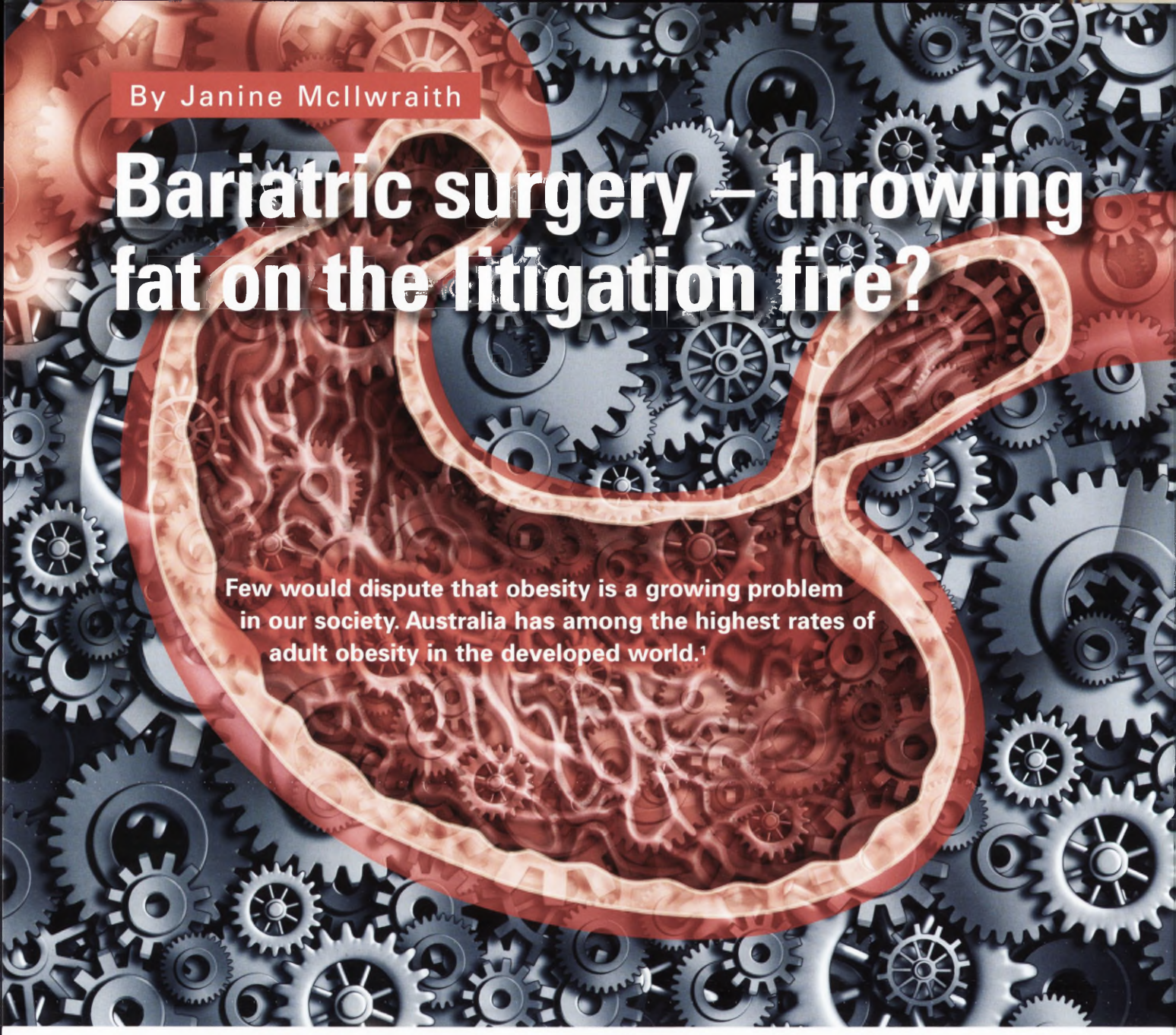
By Janine McIlwraith

Bariatric surgery – throwing fat on the litigation fire?



Few would dispute that obesity is a growing problem in our society. Australia has among the highest rates of adult obesity in the developed world.[1]

In 2011-12, 63 per cent or nearly two in three adult Australians were overweight or obese.[2] The rising obesity rates are a major public health concern, with many believing it will become one of the greatest health challenges of the 21st century.[3] It has been described as the 'consummate pathogen'[4] as it increases the risk of developing other health problems such as type 2 diabetes, cardiovascular disease, sleep apnoea, a range of cancers and depression.

It is no wonder, then, that a medical procedure that potentially has the capacity to reduce an individual's weight and thereby improve their overall health would be very popular. Bariatric surgery thus appears to be gaining popularity in both medical and lay circles. Indeed, as far back as 2009, the Standing Committee on Health and Ageing recommended that Commonwealth, state and territory governments ensure equity in access to publicly funded bariatric surgery.[5] And the rates of bariatric surgery are increasing in Australia: in 2004, bariatric surgery was the most rapidly growing area of surgical practice in the country.[6]

However, in the United Kingdom, the major medical insurance companies now class bariatric surgery as one of the highest litigation risks.[7] While there does not seem to be any publicly available data of a similar nature in Australia,[8] anecdotally at least, plaintiff lawyer firms receive a steady number of inquiries relating to bariatric surgery.

HOW DO WE DEFINE OBESITY?

The *Clinical Practice Guidelines for the Management of Overweight and Obesity in Adults, Adolescents and Children In Australia*[9] states that a BMI greater than 30 is classed as obese, while a BMI of 25.0 – 29.9 is considered overweight. The guidelines indicate that intensive intervention (including very low-energy diets, weight loss medications and bariatric surgery) may need to be considered for patients who are obese, and/or have risk factors or co-morbidities, or who have been unsuccessful in losing weight by lifestyle modification approaches. The guidelines suggest that

intensive intervention should be considered where an individual has a BMI greater than 30 or a BMI greater than 27 with risk factors or co-morbidities. Interestingly, the previous guidelines[10] stated that bariatric surgery was indicated for patients with a BMI greater than 40 or with a BMI greater than 35 and with other serious medical co-morbidities. In the period between the two publications there seems to have been a significant widening of the suitability criteria.

WHAT IS BARIATRIC SURGERY?

Bariatric surgery refers to a variety of surgical procedures including both open and laparoscopic procedures, which aim to induce weight loss through a physical reduction in the size of the stomach or its capacity to hold contents. There are three main types of bariatric surgery:

- gastric banding (often referred to as lap-banding);
- gastric bypass (or RouX-en-Y); and
- sleeve gastrectomy.

In Australia, the vast majority of surgery performed is gastric banding,[11] with one study suggesting that less than 1 per cent of the severely obese will opt for one of the more traditional surgical approaches (gastric bypass or biliopancreatic diversion) each year.[12]

Gastric banding involves placing a silicon band around the upper portion of the stomach and an access port, connected to the band by tubing, in the abdominal wall. The band reduces the amount of food that can enter the stomach. The access port allows saline to be injected or withdrawn to increase or decrease the size of the opening the band allows. It is the least radical of the surgical options and is classed as minimally invasive. It is often performed as a laparoscopic day procedure.

Gastric bypass and sleeve gastrectomy are both major surgical procedures. Sleeve gastectomy involves stapling the stomach to create a long slender pouch and then removing the rest of the stomach. It is permanent and irreversible. In gastric bypass surgery, a small pouch of stomach is created and this is then connected to the mid-jejunum, bypassing the remainder of the stomach and the first section of the small intestine. While the procedure is considered permanent, it is potentially reversible.

WHAT ARE THE RISKS?

Bariatric surgery is not without risk. Patients undergoing bariatric surgery often have a very high incidence of co-morbidities and because of their body habitus and co-morbidities, the surgery is technically demanding for both the surgeon and anaesthetist. Bariatric surgery generally is associated with cardio-respiratory failure, wound infections, venous thrombo-embolism, bleeding, and anastomatic leaks (that is, a leak where the stomach and bowel are joined together).

Gastric banding is said to be 7 to 10 times safer than gastric bypass in terms of mortality, and is associated with fewer peri-operative complications.[13] But it is associated with more late onset complications, such as prolapse of the stomach through the band and band erosion.

WHY HAS IT BECOME A MEDICO-LEGAL HOTSPOT?

So why is it that, in the UK at least, bariatric surgery is now considered by the major medical indemnity insurers to be one of the highest litigation risks?[14] There may be a number of factors at play, including:

- the learning curve factor;
- increasing numbers of procedures;
- private vs public hospital settings affecting outcomes;
- inadequate follow-up arrangements;
- poor patient selection;
- high patient expectations; and
- inadequately informed patients.

A new procedure

In medical terms, bariatric surgery is a relatively new approach to weight management. Gastric banding, for example, has been widely offered for only 10 years approximately; since 1992, bariatric surgical procedures have been listed on the Medical Benefits Schedule (MBS). When surgical techniques are relatively new, there can be a period in which techniques are honed and improved – an initial learning curve, if you like. As the surgery is offered by more practitioners, each practitioner will also experience a learning curve period. Poor outcomes may be more prevalent in such learning curve phases, and may be reflected in a greater number of complaints and claims for compensation.

High volume of procedures

There is also no doubt that increasing numbers of bariatric surgical procedures are being undertaken. In 1998 to 1999, there were just 535 procedures performed. In stark contrast, in 2007 to 2008 there were 17,000 bariatric surgeries undertaken.[15] On a purely numerical scale, one might expect more claims as the number of procedures increases.

Clinical settings

The setting in which bariatric surgery is undertaken may also be of significance. Most bariatric surgery is performed in private healthcare facilities, on people who have private health insurance and can afford the 'gap' costs. In 2007, 96 per cent of lap-band procedures were performed in private hospitals and only 10 per cent of bariatric surgeries occurred in public hospitals.[16] Often the surgery involves only a short hospital stay. This requires the patient to be given optimal instructions with regard to post-discharge care and any warning signs of complications. It is not uncommon for a patient to experience symptoms which they wish to discuss with their doctor outside of normal business hours and the availability of the surgeon to advise a patient in such circumstances is of importance.

Post-surgery complications

Linked to where surgery takes place is that when patients do experience complications post-surgery, they often present to a different institution to where the surgery was performed (often a public hospital). This may deprive the healthcare professionals in the second hospital of much of the information regarding the surgery conducted, or cause a >>

delay in the retrieval of such information. It may also mean that the staff called upon to deal with the complication are unfamiliar with bariatric surgery and its potential complications. Inadequate discharge instructions and/or delay in the management of post-operative complications may found a claim in negligence.

Screening of candidates for procedures

A lack of veracity in patient screening and selection methods may mean that patients are being offered procedures that are not really advisable in their circumstances, or unlikely to provide the outcome they desire. The Royal Australian College of Surgeons recommends that candidates for bariatric surgery are those who are morbidly obese (BMI greater than 40); have tried to lose weight in the past; are prepared to make the necessary lifestyle changes following surgery; are not heavy drinkers; and do not have a metabolic condition that causes weight gain.[17] There may be an issue as to whether the different types of bariatric surgery are being canvassed with potential patients and whether the patient is being given the opportunity to weigh the risks, benefits and burdens of each.

Patient expectations

Patient understanding of the likely outcome may also be lacking. Research suggests that gastric bypass is the most effective in obtaining weight loss.[18] Patients undergoing gastric bypass might expect to achieve a 30 per cent weight loss over the first two years post-procedure, with a slight regaining of weight over the following 10 to 15 years.[19] Gastric banding is thought to produce much less weight loss, but with careful and persistent follow-up, Australian figures suggest a 15-20 per cent weight loss.[20] However, in the United States some studies have indicated that large numbers of patients have the band removed after two to three years due to failure to achieve any significant weight loss.[21] The other measure of success is the improvement in obesity-related health problems, and studies indicate that improvements in type 2 diabetes, for example, occur with quite modest weight loss and quite rapidly following surgery.[22]

While many advocate for bariatric surgery to be more widely available, there are also those who adopt a more cautious approach and are concerned at the light in which bariatric surgery may be cast. One report on bariatric surgery trends states: 'It is disgraceful that doctors should allow their services to be marketed in the fashion . . . where complex surgery is presented in optimistic "quick fix" terms rather than presenting balanced information about the risks and disadvantages inherent in the procedure'.[23] There may be a lack of information provided to patients not only about the likely results, but also about the extent of the lifestyle changes that must follow the procedure and the follow-up that will be required to obtain the intended result. This may be complicated by a lack of long-term data on gastric banding outcomes because of the relatively short history of the procedure.

There is little doubt that patients often approach bariatric surgery with high expectations. Consent procedures need to be very thorough and robust. Patients need to be aware that surgery is not a panacea and is only part of the solution to weight loss; they will need to be committed to life-long lifestyle modifications to benefit from the surgery. They also need to be aware that there are risks, and that complications are not infrequent; a recent article noted that complications occur in 4 out of every 10 procedures.[24] The fact that patients have often paid large sums of money to undergo the surgery may also increase their expectations and fuel their desire for retribution when the desired outcome is not achieved. The demographics of most patients undergoing bariatric surgery also means that the majority will be well-educated and capable of voicing their dissatisfaction, if they do not receive the care that they believe they should.

Finally, it should not be forgotten that these are complex surgeries and many of the patients have extensive co-morbidities. Therefore, when complications do occur, they may be initially difficult to diagnose and then hard to treat. It also means that complications can quickly cascade and outcomes can be disastrous.

WHAT TYPES OF CLAIMS ARE ARISING?

Claims arising out of bariatric surgery appear to fall into three categories:

1. informed consent;
2. negligent performance of the surgery itself; and
3. inadequate post-operative management/follow-up.[25]

A study of claims in the UK related to bariatric surgery concluded that the main foundations for claims of negligence related to bariatric surgery were leaks and delayed diagnosis of complications.[26] Surprisingly, claims relating to the consent process were relatively uncommon.

There may also be claims to which the issue of bariatric surgery is central, but do not relate to the actual performance of the procedure. For example, in *Almario v Varipatis (No. 2)*,[27] Campbell J held that 'it is incumbent upon a medical practitioner to do more than merely point out the risks and counsel weight loss' [85]. He went on to state that he was satisfied that a reasonable GP would refer a person in Mr Almario's situation, with his history of failed weight loss attempts and his co-morbidities, directly to a bariatric surgeon for consideration of surgical management (at [91]). However, in *Varipatis* v *Almario*[28] the court allowed the appeal and reversed the finding of Campbell J. Basten JA (with whom Ward JA agreed) stated (at [38]):

> 'A general practitioner may be obliged, in taking reasonable care for the health of a patient, to advise in unequivocal terms that weight loss is necessary to protect his or her health, to discuss the means by which that may be achieved and to offer (and encourage acceptance of) referrals to appropriate specialists or clinics . . . If the plaintiff refused to take the firm advice of his general practitioner, and of experts to whom he had been referred, there was no breach of duty on the part of a general practitioner in failing to write a further referral. The duty of care stopped short of requiring an exercise in futility.'

The overturning of the decision in *Varipatis* does not appear

to rule out a finding of negligence against a GP for failure to adequately advise and treat on weight management, if the factual matrix is right.

An example of case that considered the nature of the duty to inform in relation to the risks associated with gastric banding surgery is *Coppolina v Kierath*.[29] *Medical Board of Western Australia and McGushin*[30] considered deficiencies in the doctor's practice of bariatric surgery and the appropriate penalty to be imposed in circumstances where the doctor had admitted to a number of allegations of gross carelessness but had undertaken considerable retraining to address the deficiencies in his practice and was prepared to accept conditions on his registration.

CONCLUSION

There are many advocates of bariatric surgery and significant media attention has recently been given to calls for bariatric surgery to be made more widely available. Some experts go so far as to suggest that bariatric surgery should be more widely available through the public health system for adolescents.[31] A rise in the number of procedures being performed is of itself likely to be one reason for a spike in claims related to bariatric surgery. However, it is unlikely to be the sole cause.

Bariatric surgery is an elective procedure and, as such, may have a relatively high requirement for thorough and frank information to be provided to the patient.[32] Where patients do not understand both the immediate risks and benefits of the procedure as well as the long-term implications of the surgery, the possibility of a claim for lack of informed consent arises.

At present, bariatric surgery in Australia is most commonly performed in a private setting. Discharge instructions and post-operative follow-up are of particular importance, given that patients are often discharged home quite quickly after their procedure. Delay in diagnosing and treating complications of bariatric surgery is a documented source of medical litigation. Our public hospitals need to be equipped to recognise and deal with complications arising from bariatric surgery, a skill that may be fostered if there was an increase in procedures being performed in the public hospital setting.

Few claims in the medical negligence arena are straightforward and claims related to bariatric surgery are no different. However, the UK experience suggests that scrutiny of the consent procedures, post-operative care and follow-up and the performance of the surgery itself may result in higher numbers of claims than for other elective surgical procedures or areas of medicine more generally. ■

Notes: **1** OECD (2013), *Health at a Glance* 2013: *OECD Indicators*, OECD Publishing, p 58. Accessible at http://www.oecd.org/els/health-systems/Health-at-a-Glance-2013.pdf **2** COAG Reform Council Report, *Healthcare 2011-2012: Comparing performance across Australia*, released in May 2013. Accessible at http://www.coagreformcouncil.gov.au/reports/healthcare/healthcare-2011-12-comparing-performance-across-australia **3** O'Brien P, Brown W, & Dixon J, 'Obesity, weight loss and bariatric surgery', *MJA* 2005; 183 (6): 310-14. **4** *Ibid.*. **5** House of Representatives, Standing Committee on Health and Ageing, *Weighing it up: Obesity in Australia*, May 2009. Accessible at http://www.aph.gov.au/Parliamentary_Business/Committees/House_of_Representatives_Committees?url=haa/./obesity/report/fullreport.pdf **6** O'Brien P, Dixon J, & Brown W, 'Obesity is a surgical disease: overview of obesity and bariatric surgery', *ANZ J Surg*, 2004; 74:200-4. **7** Khan, O and Reddy, K, 'Bariatric Surgery: A Medico-legal perspective. Available at http://connect.avma.public-i.tv/document/Bariatric_surgery_medicolegal_guide.pdf **8** The Australian Institute of Health and Welfare, *Report on Australia's medical indemnity claims 2011-12* does not identify bariatric surgery as a separate practice area. See at page 32. Accessible at https://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=60129543595 **9** National Health and Medical Research Council (2013) *Clinical practice guidelines for the management of overweight and obesity in adults, adolescents and children in Australia*. Melbourne: National Health and Medical Research Council; available at http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/n57_obesity_guidelines_131204_0.pdf [accessed 28/01/14]. **10** Department of Health and Ageing (updated March 2004) *Clinical practice guidelines for the management of overweight and obesity in adults*. This is an historical version of the document and no longer appears to be available on the internet **11** Korda, R et al, (2012) 'Inequalities in bariatric surgery in Australia: findings from 49,364 obese participants in a prospective cohort study', *MJA* 197 (11/12): 631-6. **12** O'Brien P & Dixon J, Laparoscopic Adjustable Gastric Banding in the Treatment of Morbid Obesity, *Arch Surg* (2003); 138: 376-2. **13** *Ibid.* **14** Khan, O and Reddy, K, 'Bariatric Surgery: A Medico-legal perspective'. http://connect.avma.public-i.tv/document/Bariatric_surgery_medicolegal_guide.pdf **15** Korda, R et al, see note 11 above. **16** Allergan Australia Pty Ltd, *Submission No 75 to the Review of Obesity in Australia Inquiry* June 2008. **17** Royal Australasian College of Surgeons, The Obesity Surgery Society of Australia and New Zealand, *Weight Loss Surgery: A guide for patients about bariatric surgery* Ed 1 (19 May 2009). **18** Kushner R and Noble C, Long-term Outcome of Bariatric Surgery: An Interim Analysis, *Mayo Clin Proc* (2006); 81 10, suppl): ss46-51. **19** Interview with David Flum on Radio National, *The Health Report*, on 26 July 2004. **20** See note 16 above. **21** See note 16 above. **22** Brolin R, 'Bariatric Surgery and Long-term Control of Morbid Obesity', *JAMA* (2002); 288 (22): 2793-6. **23** Martin, I C et al, *Too Lean a Service? A review of the care of patients who underwent bariatric surgery. A report of the National Confidential Enquiry into Patient Outcome and Death* (2012). Available at http://www.ncepod.org.uk/2012report2/downloads/BS_report_summary.pdf **24** Agency for Healthcare Research and Quality Obesity Surgery Complication Rates Higher Over Time. Press Release, July 24 2006. **25** Khan, O and Reddy, K, see note 14 above. **26** Cottam, D et al, 'Medicolegal analysis of 100 malpractice claims against bariatric surgeons', *Surgery for Obesity and Related Diseases* 3 (2007) 60-7. **27** *Almario v Varipatis (No. 2)* 2012 NSWSC 1578. **28** *Varipatis* v *Almario* (2013) NSWCA 76. **29** *Coppolina v Kierath* [2003] WADC 141 (20 June 2003). **30** *Medical Board of Western Australia and McGushin* [2009] WASAT 128 (26 June 2009). **31** See article 'Weight loss surgery "life changing"', *MJA*, insight 11/11/13 available at http://www.mja.com.au/insight/2013/43/weight-loss-surgery-life-changing [accessed 11/11/13]. **32** See the discussions in *O'Brien v Wheeler* (NSWCA), Mason P, Powell and Stein JJA, No 40205/95, 23 May 1997, BC9708022, unreported); *Bustos v Hair Transplant Pty Ltd* (NSWCA, Gleeson J, Powell and Beazley JJA, No 40045/95, 15 April, 1997, unreported); *Olbourne v Wolf* [2004] NSWCA 141; and *Tan v Benkovic* [2000] NSWCA 295.

Janine McIlwraith *is a senior lawyer with Catherine Henry Partners. She is also the co-author of Australian Medical Liability, Health Care and the Law 6th ed., and the National Disability Insurance Scheme Handbook as well a number of chapters for Halsburys Laws of Australia relating to health law and professional regulation.* **PHONE** *(02) 4929 3995*

EMAIL *janinem@chpartners.com.au*