number of deaths between people receiving and not

receiving vitamin D (16.5% v 17.4%) rather than between those receiving and not receiving calcium (17.7% v 16.2%).<sup>4</sup> The trend for increased deaths with calcium supplementation in RECORD was greater when analysis was restricted to those treated with calcium monotherapy (18.5%) and placebo (16.3%).

As our study was of calcium monotherapy, the results of Tang and Nordin's meta-analysis are of questionable relevance to our findings. In addition, ours was a 5-year study, and the differences in vascular events between the groups only emerged after 2 years.<sup>2</sup> Only one study in Tang and Nordin's meta-analysis had an average follow-up duration of more than 25 months.<sup>4</sup>

Further, there is evidence from other studies of trends towards vascular events occurring more frequently in people who take calcium monotherapy.<sup>2,5,6</sup> In three out of four studies that reported mortality, there were trends towards increased death rates in people receiving calcium.<sup>2,4,6</sup> As we concluded,<sup>2</sup> these data are not definitive, but flag cardiac health as an area of concern in relation to calcium use.

Finally, we did not suggest that calcium supplementation should not be given to older women. However, in view of the evidence that any fracture risk reduction with calcium is small (<10%),<sup>7,8</sup> and the suggestions that calcium supplementation might increase the risk of hip fractures<sup>9–11</sup> and vascular events, it seems reasonable and timely to reassess the role of calcium supplementation.

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1 Tang BMP, Nordin BEC. Calcium supplementation does not increase mortality [letter]. *Med J Aust* 2008; 188: 547.

2 Bolland MJ, Barber PA, Doughty RN, et al. Vascular events in healthy older women receiving calcium supplementation: randomised controlled trial. *BMJ* 2008; 336: 262–266.

3 Harwood RH, Sahota O, Gaynor K, et al. A randomised, controlled comparison of different calcium and vitamin D supplementation regimens in elderly women after hip fracture: the Nottingham Neck of Femur (NoNOF) Study. *Age Ageing* 2004; 33: 45–51.

4 Grant AM, Avenell A, Campbell MK, et al. Oral vitamin D3 and calcium for secondary prevention of low-trauma fractures in elderly people (Randomised Evaluation of Calcium Or vitamin D, RECORD): a randomised placebo-controlled trial. *Lancet* 2005; 365: 1621–1628.

5 Prince RL, Devine A, Dhaliwal SS, et al. Effects of calcium supplementation on clinical fracture and bone structure: results of a 5-year, double-blind,

placebo-controlled trial in elderly women. *Arch Intern Med* 2006; 166: 869–875.

6 Baron JA, Beach M, Mandel JS, et al. The Calcium Polyp Prevention Study Group. Calcium supplements for the prevention of colorectal adenomas. *N Engl J Med* 1999; 340: 101–107.

7 Tang BMP, Eslick GD, Nowson C, et al. Use of calcium or calcium in combination with vitamin D supplementation to prevent fractures and bone loss in people aged 50 years and older: a meta-analysis. *Lancet* 2007; 370: 657–666.

8 Freyschuss B, Ljunggren O, Saaf M, et al. Calcium and vitamin D for prevention of osteoporotic fractures. *Lancet* 2007; 370: 2098–2099; author reply 2099.

9 Bischoff-Ferrari HA, Dawson-Hughes B, Baron JA, et al. Calcium intake and hip fracture risk in men and women: a meta-analysis of prospective cohort studies and randomized controlled trials. *Am J Clin Nutr* 2007; 86: 1780–1790.

10 Reid IR, Bolland MJ, Grey A. Effect of calcium supplementation on hip fractures. *Osteoporos Int* 2008; 20 Feb [Epub ahead of print].

11 Cumming RG, Cummings SR, Nevitt MC, et al. Calcium intake and fracture risk: results from the study of osteoporotic fractures. *Am J Epidemiol* 1997; 145: 926–934. □

Benjamin M P Tang and  
B E Christopher Nordin

**IN REPLY:** In Table 5 of Bolland and colleagues' study, the  $P$  value after allowing for covariables was 0.08,<sup>1</sup> which is not significant. This was without including smoking, which would undoubtedly have reduced the significance further as there were more smokers in the calcium group.

Based on Bolland and colleagues' suggestion, we reanalysed the data by removing the group receiving vitamin D but no calcium supplements in the NoNOF (Nottingham Neck of Femur) study,<sup>2</sup> and using data for those treated with calcium monotherapy (18.5%) compared to placebo (16.3%) in the RECORD (Randomised Evaluation of Calcium Or vitamin D) study.<sup>3</sup> The reanalysis still failed to show any evidence of an increase in mortality (relative risk, 1.05; 95% CI, 0.88–1.26;  $P=0.56$ ).

Benjamin M P Tang, Associate Researcher<sup>1</sup>

B E Christopher Nordin, Professor<sup>2</sup>

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1 Bolland MJ, Barber PA, Doughty RN, et al. Vascular events in healthy older women receiving calcium supplementation: randomised controlled trial. *BMJ* 2008; 336: 262–266.

2 Harwood RH, Sahota O, Gaynor K, et al. A randomised, controlled comparison of different calcium and vitamin D supplementation regimens in elderly women after hip fracture: the Nottingham Neck of Femur (NoNOF) Study. *Age Ageing* 2004; 33: 45–51.

3 Grant AM, Avenell A, Campbell MK, et al. Oral vitamin D3 and calcium for secondary prevention of low-trauma fractures in elderly people (Randomised Evaluation of Calcium Or vitamin D, RECORD): a randomised placebo-controlled trial. *Lancet* 2005; 365: 1621-1628. □

## Apical lung hernia

George R Crowe

**TO THE EDITOR:** My attention was drawn to the *Snapshot* of an apical lung hernia published in the Journal last year.<sup>1</sup>

Persons with emphysematous hypertrophic lungs are often found to have clinically discernible supraclavicular swellings (Box). The finding of these swellings is a surprisingly common sign that is little remarked upon in clinical descriptions.

These swellings are the bullous expansions of the apices of the lungs.

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1 Joshi JM. Apical lung hernia. *Med J Aust* 2007; 187: 368. □

### Supraclavicular swelling in patients with emphysematous hypertrophic lungs



A woman (A) and a man (B) with visible supraclavicular swellings. ◆

### Correction

Re: “Bystander basic life support: an important link in the chain of survival for children suffering a drowning or near-drowning episode”, by Jeanette Marchant, Nicholas G Cheng, Lawrence T Lam, Fiona E Fahy, SV Soundapound, Danny T Cass and Gary J Browne, in the 21 April 2008 issue of the Journal (*Med J Aust* 2008; 188: 484-485). The fifth author's name was spelled incorrectly. The correct spelling of the author's name is SV Soundappan. The web version of this article was corrected on 2 June 2008. □

### Correction and notice

Re: “Misleading advertising of PI-based drug information?”, the letter by Jim R Stockigt, in the printed version of the 2 June 2008 issue of the Journal (*Med J Aust* 2008; 188: 679-680). Professor Stockigt's affiliations were incorrect and incomplete, and should have read:

Jim R Stockigt, Endocrinologist,<sup>1</sup> Emeritus Consultant,<sup>2</sup> and Professor of Medicine<sup>3</sup>

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3 Monash University, Melbourne, VIC.  
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Further, it should be noted that the question mark in the title was added at the Editor's discretion. □

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### Actelion Pharmaceuticals

Tracleer — Breathless, listless, lifeless . . . . . p48

Tracleer — PBS Information . . . . . p49

### Avant

Medical indemnity . . . . . Outside back cover

### Covidien

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### MIGA

Medical indemnity . . . . . p50

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