

Implementing US-style anti-fraud laws in the Australian pharmaceutical and health care industries

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Government expenditure on medicines and health care in Australia runs to billions of dollars annually. Federal expenditure on the Pharmaceuticals Benefits Scheme (PBS) increased from A\$3.2 billion in the 1998–99 financial year to A\$8.3 billion in 2009–10.¹ In 2008, the federal government spent A\$45 billion on health care and state governments spent A\$26 billion.² Federal expenditure on health care in general is expected to be over A\$70 billion in 2011 and will increase partly as a result of projected changes to federal–state administrative arrangements.³ Per capita yearly government expenditure on health (calculated using the average exchange rate) is about US\$4000 in Australia and US\$7000 in the United States.⁴

Risks of corporate fraud in Australian health care

In the US, the health sector is a major target for fraudulent corporate activities, such as reporting false claims or costs, billing for services or procedures not performed or medically unnecessary, hiding improper financial arrangements with health care goods and service providers, as well as promoting off-label uses to physicians, lying about the true wholesale price and submitting false performance records⁵ (Box 1).

In Australia, a recent representative proceeding (class action) in the Federal Court found that Merck Sharpe and Dohme trained its representatives to minimise physician concerns about adverse cardiovascular effects of Vioxx (rofecoxib). The company even created a publication called the *Australasian Journal of Bone and Joint Medicine*, which was neither peer-reviewed nor independent, to advertise a product subsequently found under the *Trade Practices Act 1974* (Cwlth) to be defective (s 75AD) and not reasonably fit for purpose (s 74B) or of merchantable quality (s 74D).⁶ This heightens concerns that the Australian pharmaceutical market is unlikely to be immune from US-style false claims and fraud, if only because most of the major drug companies proven to have engaged in such conduct against the US government also dominate the Australian market (Box 2). A report by the University of Melbourne and KPMG estimated that the total amount of money lost to corporate fraud in Australia, including in the health care sector, was about A\$350 million in 2010 and growing at an annual rate of 7%, with only a third being detected.⁷

Under the *Medicare Australia Act 1973* (Cwlth), Medicare is empowered to monitor payments on claims paid for both Medicare and the PBS for fraud. It does this through a program of audits as well as sophisticated methods of data analysis. Under the *Health Insurance Act 1973* (Cwlth), civil penalties can be imposed on providers of pathology or diagnostic services for asking for or accepting prohibited benefits (s 23DZZIK), offering or providing prohibited benefits (s 23DZZIL) and making threats to induce the above conduct (s 23DZZIM) (Box 3). Within 6 years of a wrongdoer contravening a civil penalty provision, the Chief Executive Officer of Medicare Australia may apply on behalf of the Commonwealth to the Federal Court for an order that the wrongdoer pay the Commonwealth a pecuniary penalty (s 125A(1)). In the 2006–07 financial year, Medicare pursued 499 individuals for A\$3.4

ABSTRACT

- This article critically analyses the prospects for introducing United States anti-fraud (or anti-false claims) laws in the Australian health care setting.
- Australian governments spend billions of dollars each year on medicines and health care. A recent report estimates that the money lost to corporate fraud in Australia is growing at an annual rate of 7%, but that only a third of the losses are currently being detected.
- In the US, *qui tam* provisions — the component of anti-fraud or anti-false claims laws involving payments to whistleblowers — have been particularly successful in providing critical evidence allowing public prosecutors to recover damages for fraud and false claims made by corporations in relation to federal and state health care programs.
- The US continues to strengthen such anti-fraud measures and to successfully apply them to a widening range of areas involving large public investment.
- Australia still suffers from the absence of any comprehensive scheme that not only allows treble damages recovery for fraud on the public purse, but crucially supports such actions by providing financial encouragement for whistleblowing corporate insiders to expose evidence of fraud. Potential areas of application could include direct and indirect government expenditure on health care service provision, pharmaceuticals, medical devices, defence, carbon emissions compensation and tobacco-related illness.
- The creation in Australia of an equivalent to US anti-false claims legislation should be a policy priority, particularly in a period of financial stringency.

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million in “incorrect payments” and 550 investigations into fraudulent claiming were begun, with 79 referred to the Commonwealth Director of Public Prosecutions, who successfully prosecuted 56 individuals to recover A\$312 927.⁸ Yet in Australia (unlike the US) large-scale anti-fraud and anti-competitive prosecutions in the pharmaceutical sector have been rare. One example was the 2001 Australian Competition and Consumer Commission prosecution in the Federal Court of Roche Vitamins Australia (A\$15 million penalty), BASF Australia (A\$7.5 million) and Aventis Animal Nutrition (A\$3.5 million), in connection with a global price-fixing cartel supplying vitamins A and E in animal feeds, which inflated general food prices.⁹

Comparison with the anti-fraud measures in the US health care sector

The False Claims Act (31 US Code ss 3729–3733) (FCA) began during the US Civil War and was substantially amended in 1986 by the Reagan administration, and in 2009 by the Obama adminis-

1 Types of fraudulent and false claims successfully prosecuted under the United States False Claims Act*

- Billing for goods and services never delivered or rendered; marketing and lobbying; inappropriate or unnecessary medical procedures; work or tests not performed; inferior equipment as premium equipment; automatic laboratory tests based on range not request; patented drugs when generic drugs were provided; unlicensed or unapproved drugs; research that was never conducted.
- Billing at doctors rates for work by a nurse, resident or intern.
- Billing to increase revenue not for actual work performed.
- Double billing for the same goods or service.
- Unbundling — using multiple billing codes instead of one billing code for a drug panel test in order to increase remuneration.
- Bundling — billing for a panel when a single test was ordered.
- Upcoding — inflating bills by using diagnosis billing codes that suggest a more expensive illness or treatment.
- Charging for employees who were not actually on the job, or billing for made-up hours to maximise reimbursements.
- Failing to report known product defects in order to be able to continue to sell or bill the government for the product.
- Falsifying research data paid for by the government.
- “Lick and stick” prescription rebate fraud and “marketing the spread” prescription fraud (lying to the government about true wholesale price of prescription drugs).
- Pumping, mining or harvesting more natural resources from public lands than is actually reported to the government.
- Not reporting overpayment by the government.
- Misrepresenting the value or origin of imported goods.
- Falsely certifying that a contract falls within certain guidelines (ie, the contractor is part of a minority group or is a veteran).
- Submitting false performance records or samples.
- Presenting broken or untested equipment as operational.
- Certifying a product as having passed a test when it has not.
- Yield burning — skimming profits from sale of municipal bonds.
- Winning a contract through kickbacks or bribes.
- Prescribing a medicine or recommending a type of treatment or diagnosis regimen to win kickbacks from hospitals, laboratories or pharmaceutical companies.
- Forging physician signatures when such signatures are required for reimbursement from Medicare or Medicaid.

* Source: False Claims Act Legal Center website at <http://www.taf.org/legalupdate.htm>.

tration. It now imposes liability upon anyone who knowingly or with “deliberate ignorance” or “reckless disregard” of the truth submits, or conspires with another to submit, a false claim or related false record:

- for payment from the US Government or from an entity administering government funds; or
- to avoid or decrease an obligation to pay the US Government.

Qui tam provisions are a component of these false claims laws that have proved extremely effective in encouraging whistleblowers to provide (in a private–public enforcement partnership) crucial “insider” evidence about corporate fraud in a wide range of settings (Box 1). The words *qui tam* are an abbreviation of a Latin legal maxim broadly meaning “he who sues on behalf of himself also sues on behalf of the state”. *Qui tam* laws allow private citizens (relators) the right to provide documents establishing fraud or false

claims (the terms are generally interchangeable in this context) upon the government to a no-win–no fee lawyer who, if convinced of the merits, will fund and file with a Department of Justice office a lawsuit under seal (not initially disclosed to the defendant) (s 3730(b)). Whistleblowers are rewarded with between 15% and 30% of whatever proceeds the government recovers from the civil suit (ss 3729(a), 3730(d)(1), 3730(d)(2)).¹⁰ The prospects of success are greater if federal or state justice department officials can be convinced to join the case.¹¹ In such instances, the *qui tam* relator and his or her counsel act as force multipliers for the often cash-strapped public prosecutors, contributing valuable human and financial resources to the action.

Qui tam whistleblower suits constitute about 80% of all false claims actions and have been very successful in achieving substantial recoveries from corporations in the health service, pharmaceutical, education, defence, and oil and gas sectors.¹² In 2010, recoveries from pharmaceutical and medical device companies accounted for 65% of the US\$2.5 billion recovered from health care fraud claims.¹³ *Qui tam* actions against pharmaceutical companies are now the most successful type of anti-false claims litigation¹⁴ (Box 4). In recent years, nearly half of all US states have enacted their own anti-false claims statutes.

Treble damages, civil penalties and criminal offences

In addition to prosecution for criminal offences and penalties, since 1986, the FCA has provided for treble damages, which the US Supreme Court has held to be largely compensatory or remedial rather than punitive.¹⁵ Treble damages give public law enforcement agencies a substantial financial incentive to undertake protracted investigations and actions, while the potential to receive 15%–30% of that amount creates a critical incentive for corporate insiders to overcome their concerns about the risks associated with whistleblowing (such as intimidation, loss of livelihood, friends and family, and mental anguish).¹⁶ Civil fines of about US\$11 000 per claim (eg, per billing item) are also imposed. Companies convicted of offences under the FCA can be barred from involvement in government programs, though some companies appear to have circumvented this by shifting liability to subsidiary corporate entities.

The expanding scope of the FCA

The range of fraudulent activities in health care covered by the FCA is fairly broad and extends to prohibited conduct prescribed in other federal statutes, such as the Anti-Kickback Statute of 1972, the Anti-Self Referral (“Stark”) Law of 1995, the Fraud Enforcement and Recovery Act 2009 and the Patient Protection and Affordable Care Act 2010. False claims liability was an important public interest protection built into the financial sector bailouts of the Troubled Asset Relief Program under the Emergency Economic Stabilization Act 2008.

Although the FCA traditionally did not apply to taxation, in the circumstances specified in the Tax Relief and Health Care Act 2006 (s 406), treble damages and whistleblower awards of 15%–30% of the amount recovered by the Internal Revenue Service apply if the tax, penalties and interest in dispute exceed US\$2 million. It is even arguable that anti-false claims actions may be available under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) 2009, by which the US Food and Drug Administration specifies criteria for manufacturing, registration and marketing approvals for tobacco products (including receiving all relevant

2 Eight Australian Pharmaceutical Benefits Scheme (PBS) suppliers with highest market share and representative United States False Claims Act (FCA) actions against their related companies in the US

Australia		US	
PBS supplier	Market share*	Related company	FCA action
Alphapharm	14%	Mylan Inc.	US\$65 million (2010)
Pfizer Australia	10%	Pfizer Inc.	US\$2300 million (2009)
Sigma	10%	Aspen USA	None
AstraZeneca Australia	9%	AstraZeneca US	US\$520 million (2010)
Sanofi-Aventis ANZ	8%	Sanofi-Aventis US	US\$95.5 million (2009)
GlaxoSmithKline Australia	5%	GlaxoSmithKline US	US\$150 million (2005); US\$750 million (2010)
Merck Sharpe and Dohme (Australia)	3%	Merck	US\$650 million (2008)
Bristol-Myers Squibb Australia	3%	Bristol-Myers Squibb	US\$515 million (2007)

* Based on number of prescriptions in the 2008–09 financial year.¹ ◆

corporate research [s 904]), among other reasons to restrain government payments under Medicare and Medicaid for tobacco-related illness.

In the words of the US Supreme Court, “the [FCA] was intended to reach all types of fraud, without qualification, that might result in financial loss to the Government.”¹⁷ The enforcement partnership has proven extremely cost-effective, recouping US\$15 for every US\$1 spent on *qui tam* investigations and litigation.¹⁸ *Qui tam* laws can act as potent deterrents for fraudulent activities as they amplify the threat of detection and prosecution, and create incentives for compliance with government requirements and conditions. The relevant government law enforcement body retains control. Where the government decides to intervene in the action, it takes over the prosecution of the claim, and the relator must tender full cooperation, or the government may compel the court to limit the relator’s role in litigation (ss 3730(b)(4), 3730(c)(1), 3730(c)(2)(B), 3730(c)(2)(C)). Even if the government refuses to intervene, allowing the relator to proceed with the lawsuit on the government’s behalf (s 3730(b)(4)(B)), it still actively monitors the case and has a right to review all pleadings and to later join the case where good cause is shown (ss 3730(b)(3), 3730(c)(3)). As such, fears about perverse incentives driving enforcement¹⁹ or over-enforcement,²⁰ are unfounded.

Checks and balances against inappropriate claims

Frivolous or parasitic *qui tam* claims are curtailed not only by the large amounts that plaintiff lawyers acting for “relators” must pay up-front and by scrutiny of the case by Department of Justice officials, but by statutory bars to individuals who have made no material contribution to uncovering the fraud or providing the factual basis of the claim.¹² In a recent case where the relator could not identify each false claim the defendant had submitted to US

Medicare and Medicaid, the court found that the relator’s allegations were sufficiently particular because they identified the providers whom the defendant had caused to submit false claims, the dates of the claims, the monetary amounts, and the number of claims.²¹

The 2009 amendments to the FCA clarified that, while a relator cannot base a *qui tam* action on publicly disclosed allegations (already in a government report, hearing, audit or investigation or in the media), a court may still have jurisdiction if the Attorney General nonetheless decides to bring the action, or if the relator is the original source of that information (s 3730(e)(4)(A)). Original source is defined as “an individual who has direct and independent knowledge of the information on which the allegations are based” (s 3730(e)(4)(B)).

Implementing *qui tam* legislation in Australia

A comparison with the situation in the US strongly suggests that one reason for the lack of large-scale anti-fraud and anti-false claims actions in the pharmaceutical and health care sectors in Australia may relate to the lack of insider information from private corporations provided to law enforcement officials. Whistleblowing is an infrequent phenomenon from within the Australian health care sector; it is not encouraged, rewarded or adequately protected.²² In 1989, a federal committee recommended that *qui tam* laws were incompatible with accepted practice in the Australian legal system.²³ By 2011, however, significant progress has been made in Australia towards a uniform legislative regime for protecting whistleblowers from unjust reprisals.²⁴ The potential application of US *qui tam* laws to facilitate whistleblowing about fraud and false claims from within the Australian private corporate health care and pharmaceutical sectors again has been suggested to the Australian Government (TAF, invited oral testimony to the Australian House of Representatives Standing Committee on Legal and Constitutional Affairs, 18 Sep 2008). Given the scale of public investment in the Australian health care service, pharmaceutical, medical device and other health-related industries, we believe that an anti-fraud regime based on that of the US should be introduced in Australia. Such laws comport with developing Australian legal principles and are likely to prove as effective here as they have been in the US.

Over the past 20 years, anti-competitive behaviour has increasingly been regarded as a serious crime by Australian regulators. No win–no fee advertising is now common, and litigation funding

3 Offences with penalties under the *Health Insurance Act 1973 (Cwlth)* that could also allow governments to recover treble damages if *qui tam* statutes were enacted in Australia

- Prohibition of certain medical insurance (s 126).
- Preclusion on agreements to assign Medicare benefits (s 127).
- Offences in relation to tax returns (s 128).
- False statements relating to Medicare benefits (s 128A).
- Knowingly making false statements relating to Medicare benefits (s 128B).
- Charging fees for provision of public hospital services to public patients (s 128C).
- Making false statements (s 129).
- Bribery in relation to admissions to private hospitals (s 129AA). ◆

4 Prominent *qui tam* claims in the United States pharmaceutical industry, 2001–2010

Company	Year	Settlement* (US\$ million)	Relator's share† (US\$ million)	Drug	Fraudulent or false claim
TAP	2001	875	95.0 (10.9%)	Lupron	Reported false average sale price for drugs reimbursed by Medicare and Medicaid; anti-kickback violations
Bayer	2003	257	34.2 (13.3%)	Cipro, Adalat CC	Illegal sale of cheaper relabelled drugs to private payers; falsified information to avoid paying rebates to the government
Warner-Lambert	2004	430	24.6 (5.7%)	Neurontin	Illegal marketing for off-label use unapproved by the FDA; false claims about the safety of the drug
Schering-Plough	2004	345	31.7 (9.2%)	Claritin	Anti-kickback violations to protect top-selling allergy drug
GlaxoSmithKline	2005	150	26.0 (17.3%)	Zofran, Kytril	Reported false average sale price for drugs reimbursed by Medicare and Medicaid
Serono	2005	704	51.8 (7.4%)	Serostim	Anti-kickback violations to make patients appear to be candidates for the drug
Bristol-Myers Squibb	2007	515	50.0 (9.7%)	Pravachol, Glucophage and others	Illegal marketing for off-label uses unapproved by the FDA; anti-kickback violations to induce prescription
Merck	2008	650	68.0 (10.5%)	Vioxx, Pepcid	Anti-kickback violations to induce prescription; failed to administer proper rebates to government programs
Cephalon	2008	425	46.5 (11.0%)	Provigil, Gabitril, Actiq	Illegal marketing for off-label uses unapproved by the FDA
Eli Lilly	2009	1400	79.0 (5.6%)	Zyprexa and others	Illegal marketing for off-label uses to children and to elderly patients in long-term care facilities; false claims about the safety of the drug
Alpharma Inc.	2009	42.5	5.3 (12.5%)	Kadian	Anti-kickback violations to induce prescriptions; false claims about the safety and efficacy of the drug
Pfizer Inc.	2009	2300	102.0 (4.4%)	Bextra and others	False claims submitted to Medicare and Medicaid based on off-label uses unapproved by the FDA
Novartis Pharmaceuticals	2010	72.5	7.8 (10.8%)	TOBI	False claims submitted to Medicare and Medicaid based on off-label uses unapproved by the FDA
Johnson and Johnson	2010	81	9.0 (11.1%)	Topamax	Illegal marketing for off-label uses unapproved by the FDA; anti-kickback violations to induce prescriptions
AstraZeneca	2010	520	45.0 (8.7%)	Seroquel	Anti-kickback violations; illegal marketing for off-label uses unapproved by the FDA
GlaxoSmithKline	2010	750	96.0 (12.8%)	Paxil CR, Avandamet, Bactroban, Kytril	Manufactured and distributed defective and adulterated drugs from now-closed manufacturing facility in Puerto Rico

FDA = Food and Drug Administration. * Includes criminal fines. † Average relator's share = US\$50.8 million (10.4%). Percentages are calculated against the entire recovery to government, including criminal fines and civil recoveries to the federal and state governments. In practice, the relator does not receive a share of the criminal fine or the civil recovery to a state that does not have a *qui tam* statute; thus percentages and amounts eligible for relator's share would be higher than those reported here. ♦

companies are permitted to back public interest class actions.²⁵ The Australian High Court has now supported the right of any person to seek injunctive relief for a breach of specified provisions of the Trade Practices Act against a corporation.²⁶ It has also upheld the capacity of a plaintiff to bring an action, not to vindicate a private right, but to prevent the violation of a public right or to enforce the performance of a public duty.^{27,28}

Litigation-funding companies in Australia already accept the risk of paying the other side's costs if a case fails, in return for a set share of the proceeds if it succeeds. These arrangements have withstood challenges in Australian courts, in part because they fulfil public policy imperatives such as access to justice, particularly in public health-related class actions.²⁵

While some Australian courts may consider the treble damages provided for under the FCA to be an extraordinary remedy, appropriate only in cases of truly outrageous conduct,²⁹ others are

likely to agree with US courts that treble damages in *qui tam* actions are primarily remedial in nature¹⁰ or even justifiably punitive.³⁰ Moreover, treble damages have been considered previously as a deterrent for insider trading, and Australian regulators have generally been in favour of them.³¹ Considerable financial benefits would arise from applying such damages even to existing penalties under, for example, the Health Insurance Act (Box 3). The recently announced Tobacco Plain Packaging Bill 2011 could include provisions establishing an anti-fraud system related to industry claims required to be made under government regulation of the manufacture and marketing of tobacco (including mandatory disclosure of tobacco industry research about the harmfulness or addictiveness of its products).

The key strengths of the US *qui tam* anti-fraud regime, particularly in a period of financial stringency, lie in its recovery of large amounts of public monies, its encouragement of good corporate

practice, the incentives it provides and the protection it affords whistleblowers from within the private sector, and its various checks and balances to ensure that only presumptively meritorious claims are processed. If designed carefully, Australian *qui tam* anti-fraud laws may provide a mechanism for sustained and diligent oversight of claims by health care services, the financial sector, and the pharmaceutical, medical device, defence and fossil fuel industries on the public purse without significantly impeding their growth. Australian *qui tam* legislation could also play a significant role in reducing fraud and false claims in relation to other large investments or redistributions of public monies in public health-related fields such as carbon emissions compensation and the costs of treating tobacco-related illness.

Competing interests

Thomas Faunce and Gregor Urbas are Chief Investigators and Lesley Skillen is a Partner Investigator on an Australian Research Council (ARC) Discovery Grant in this area. The ARC was not involved in the writing of this paper. Lesley Skillen is a senior partner with Getnick and Getnick LLP, a US firm specialising in anti-false claims litigation.

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