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# Recovering fraudulent claims for Australian federal expenditure on pharmaceuticals and medical devices

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*The Australian Federal Government expends increasingly large amounts of money on pharmaceuticals and medical devices. It is likely, given government experience in other jurisdictions, that a significant proportion of this expenditure is paid as a result of fraudulent claims presented by corporations. In the United States, legislation such as the False Claims Act 1986 (US), the Fraud Enforcement and Recovery Act 2009 (US), the Stark (Physician Self-Referral) Statute 1995 (US), the Anti-Kickback Statute 1972 (US), the Food, Drug and Cosmetic Act 1938 (US), the Social Security Act 1965 (US), and the Patient Protection and Affordable Care Act 2010 (US) has created systematic processes allowing the United States Federal Government to recover billions of dollars in fraudulently made claims in the health and procurement areas. The crucial component involves the creation of financial incentives for information about fraud to be revealed from within the corporate sector to the appropriate state officials. This article explores the opportunities for creating a similar system in Australia in the health care setting.*

## INTRODUCTION: CURRENT AUSTRALIAN REGULATION AGAINST HEALTH CARE FRAUD

Most developed countries, including Australia, allocate a substantial amount of public funding to pharmaceuticals and the insertion of medical devices.<sup>1</sup> In Australia, the Pharmaceutical Benefits Scheme (PBS), after a process of cost-effectiveness analysis supervised by the Pharmaceutical Benefits Advisory Committee (PBAC), reimburses most of the cost of pharmaceuticals to pharmacists who are then able to sell those drugs to the public at the price of a relatively small co-payment.<sup>2</sup> Australian public expenditure on pharmaceuticals amounts to approximately A\$6 billion per year.<sup>3</sup> In addition to this, significant public funds are spent annually on medical devices under the supervision of the Medical Services Advisory Committee (MSAC).<sup>4</sup>

The extent of corporate fraud in these areas in Australia is, in all probability, significant. The Medicare *Program Abuse Information Report* commenced operation on 1 July 1996 and as at 30 June 2001 a total of 12,000 reports had been received.<sup>5</sup> Medicare Australia is empowered under the

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<sup>1</sup> Faunce TA, "Global Intellectual Property Protection for Innovative Pharmaceuticals: Challenges for Bioethics and Health Law" in Bennett B and Tomossy GF (eds), *Globalisation and Health* (Springer, Dordrecht, 2006) p 87.

<sup>2</sup> In Australia, patients usually contribute a co-payment of approximately \$30, regardless of whether they hold private insurance cover.

<sup>3</sup> Faunce TA and Lexchin J, "'Linkage' Pharmaceutical Evergreening in Canada and Australia" (2007) 4(8) *Australia and New Zealand Health Policy*, <http://www.anzhealthpolicy.com/content/4/1/8> viewed 20 October 2010.

<sup>4</sup> See Faunce, n 1.

<sup>5</sup> Australian Government, Medicare Australia, *Fraud*, <http://www.medicareaustralia.gov.au/provider/business/audits/fraud.jsp> viewed 20 October 2010.

*Medicare Australia Act 1973* (Cth) to monitor payments on claims paid for both Medicare and the PBS for fraud through a program of audits as well as sophisticated methods of data analysis. Under the *Health Insurance Act 1973* (Cth), 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). Within six years of a person (the wrongdoer) contravening a civil penalty provision, the Medicare Australia Chief Executive Officer (CEO) may apply on behalf of the Commonwealth to the Federal Court of Australia for an order that the wrongdoer pay the Commonwealth a pecuniary penalty (s 125A(1)). The rules and procedures for civil proceedings, including the “balance of probabilities” standard of proof, apply (s 125A(4)). If the court is satisfied that the wrongdoer has contravened a civil penalty provision, the court may order the wrongdoer to pay to the Commonwealth for each contravention the pecuniary penalty that the court determines is appropriate (but not more than the maximum amount specified for the provision) (s 125A(2)). In determining the appropriate pecuniary penalty, the court must have regard to all relevant matters including (s 125A(3)):

- (a) the nature and extent of the contravention;
- (b) the nature and extent of any loss or damage suffered as a result of the contravention;
- (c) the circumstances in which the contravention took place; and
- (d) whether the person has previously been found by the court in proceedings under this Act to have engaged in any similar conduct.

Other offences include

- prohibition of certain medical insurance (s 126);
- preclusion on agreements to assign Medicare benefits (s 127);
- offences in relation to returns (s 128);
- false statements relating to Medicare benefits (s 128A);
- knowingly making false statements relating to Medicare benefits (s 128B);
- charging of fees for provision of public hospital services to public patients (s 128C);
- making false statements (s 129); and
- bribery in relation to admissions to private hospitals (s 129AA).

If the Federal Court of Australia orders a person to pay a pecuniary penalty, then (a) the penalty is payable to the Commonwealth, and (b) the Medicare Australia CEO may enforce the order as if it were a judgment of the court (s 125D). The court is prevented from making a pecuniary penalty order against a person for a contravention of a civil penalty provision if the person has been convicted of an offence constituted by conduct that is substantially the same as the conduct constituting the contravention (s 125E), and civil penalty proceedings are stayed if criminal prosecution in relation to substantially the same conduct commences (s 125F). Additional provisions allow the Medicare Australia CEO to recover amounts paid because of false statements, including interest, recoverable as a debt from the person on whose behalf the false statement was made or that person’s estate (s 129AC), and to recover amounts paid in respect of certain diagnostic imaging services (s 129AE). Importantly, however, the *Health Insurance Act 1973* (Cth) does not make any provision for civil recovery proceedings to be initiated by any party except the Medicare Australia CEO.

This article outlines current regulatory measures in operation in the United States that have proved highly successful in recovering public money fraudulently obtained from federal programs (like Australia’s PBS) associated with improving equitable access to pharmaceuticals and medical devices. In particular, it discusses a regime where the United States (unlike Australia) operates a system of civil recovery of false claims made against the government that involves financial incentives for recovery proceedings to be initiated (through specialist legal firms) by private whistleblowers who then present the case for further action by United States federal or State justice officials. The article discusses the prospects for introducing this system into Australia and various legal and policy obstacles that will need to be overcome.

## UNITED STATES LEGISLATIVE MEASURES AGAINST PHARMACEUTICAL FRAUD

It is estimated that, in the United States, as much as 10% of general public health expenditure is being eroded by some form of fraud or anti-competitive behaviour, even where appropriate laws and

regulations are in place.<sup>6</sup> In the health care area, statutes such as the *False Claims Act 1986* (US),<sup>7</sup> the *Fraud Enforcement and Recovery Act 2009* (US), the *Stark (Physician Self-Referral) Statute 1995* (US), the *Anti-Kickback Statute 1972* (US), the *Food, Drug and Cosmetic Act 1938* (US), the *Social Security Act 1965* (US) and the *Patient Protection and Affordable Care Act 2010* (US) have created systematic processes whereby the Federal Government has recovered billions of dollars in fraudulently made claims. In the financial year 2009, eg, the government recovered US\$2.43 billion as a result of anti-fraud actions, 67% of this involving health care and 81% of such actions being initiated by whistleblowers who received a percentage (typically around 20-30%) of the public moneys ultimately recovered.<sup>8</sup> As well as the federal *False Claims Act*, 25 State jurisdictions in the United States, as well as the District of Columbia (DC), New York City, Chicago and San Francisco, now have legislative mechanisms allowing whistleblowers, such as corporate insiders, to reveal to law enforcement officials allegedly fraudulent practices involving public moneys in return for a percentage of the damages amount ultimately recovered.<sup>9</sup>

The federal *False Claims Act* allows a private citizen, referred to in litigation as the “relator”, to file an action on behalf of the government, known as a “qui tam” action,<sup>10</sup> and to claim a share of the funds recovered.<sup>11</sup> A qui tam action can be brought by anyone who has knowledge of fraud on the government, provided that it is not based on already publicly disclosed allegations or transactions in a criminal, civil or administrative hearing; in a congressional, administrative or Government Accounting Office report, hearing, audit or investigation; or from the news media and the person is an “original source” of the information.<sup>12</sup> These limitations are designed to avoid “parasitic claims” by individuals who have made no material contribution to uncovering the fraud or providing the factual basis of the case.<sup>13</sup> A qui tam action is filed under seal, and a “disclosure statement” containing all the relevant and material facts is served (in the case of federal *False Claims Act* filings, which may also include pendant State *False Claims Act* claims) on the Department of Justice (DOJ) in Washington DC, the local attorney in whose district the case is filed, and (if State *False Claims Act* claims are included) designated State government officials.<sup>14</sup>

Following a preliminary investigation, if the relevant government decides to intervene within the statutory time period, it takes over the running of the case.<sup>15</sup> The individual who initially made the disclosure remains as a relator to the proceedings. If the government declines to intervene, the relator through her or his lawyers can still proceed alone;<sup>16</sup> however, this type of action is far less

<sup>6</sup> Hyman DA, “HIPAA and Healthcare Fraud: An Empirical Perspective” (2002) 22 *Cato Journal* 151.

<sup>7</sup> US Code, Title 31 Money and Finance, §§ 3729-3733. The original *False Claims Act*, sometimes referred to as “Lincoln’s Law”, dates from 1863 and was enacted during the Civil War, in part to prosecute suppliers who sold substandard ammunitions, pack animals and other items to Union army purchasers: see Haron DL, Dordeski MV and Lahmann LD, “Bad Mules: A Primer on the Federal and Michigan False Claims Acts” (Nov 2009) *Michigan Bar Journal* 22, <http://www.michbar.org/journal/pdf/pdf4article1590.pdf> viewed 21 October 2010.

<sup>8</sup> Laemmle-Weidenfeld L, “Health Care Fraud Enforcement Post-FERA”, paper presented at the “False Claims Act and Qui Tam Litigation” Conference, San Francisco, 29-30 April 2010; United States Department of Justice, Civil Division, *Fraud Statistics*, <http://www.taf.org/FCAstats2009.pdf> viewed 21 October 2010.

<sup>9</sup> Eubanks M and Raspanti M, “States, Statutes, and Fraud: An Empirical Study of Emerging State False Claims Acts” (2005) 80 *Tulane L Rev* 465; Boese JT, “Fundamentals of the Civil False Claims Act and Qui Tam Enforcement”, paper presented (A-1) at the Eighth Annual National Institute on the Civil False Claims Act and Qui Tam Enforcement, 2-4 June 2010, Washington DC.

<sup>10</sup> Derived from the Latin “qui tam pro domino rege quam pro sic ipso in hoc parte sequitur” meaning “who as well for the King as for himself sues in this matter”.

<sup>11</sup> 31 USC § 3730 (b)(1), (d).

<sup>12</sup> 31 USC § 3730(e)(4).

<sup>13</sup> Skillen LA, “City False Claims Act: Next Chapter in Anti-fraud Crusade”, *New York Law Journal* (13 October 2005) p 4.

<sup>14</sup> 31 USC § 3730(b)(2).

<sup>15</sup> 31 USC § 3730(b)(4).

<sup>16</sup> 31 USC § 3730(b)(4).

successful.<sup>17</sup> When a qui tam action is successfully prosecuted, the relator is allowed a 15% to 20% share of the recovery if the government intervenes;<sup>18</sup> and between 25% and 30% where the government does not.<sup>19</sup>

Under the “American rule”, each party to an action generally pays their own costs; however, a successful qui tam relator is entitled under the statute to have attorneys’ fees and costs reimbursed by the defendant,<sup>20</sup> in addition to receiving a percentage of the recovery. Crucial differences from the Australian position are that a criminal prosecution is no bar to civil proceedings (in fact, parallel criminal and civil investigations and recoveries are common) and that the government obtains triple the damages it sustained because of the false claim as well as a civil penalty of between US\$5,500 and \$11,000 per false claim.<sup>21</sup> The United States Government can recover *False Claims Act* penalties even where it can prove no damage.<sup>22</sup> Where the government paid for goods that were never received, or services, such as medical treatment, which were not actually performed, the single damages (ie, before trebling) are equal to the full amount paid by the government for the non-existent goods or services.<sup>23</sup> Where, due to under-delivery or under-performance, the government was overcharged, the general rule is that the single damages are measured by the difference between what the government paid for the items or services and what it should have paid.<sup>24</sup> Where the government has been overcharged as a result of collusive bidding or bid-rigging, the single damages are calculated as the difference between the amount the government actually paid, and the amount it would have paid in an open and competitive bidding environment.<sup>25</sup> The government can recover full *False Claims Act* damages where the goods or services were provided as a result of some underlying fraudulent conduct such as false statements or violations of the *Anti-Kickback Statute 1972* (US).<sup>26</sup> The United States Government’s *False Claims Act* damages are trebled before any offset or compensatory payments received by that government are taken into account.<sup>27</sup>

The legislative scheme has allowed recovery of damages for a range of common fraudulent practices in the United States pharmaceutical, medical device and health care sectors that are likely to exist also in Australia. These include:

- making claims for government money involving a false certification;
- over-utilisation of clinical laboratory and diagnostic services;
- inflating the price used for government reimbursement above that charged to pharmacists and other private payers;
- concealing discount prices afforded to non-government payers and otherwise improperly pricing drugs, misbranding, providing defective and poor-quality health care items and services;
- billing for medicines or health services not provided or inadequately or inappropriately provided;
- colluding to inflate price, “off-label” promotion of drugs (ie marketing for unapproved uses);

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<sup>17</sup> According to official Department of Justice statistics, between 1986 and 2009, the United States recovered \$15.6 billion in qui tam cases in which the government intervened and \$472 million in cases in which the government did not intervene: United States Department of Justice, Civil Division, n 8. These numbers do not include *False Claims Act* recoveries by the States or recoveries in parallel criminal cases.

<sup>18</sup> 31 USC § 3730(d)(1).

<sup>19</sup> 31 USC § 3730(d)(2).

<sup>20</sup> 31 USC § 3730(d)(1), (2); Satiani B, “The Whistleblower Act (Qui Tam)” (2005) 137(4) *Surgery* 472.

<sup>21</sup> 31 USC § 3729(a).

<sup>22</sup> *United States ex rel Hagood v Sonoma County Water Agency* 929 F 2d 1416 at 1421 (1991).

<sup>23</sup> *United States v Pani* 717 F Supp 1013 (1989).

<sup>24</sup> *United States v TDC Management Corp Inc* 288 F 3d 421 (2002).

<sup>25</sup> *Brown v United States* 524 F 2d 693 at 706 (1975).

<sup>26</sup> *United States v Mackby* 261 F 3d 821 at 824-826 (2001); *United States v Rogan* 517 F 3d 449 at 453 (2008): “[t]he government offers a subsidy (from the patients’ perspective, a form of insurance), with conditions. When the conditions are not satisfied, nothing is due.”

<sup>27</sup> *United States v Bornstein* 423 US 303 at 316 (1976).

- providing kickbacks to doctors and institutions that prescribe or purchase products; and
- discounting medicines to hospitals which then charge the Federal Government a higher price.<sup>28</sup>

In response to the global financial crisis, Congress enacted the *Fraud Enforcement and Recovery Act* (FERA) in 2009, which included amendments to the *False Claims Act* strengthening the legislative scheme by overturning certain court rulings that did not reflect the original intent of the *False Claims Act*.<sup>29</sup> It is now clear that the *False Claims Act* applies to all recipients of government funds, including subcontractors, private contractors administering government health programs and recipients of federal block grants. It is enough to activate its provisions that a false statement made by a contractor or subcontractor was “material” to the government’s decision to pay, regardless of the entity to whom the false statement is made.<sup>30</sup> The *Fraud Enforcement and Recovery Act* also amended the *False Claims Act* to make it actionable to retain (or conspire to retain) for more than 60 days, public funds known to have been paid in error.<sup>31</sup>

A terminated whistleblower’s signing of a release of all claims against her or his former employer does not bar the subsequent filing of a qui tam suit against the employer putting the government on notice of a fraud.<sup>32</sup> However, where the government was sufficiently aware of the alleged wrongdoing prior to the qui tam filing, a pre-filing release signed by the relator will be upheld and the qui tam action will not be permitted.<sup>33</sup> Although the *False Claims Act* prohibits the settlement (or voluntary dismissal) of a qui tam action without the government’s consent,<sup>34</sup> this only applies to settlements reached after a qui tam action has been filed.<sup>35</sup>

Another tool the United States Government has used to seek recompense from the pharmaceutical industry is an anti-trust statute, the *Hart-Scott-Rodino Antitrust Enforcement Act 1976* (US). This Act is administered by the Federal Trade Commission (FTC) and the Antitrust Division of the United States Department of Justice (DOJ). The FTC recently filed a case, *FTC v Ovation Pharmaceuticals Inc*,<sup>36</sup> seeking to recover profits relating to Ovation’s 2006 acquisition of a monopoly over medications to treat a serious heart condition that primarily affects low birth-weight infants. Once a monopoly was obtained, Ovation raised the price for NeoProfen and Indocin, the only FDA-approved drugs to treat the condition.

Recent examples from Europe highlight the global significance of the problem of collusion in the pharmaceutical industry and the difficulties associated with detecting, investigating and prosecuting fraud in these sectors. In 2008, the Competition Commissioner of the European Commission coordinated unannounced raids on the offices of leading pharmaceutical companies, including GlaxoSmithKline (United Kingdom), AstraZeneca (United Kingdom), Sanofi-Aventis (France), Pfizer (United States) and Novartis AG (Switzerland).<sup>37</sup> The raids were considered to be the only practicable

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<sup>28</sup> Skillen LA, *Fighting Medicare Fraud: The Deficit Reduction Act, Federal Incentives to Enact State Qui Tam Laws and the New York State False Claims Act* (American Bar Association National Institute on White Collar Crime, 2008), <http://www.getnicklaw.com/media/FightingMedicareFraud.pdf> viewed 21 October 2010.

<sup>29</sup> *Allison Engine Co v United States ex rel Sanders* 128 S Ct 2123 (2008); *United States ex rel Totten v Bombardier Corp* 380 F 3d 488 (2004); *United States ex rel DRC Inc v Custer Battles LLC* 376 F Supp 2d 617 (2005).

<sup>30</sup> 31 USC § 3729(a)(1)(A), (B).

<sup>31</sup> 31 USC § 3729(a)(1)(C), (G) and (b)(3); Boese, n 9; Morgan FM Jr and Shaey LC, “FERA This! – Congress Repairs the False Claims Act to Address Contemporary Fraud and Abuse and Remedy Judicial Activism”, paper presented (H-17) at the Eighth Annual National Institute on the Civil False Claims Act and Qui Tam Enforcement, 2-4 June 2010, Washington DC.

<sup>32</sup> *United States v Northrop Corp* 59 F 3d 953 (1995): public interest served by uncovering fraud outweighed the general public policy favouring settlements.

<sup>33</sup> *United States v Purdue Pharma LP* 600 F 3d 319 (2010); *United States ex rel Ritchie v Lockheed Martin Corp* 558 F 3d 1161 (2009).

<sup>34</sup> 31 USC § 3730(b)(1).

<sup>35</sup> *United States ex rel Radcliffe v Purdue Pharma LP* 582 F Supp 2d 766 (2008); *United States ex rel Radcliffe* 2010 WL 1068229 (2010); see also *United States ex rel Ritchie v Lockheed Martin Corp* 558 F 3d 1161 at 1169 (2009).

<sup>36</sup> Complaint, *FTC v Ovation Pharmaceuticals Inc*, No 08-cv-06379-JNE-JJG (D Minn), filed 16 December 2008.

<sup>37</sup> All of these companies operate throughout the world, including in Australia.

option available to gather evidence that fraud and anti-competitive practices, such as strategic “evergreening”<sup>38</sup> of patent clusters in the sector, had stalled innovation and blocked the entry of cheap generics into the market.<sup>39</sup> Like Australia, the European Union lacks civil fraud recovery provisions similar to the United States *False Claims Act*’s *qui tam* mechanism.<sup>40</sup>

A particularly pertinent example of a *False Claims Act* case in the United States pharmaceutical sector with potential application in the context of Australia’s PBS, involves the pharmaceutical company Eli Lilly, which pleaded guilty in 2009 to a criminal charge of promoting the anti-psychotic Zyprexa for use outside FDA guidelines and was required to pay a criminal fine of \$US515 million, plus a US\$100 million forfeiture, for a total criminal resolution of US\$615 million. In addition, the company agreed to pay up to US\$800 million, to be split between the Federal Government and participating States, to settle civil claims of Medicaid and Medicare fraud. Altogether, the settlement yielded a total recovery of US\$1.415 billion.<sup>41</sup> The company promoted Zyprexa as a sedative in nursing homes, despite known risks of heart failure and pneumonia; and for use in disruptive children, despite known risks of severe weight gain. In this case, over US\$78 million of the government’s civil recovery was shared among six *False Claims Act* relator employees. Most of Zyprexa’s United States sales (which have totalled \$US39 billion since FDA approval in 1996) have been paid for by federal government programs, as the drug is largely prescribed among indigent or disabled populations. The crucial factor in the case was hundreds of internal Eli Lilly documents and email messages among top company managers that showed that the company had sought to play down Zyprexa’s tendency to cause weight gain and metabolic disorders, including diabetes, over a long period of time, while promoting the drug for unapproved uses.<sup>42</sup>

In October 2010 GlaxoSmithKline (GSK) agreed to pay US\$750 million to settle a *False Claims Act* case. Of this amount, \$150 million was a criminal fine and \$600 million went to settle civil FCA charges. The whistleblower and her legal team shared a \$96 million award to be paid by GSK. The fraud involved systematic deceit concerning product contamination and dosage irregularities (involving drugs such as Paxil, Avandia, Avandament, Coreg, Bactroban, Abreva, Cimetidine, Compazine, Denavir, Dyazide, Thorazine, Stelazine, Ecotrin, Tagamet, Relafen, Kytril, Factive, Dyrenium, and Albenza) at GSK’s plant in Cidra, Puerto Rico.<sup>43</sup> Other notable examples are set out in Table 1.

## AUSTRALIAN REGULATORY APPROACHES TO PHARMACEUTICAL FRAUD

While there have been numerous successful investigations and prosecutions for fraud and anti-competitive behaviour in the pharmaceutical sector in the United States, they have been rare in Australia. One such example was the 2001 Australian Competition and Consumer Commission (ACCC) prosecution in the Federal Court of Roche Vitamins Australia Pty Ltd (A\$15 million penalty), BASF Australia Ltd (A\$7.5 million) and Aventis Animal Nutrition (A\$3.5 million), for establishing a global price-fixing cartel concerning the supply of vitamins A and E in animal feeds, which inflated

<sup>38</sup> “Evergreening” refers to a range of legal and business strategies by which technology producers with patents over products that are about to expire, retain income by establishing new patents (such as over associated delivery systems, or new pharmaceutical mixtures) or by buying out or frustrating competitors, for longer time periods than would normally be permitted.

<sup>39</sup> This is contrary to European Community (EC) rules against anti-competitive business practices and abuse of dominant market position, which are enshrined in Arts 81 and 82 respectively of the EC Treaty.

<sup>40</sup> Riley A, “The Civil False Claims Act: Using Lincoln’s Law to Protect the European Community Budget”, *Centre for European Policy Studies (CEPS) Policy Brief No 34* (December 2003), <http://www.ceps.eu/book/civil-false-claims-act-using-lincolns-law-protect-european-community-budget> viewed 21 October 2010.

<sup>41</sup> United States Department of Justice, “Eli Lilly and Company Agrees to Pay \$1.415 Billion to Resolve Allegations of Off-label Promotion of Zyprexa”, *Media Release* (15 January 2009), <http://www.justice.gov/opa/pr/2009/January/09-civ-038.html> viewed 21 October 2010.

<sup>42</sup> Harris G and Berenson A, “Lilly Said to be Near \$1.4 Billion US Settlement”, *New York Times* (14 January 2009), <http://www.nytimes.com/2009/01/15/business/15drug.html> viewed 21 October 2010.

<sup>43</sup> *Taxpayers Against Fraud, False Claims Act Legal Center*, <http://www.taf.org> viewed 2 November 2010.

**TABLE 1 United States drug companies and moneys recovered under False Claims Act actions\***

Pharmaceutical company	Date settled	Primary fraud alleged	Whistleblower/s	Criminal fine	Civil settlement	Total recovery
<b>Pfizer / subsidiary Pharmacia &amp; Upjohn</b>	2/09/2009	Off-label promotion; kickbacks	2 Pfizer sales reps; 1 Pfizer sales manager; 1 senior sales consultant at Pharmacia; 1 independent physician; 1 position unknown	\$1.3 billion	\$1 billion	\$2.3 billion
<b>Eli Lilly</b>	15/01/2009	Off-label promotion; kickbacks	Several former sales representatives	\$515 million fine, \$100 million forfeiture	\$800 million	\$1.415 billion
<b>TAP</b>	3/10/2001	Marketing the spread; kickbacks	TAP v-p of sales and HMO medical director	\$290 million	\$585 million	\$875 million
<b>Serono</b>	17/10/2005	Off-label promotion; kickbacks	5 Serono employees (lab and sales)	\$136.9 million	\$567 million	\$704 million
<b>Merck</b>	7/02/2008	Concealing best price/kickbacks	Merck district sales manager/physician		\$650 million	\$650 million
<b>Purdue</b>	10/05/2007	Misbranding		\$500,000	\$634 million	\$634.5 million
<b>AstraZeneca</b>	27/04/2010	Off-label promotion; kickbacks	AstraZeneca sales representative		\$520 million	\$520 million
<b>Bristol Myers Squibb</b>	28/07/2007	Off-label promotion; marketing the spread	Independent pharmacy and others		\$515 million	\$515 million
<b>Schering Plough</b>	29/08/2006	Concealing best price; off-label promotion	3 Schering Plough sales representatives	\$180 million	\$255 million	\$435 million
<b>Warner-Lambert</b>	13/05/2004	Off-label promotion; kickbacks	Warner Lambert medical liaison	\$240 million	\$190 million	\$430 million
<b>Cephalon</b>	29/09/2008	Off-label promotion; kickbacks	3 Cephalon sales representatives	\$50 million	\$375 million	\$425 million
<b>AstraZeneca</b>	20/06/2003	Marketing the spread; concealing best price	TAP vice-president of sales	\$63.9 million	\$291 million	\$355 million
<b>Schering-Plough</b>	30/07/2004	Concealing best price; kickbacks	Senior managers at Schering subsidiary	\$52.5 million	\$293 million	\$345.5 million
<b>Bayer</b>	16/04/2003	Concealing best price	Bayer marketing executive	\$6 million	\$251 million	\$257 million
<b>Aventis</b>	17/09/2007	Marketing the spread	Independent pharmacy		\$190 million	\$190 million

\* Modified from Skillen (2010). An earlier version of this table was included in a (successful) Australian Research Council Discovery Grant application submitted in March 2009.

Recovering fraudulent claims for expenditure on pharmaceuticals and medical devices

Pharmaceutical company	Date settled	Primary fraud alleged	Whistleblower/s	Criminal fine	Civil settlement	Total recovery
GlaxoSmithKline	20/09/2005	Marketing the spread	Independent pharmacy		\$150 million	\$150 million
King Pharmaceuticals	31/10/2005	Overcharging, underpaying rebates	King director of contracts and national accounts		\$124 million	\$124 million
Mylan / UDL Laboratories	19/10/2009	Underpaying rebates	Independent pharmacy		\$118 million	\$118 million
Aventis	28/05/2009	Concealing best price			\$95.5 million	\$95.5 million
GlaxoSmithKline	16/04/2003	Concealing best price	Bayer marketing executive		\$88 million	\$88 million
Johnson & Johnson subs Ortho-McNeil, Ortho-McNeil-Janssen	29/04/2010	Off-label promotion	2 Ortho-McNeil sales representatives; 1 independent physician	\$6.14 million	\$75.37 million	\$81.51 million
Novartis	4/05/2010	Off-label promotion	3 former executives of Novartis predecessor Chiron		\$72.5 million	\$72.5 million
Pfizer	28/10/2002	Concealing best price	Pfizer national accounts manager		\$49 million	\$49 million
Alpharma Inc	16/03/2010	Kickbacks; misrepresenting drug safety/efficacy	Former Alpharma employee		\$42.5 million	\$42.5 million
InterMune	27/10/2007	Off-label promotion			\$36.8 million	\$36.8 million
Pfizer	2/04/2007	Off-label promotion; kickbacks	Pfizer vice president	\$35 million		\$35 million
Schering-Plough	3/05/2004	Marketing the spread	Independent pharmacy		\$27 million	\$27 million
Schwarz Pharma	29/04/2010	Misrepresenting to CMS the status of 2 unapproved drugs	2 individuals, positions unknown		\$22 million	\$22 million
Schering-Plough subsidiary Warriek	17/12/2009	Inflating AWP; settlement with State of California under the California False Claims Act	Independent pharmacy		\$21.3 million	\$21.3 million



general food prices.<sup>44</sup> However, there have been instances where further investigation of anti-competitive conduct appears to have been warranted. For example, on 23 July 2008, the Brisbane-based company Progen Pharmaceuticals announced its decision to discontinue Phase III trials of the drug PI-88, despite its proven ability to inhibit tumour metastasis and reduce primary tumour growth.<sup>45</sup> Progen claimed its decision was based on issues about the commercial viability of PI-88 trials.<sup>46</sup> However, there was press speculation that the primary reason was, in fact, anti-competitive behaviour by the multinational pharmaceutical company Bayer, which had recently launched a competitive Phase III trial assessing its new drug Nexavar for the same purpose.<sup>47</sup> As another instance, in February 2009, Ventracor announced a worldwide ban on new implants of its VentrAssist device for treating heart failure until transplant. This followed a Therapeutic Goods Administration investigation of the death of three patients whose heart pumps had failed after the leads were damaged. Allegations were made that the company had failed to meet disclosure obligations to the Australian Securities Exchange, but these were difficult to establish in the absence of a whistleblower from the company.<sup>48</sup>

The ACCC's existing strategy for obtaining anti-trust evidence is based on granting immunity from civil proceedings. The relevant eligibility criteria include being the first participant in a particular cartel to admit its conduct to the ACCC, where that party was not the "ringleader"; and where full admissions and ongoing assistance are provided to the ACCC. New criminal sanctions for executives involved in cartels, including 10-year jail terms,<sup>49</sup> appear to confirm the ineffectiveness of the ACCC's immunity policy. In January 2009, the Commonwealth Director of Public Prosecutions (CDPP) changed its prosecution policy and created an exception for disclosures of cartel behavior.<sup>50</sup> Whistleblowers can now apply to the ACCC for both civil and criminal immunity. The ACCC will then examine the case and decide whether it meets certain conditions. If the conditions are met, it will recommend to the CDPP that criminal immunity be granted. Some uncertainty remains with respect to how the relationship between the ACCC and CDPP will work in practice.<sup>51</sup> No Australian research to date has compared this strategy with *False Claims Act*-type strategies in operation in the United States.

The Australian anti-fraud and anti-trust litigation system has developed considerably since 1989, when a federal committee on insider trading recommended that *qui tam* laws were "incompatible" with accepted principles and practice in the Australian legal system.<sup>52</sup> Over the past 20 years, anti-competitive behaviour has increasingly been regarded as a serious crime by Australian regulators. Champerty has been abolished in most jurisdictions, and litigation funding companies are permitted to

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<sup>44</sup> Editorial, "Vitamin Firm Price-fixers Face Record Court Fines", *Australian Financial Review* (6 December 2000).

<sup>45</sup> Parish C, *Development of the New Anti-Cancer Drug – PI-88 – and Beyond* (John Curtin School of Medical Research, Australian National University, 2007).

<sup>46</sup> Eutick M, *Progen Terminates PATHWAY Trial & Confirms Focus on Potential High Value Molecules and M&A* (Progen Pharmaceuticals Ltd, 23 July 2008).

<sup>47</sup> Skilton N, "Drug Trial Blow a Bitter Pill to Swallow", *Canberra Times* (15 December 2008), <http://www.canberratimes.com.au/news/local/news/general/drug-trial-blow-a-bitter-pill-to-swallow/1386153.aspx?storypage=1> viewed 21 October 2010.

<sup>48</sup> Urban R, "Pump-maker Ventracor Aware of Deaths", *The Australian* (17 February 2009).

<sup>49</sup> *Trade Practices Act 1974* (Cth), Pt IV, Div 1 – Cartel Conduct, s 44ZZRF (Making a contract etc containing a cartel provision) and s 44ZZRG (Giving effect to a cartel provision).

<sup>50</sup> See Commonwealth Director of Public Prosecutions, *Disclosure Policy*, <http://www.cdpp.gov.au/Publications/DisclosurePolicy> viewed 21 October 2010.

<sup>51</sup> Berkovic N, "Corporate Bosses Who Blow the Whistle on Cartel Conduct Will be Granted Immunity", *The Australian* (2 December 2008).

<sup>52</sup> House of Representatives Legal and Constitutional Affairs Committee, *Insider Trading in Australia* (AGPS, Canberra, 1989) p 45.

back public interest class actions.<sup>53</sup> It is undisputed that large-scale corporate fraud and anti-competitive behaviour are incompatible with Australian values.

## OPTIONS FOR DEVELOPING AUSTRALIAN FALSE CLAIMS LEGISLATION

Public expenditure on pharmaceutical and medical devices in Australia is one of the government's largest investments (over \$6 billion per year). Further research on appropriate law and policy regulation of anti-fraud and anti-trust regulation in the Australian pharmaceutical and medical device industries would help to ensure that this expenditure is invested effectively. The potential application of *qui tam* legislation to facilitate whistleblowing about fraud from within the Australian corporate sector has been suggested to the Australian Government in the past.<sup>54</sup> It is now the subject of an extensive academic debate.<sup>55</sup> A reform of this type would need to be based on a coherent framework for integrating United States measures into the existing Australian immunity and self-regulation approaches. While Medicare Australia, within the Federal Department of Health and Ageing, has an anti-fraud program, it is primarily focused on discovering fraud by individual health care professionals. Further, the pharmaceutical and medical device sector has not been listed by the ACCC as one of its regulated industries. The ACCC's anti-trust model in this area is based on an immunity policy, and tight controls on a voluntary code of conduct. Its effectiveness in comparison with United States anti-trust laws has never been systematically investigated. There could be significant benefits to the Australian Government, and community more broadly, by implementing *qui tam* reforms and new evidentiary techniques for discovering fraud and anti-competitive behaviour in these sectors.

The amount of public money that reforms in this area could recover is significant. It is estimated that the return to the United States Government is \$15 for every \$1 spent on *qui tam* investigations and litigation.<sup>56</sup> In 2009, the United States DOJ announced that it had recovered over US\$24 billion for the Federal Government since 1987, \$15.6 billion of which resulted from *qui tam* actions.<sup>57</sup> These numbers are actually understated, as they do not include civil *False Claims Act* recoveries by the States or criminal fines arising from parallel criminal/civil cases. For example, the official DOJ total for 2009 is \$2.4 billion. When State recoveries and criminal fines are included, the total is \$5.6 billion.<sup>58</sup> Since 1987, relators who made public interest disclosures in *qui tam* proceedings have been paid approximately US\$2.4 billion.<sup>59</sup>

Under the *Australia–United States Free Trade Agreement* (AUSFTA), pharmaceutical “innovation” in Australia must be regulated either by the operation of “competitive markets”, or by systems

<sup>53</sup> Standing Committee of Attorneys-General, *Litigation Funding in Australia* (AGPS, Canberra, 2005).

<sup>54</sup> Faunce TA, via invited oral testimony to the Australian House of Representatives Standing Committee on Legal and Constitutional Affairs, *Whistleblowing Protection in the Australian Public Sector* (18 September 2008).

<sup>55</sup> White S, “EU Anti-fraud Enforcement: Overcoming Obstacles” (2010) 17(1) *Journal of Financial Crime* 81; Boumil J et al, “Whistleblowing in the Pharmaceutical Industry in the United States, England, Canada, and Australia” (2010) 31(1) *Journal of Public Health Policy* 17; Button M et al, “The Fraud Review and the Policing of Fraud: Laying the Foundations for a Centralized Fraud Police or Counter Fraud Executive?” (2008) 2(2) *Policing* 241; Pascoe J, “Corporate Sector Whistleblowing in Australia: Ethics and Corporate Culture” (2009) 27 *C&SLJ* 524; Kesselheim A, “Whistleblower-initiated Enforcement Actions against Health Care Fraud and Abuse in the United States, 1996-2005” (2008) 149 *Annals of Internal Medicine* 342; *KPMG Fraud Survey* (2008); Levi M, “Organised Fraud and Organizing Frauds” (2008) 8(4) *Criminology and Criminal Justice* 389; Martin B, “Illusions of Whistleblower Protection” (2003) 5 *UTS Law Review* 119; Smith R, “Coordinating Individual and Organisational Responses to Fraud” (2008) 49 *Crime Law and Social Change* 379; Kostakis B, “Creating a Hybrid Weapon Against Healthcare Fraud” (2007) 37 *University of Memphis Law Review* 395; Levi M, “Measuring the Impact of Fraud in the UK” (2008) 48 *British Journal of Criminology* 293; Pacini C, “Qui Tam Actions: Fighting Fraud Against the Government” (2007) 14 *Journal of Financial Crime* 64; *UK National Fraud Strategy: A New Approach to Combating Fraud* (2009-2011).

<sup>56</sup> Meyer JA, *Fighting Medicare Fraud: More Bang for the Federal Buck* (Taxpayers Against Fraud Education Fund, 2006), <http://www.taf.org/publications.htm> viewed 21 October 2010.

<sup>57</sup> See United States Department of Justice, Civil Division, n 8.

<sup>58</sup> *FY 2009 False Claims Act Settlements* (1 October 2009), <http://www.taf.org/total2009.htm> viewed 21 October 2010

<sup>59</sup> See n 55.

that value “objectively demonstrated therapeutic significance”.<sup>60</sup> In relation to the former requirement, further research could establish whether it would support increased monitoring of anti-competitive behaviour in the Australian pharmaceutical market. The significance of drawing on United States models is strengthened by the fact that pharmaceutical and medical device regulation is developing in an international, rather than a national, context.<sup>61</sup> It is likely that there are proportionate levels of fraudulent activity in the Australian market, given that most of the pharmaceutical entities listed as being offenders in the United States are major providers of pharmaceuticals in the Australian market, and are marketed through global strategies.

Further research could identify potential legal obstacles to adopting a variation of the United States *qui tam* provisions in Australia. As mentioned, there are indications that the Australian legal system is now more receptive to innovative funding arrangements for public interest litigation. 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 due to the fact that they fulfil public policy imperatives such as access to justice, particularly in public health-related class actions.<sup>62</sup> The possibility of not-for-profit *qui tam* litigation funding arrangements is another avenue that could be examined in more detail. Other potential legal issues include the implications of the High Court’s support of the right of “any person” to seek injunctive relief for a breach of specified provisions of the *Trade Practices Act 1974* (Cth) against a corporation. In *Truth About Motorways Pty Ltd v Macquarie Infrastructure Investment Management Ltd* (2000) 200 CLR 591, the court noted that Parliament can decide who may bring an action to “prevent the violation of a public right or to enforce the performance of a public duty”, with Gleeson CJ and McHugh J observing (at [2], notes omitted):

The common law requirement that a plaintiff who brings 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, must have a special interest to protect, is based upon considerations of public policy which the legislature would not lightly disregard. Nevertheless, it is not difficult to understand why, in the case of certain laws, it might be considered in the public interest to provide differently. Apart from statute, there are ample precedents for private enforcement of laws.

Australian criminal law recognises the right of a private citizen to institute a proceeding, commonly referred to as a “private prosecution”. While Commonwealth law requires that “indictable offences against the laws of the Commonwealth are to be prosecuted by indictment in the name of the Attorney-General of the Commonwealth or such other person as the Governor-General appoints in that behalf”,<sup>63</sup> s 13 of the *Crimes Act 1914* (Cth) provides:

- Unless the contrary intention appears in the Act or regulation creating the offence, any person may:
- (a) institute proceedings for the commitment for trial of any person in respect of any indictable offence against the law of the Commonwealth; or
  - (b) institute proceedings for the summary conviction of any person in respect of any offence against the law of the Commonwealth punishable on summary conviction.

However, such a prosecution is typically taken over by the Commonwealth Director of Public Prosecutions, who has power to continue or to discontinue it.<sup>64</sup> Prosecutions are likely to be discontinued if alternative remedies, such as the imposition of civil penalties, are reasonably available.<sup>65</sup> Even where a right to bring an action is recognised, however, this is separate from the right to claim a share of the penalty or bounty.<sup>66</sup> In Australia, the common law origins of the *qui tam* action are acknowledged, but courts have taken the view that “Only offences created by statutes which

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<sup>60</sup> *Australia–United States Free Trade Agreement*, Annex 2C.4.

<sup>61</sup> See Faunce, n 1.

<sup>62</sup> Standing Committee of Attorneys-General, n 53.

<sup>63</sup> *Judiciary Act 1903* (Cth), s 69(1).

<sup>64</sup> *Director of Public Prosecutions Act 1983* (Cth), s 9(3), (5).

<sup>65</sup> See eg *Australian Securities and Investments Commission v Rich* (2005) 188 FLR 416 at [163].

<sup>66</sup> *Commonwealth Bank of Australia v Gargan* (2004) 140 FCR 1 at [38].

expressly or by necessary implication provide for qui tam action may be prosecuted by a common informer [ie a relator]” and that “[t]he onus of showing the statute so provides lies on the common informer”: *Commonwealth Bank of Australia v Gargan* (2004) 140 FCR 1 at [28]. The *Health Insurance Act 1973* (Cth), discussed above, could be amended to allow the judiciary to construe a statute in favour of a qui tam petitioner. Under the present provisions, only the Medicare CEO can claim a penalty,<sup>67</sup> and the Medicare CEO is the relevant authority to whom suspected breaches of the Act should be referred.<sup>68</sup>

Electronic evidence, such as email and computer records, is often critical in the investigation of fraud, and relevant exclusionary rules under evidence legislation in Australian jurisdictions, as well as practical barriers to investigation, require further research.<sup>69</sup> This includes:

- jurisdictional problems;
- managing strategic alliances and partnerships, and ensuring security;
- confidentiality and flexibility of response;
- dealing with different privacy regimes;
- achieving mutual assistance in real time;
- heavy reliance on cooperation and assistance from telecommunications providers and internet service providers; and
- transborder search of computer data banks and interception of communications.

It was acknowledged in a recent Federal Government inquiry on whistleblower protections that issues for individual whistleblowers from the private sector include:

- existing statutory protections;
- evidentiary credibility problems associated with witnesses having an interest in the outcome of a proceeding; as well as
- corporate reprisals for perceived disloyalty, or breach of confidence or intellectual property rights.<sup>70</sup>

Future research could investigate how to overcome difficulties in identifying and locating key sources of information, obtaining appropriate search warrants or other court orders, and ensuring the integrity and completeness of documentary evidence obtained.<sup>71</sup>

## CONCLUSION

Public funding of pharmaceuticals and medical devices is one of the most significant annual investments made by the Australian Government. While this provides great benefit to the Australian community, there is evidence that major international pharmaceutical and medical device companies, including those that operate in Australia, regularly engage in fraudulent and anti-competitive behaviour. A well-developed legal framework in the United States has proven successful at recovering public funding from companies in the health care and pharmaceutical sectors that have behaved fraudulently, including by misrepresenting their entitlement to government funds. Particularly successful has been the qui tam action, which can be brought by an individual who has direct or indirect knowledge of fraud.

The Australian legal framework for countering fraud in the pharmaceutical sector is comparatively underdeveloped, and could benefit from the application of United States regulatory

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<sup>67</sup> *Health Insurance Act 1973* (Cth), s 125A.

<sup>68</sup> *Health Insurance Act 1973* (Cth), s 89A.

<sup>69</sup> Urbas G and Choo KR, “Resource Materials on Technology-enabled Crime”, *Technical and Background Paper No 28* (2008, Australian Institute of Criminology, Canberra), <http://www.aic.gov.au/publications/current%20series/tbp/21-40/tbp028.aspx> viewed 21 October 2010.

<sup>70</sup> House of Representatives Standing Committee on Legal and Constitutional Affairs, *Whistleblower Protection: A Comprehensive Scheme for the Commonwealth Public Sector, Report of the Inquiry into Whistleblowing Protection within the Australian Government Public Sector* (AGPS, Canberra, 2009).

<sup>71</sup> The authors are conducting research under an Australian Research Council (ARC) Discovery Grant (DP1092584) for the project *Detecting Fraud and Anti-competitive Behaviour in the Australian Pharmaceutical and Medical Device Industries* (2010).

measures such as the *qui tam* (whistleblower incentive) approach. This article has highlighted the need for further research to investigate the development of this area of Australian law. This would help to ensure that the Australian Government, and the community more broadly, is obtaining the full benefit of its investment in the pharmaceutical and medical device industries.

Australian whistleblowing legislation includes no incentives to encourage the divulgence of information from within the private sector about fraud upon the government.<sup>72</sup> Instead, it is predominantly focused on dealing with information provided about the public sector. The House of Representatives Standing Committee on Legal and Constitutional Affairs recently examined the expansion of the Australian legislative protection for whistleblowers in the public sector.<sup>73</sup> The Committee recommended that the proposed legislation protect disclosures made to the media where the matter has not been acted on within a reasonable period of time.<sup>74</sup>

The fact that the proposed legislation focuses exclusively on the public sector and does not provide protection to whistleblowers from the private sector was raised by witnesses at the inquiry. One view was that:

[I]f you are trying to develop a comprehensive and effective system of whistleblowing protections it is quite an artificial distinction to be simply looking at the public sector service employees as if they operate in isolation from the private sector.<sup>75</sup>

This perspective was taken into account by the Committee in its final report. It accepted the criticism and noted that private sector whistleblowing is an issue that needs further consideration due to the underdevelopment of the relevant Australian law:

Australian legislation on protection for disclosures concerning misconduct within the private sector appears piecemeal. In view of the concerns raised on the issue during the course of this inquiry, the Committee considers that protections for the disclosure of wrongdoing within the private sector could usefully be reviewed in the future.<sup>76</sup>

In the United Kingdom, the Attorney General's Office released the *Fraud Review: Final Report* in 2006. It recommended the establishment of a National Fraud Strategic Authority (NFSA) and a National Fraud Reporting Centre (NFRC), and these bodies were subsequently established in 2007. The NFSA provides strategic authority and monitors anti-fraud performance, and the NFRC accepts reports of fraud, provides measurement of the scale of fraud, refers frauds to the most appropriate body for action, and undertakes analytical work to identify trends and *modus operandi*.

Individual whistleblowers must be encouraged to voice their concerns, and ensuring appropriate protection is central to this outcome.<sup>77</sup> The report stops short of recommending that whistleblowers be allowed to prompt government regulators into action and then, as an incentive, to recover a portion of the public moneys reclaimed.

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<sup>72</sup> There is a need for greater uniformity in the Australian law in relation to whistleblowing. At present, there is a variety of legislation across a number of Australian jurisdictions that may be relevant, but which is currently unclear. In South Australia, s 5 of the *Whistleblowers Protection Act 1993* (SA) already protects any person who discloses "public interest information". Under s 162A of the *Trade Practices Act 1974* (Cth), penalties of 12 months imprisonment and fines of \$10,000 are available to prosecute companies that intimidate whistleblowers. In some cases, Australian law requires that individuals with knowledge of fraud bring it to the attention of the police. For instance, in New South Wales, s 316 of the *Crimes Act 1900* (NSW) creates an offence for the failure to report a "serious offence" where the person knows or believes the offence has been committed and that they have information that may be of material assistance to investigators. Under the *Corporate Law Economic Reform Program (Audit Reform and Corporate Disclosure) Act 2004* (Cth), financial dealers have an obligation to report certain matters. A recent parliamentary report has noted that further reform at a Commonwealth level to address whistleblowing in the private sector would be beneficial: see House of Representatives Standing Committee on Legal and Constitutional Affairs, n 70, pp 83-84.

<sup>73</sup> House of Representatives Standing Committee on Legal and Constitutional Affairs, n 70.

<sup>74</sup> House of Representatives Standing Committee on Legal and Constitutional Affairs, n 70, Recommendation 21, p 24.1.

<sup>75</sup> Faunce, cited in n 70, p 170 at [9.5].

<sup>76</sup> Faunce, cited in n 70, p 178 at [9.30].

<sup>77</sup> Smith R, "Coordinating Individual and Organisational Responses to Fraud" (2008) 49 *Crime Law and Social Change* 379 at 395.

The “revolving door” employment system which so characterises drug manufacturers and lobbyists and drug regulators in the United States provides a strong reason for creating a system in Australia whereby whistleblowers who have access to false claims on taxpayers’ moneys in the health care sector can prompt regulatory action and be rewarded with a percentage of the proceeds. The trebling of damages would not only provide a disincentive for such action but would ensure that the moneys covered are worth the considerable expense and risks involved in either private relator (“whistleblower”) or government lawyers conducting the requisite complex investigations.