

## **Responding to Fraud in the Australian Health, Pharmaceuticals and Medical Devices Sectors: A Proposal for Reform**

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*The risk of fraud within the Australian health, pharmaceuticals and medical devices sectors is significant, but more effective legal and regulatory responses than currently exist may be required for its detection and prevention. Looking at successful models from overseas jurisdictions may be of value. In particular, enhanced whistleblower protections and the qui tam litigation mechanism in the United States offer models for more effective anti-fraud measures. The model appears viable for local adaptation, but some legal, structural and cultural issues may need consideration and further research. This paper adopts the hypothesis that there is nothing intrinsic to the Australian legal system that would prevent the adoption of such mechanisms in Australia, and assesses the potential for these reforms to be introduced there.*

**JEL Codes:** I18 - Government Policy; Regulation; Public Health  
K42 - Illegal Behaviour and the Enforcement of Law  
K41 - Litigation Process

### **1. Introduction**

The health, pharmaceuticals and medical devices sectors in developed economies such as Australia are at significant risk from fraud and anti-competitive practices (Faunce, Urbas & Skillen 2011). Health funding comes largely from government agencies such as health departments, but services and associated goods such as medicines and devices are often supplied by the private sector, creating opportunities for over-charging, and other fraudulent or anti-competitive practices. While government agencies typically have agencies directed to ensuring legal and regulatory compliance, these are often less than adequately resourced to detect and prevent false claims against the government.

Major pharmaceutical companies that operate in Australia have been prosecuted for fraud in overseas jurisdictions, and it is likely that fraudulent activity is also occurring in the Australian market (Faunce, Urbas & Skillen 2011). Government expenditure on health, pharmaceuticals and medical devices is one of its largest public investments and provides great benefits to the Australian community, but there are also risks of fraud and other forms of misappropriation or overpayment. It is therefore important that the Australian legal framework governing these sectors develops in accordance with other developed economies.

The following analysis describes key legal measures against fraud and anti-competitive practices in the health, pharmaceuticals and medical devices sectors in Australia, and makes comparisons with those of the United States. Both countries share features that

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facilitate such comparison: developed economies with modern and technologically advanced health systems, large public expenditures on health care provision, the presence of international pharmaceuticals and medical devices companies, and federal legal systems based on English common law traditions (Anderson et al. 2005; Blendon et al. 2003; Healy, Sharman & Lokuge 2007). In both countries, anti-fraud measures include criminal prosecution, civil and administrative recovery mechanisms, industry-specific responses including self-regulation and codes of conduct, and accounting practices such as auditing and reporting to government agencies. However, noteworthy differences emerge with respect to whistleblower protections and the *qui tam* litigation mechanism used in the United States. The hypothesis explored in this paper is that there is nothing intrinsic to the Australian legal system that prevents the adoption of key aspects of the US False Claims model here.

## 2. Literature Review

### 2.1 Australia

Fraud control in the health, pharmaceuticals and medical devices sectors in Australia falls within the jurisdiction of a number of bodies, including Medicare Australia, the Therapeutic Goods Administration, the Australian Competition and Consumer Commission, and Medicines Australia.

Medicare Australia, which is a public program administered through the Commonwealth Department of Human Services, is empowered to monitor payments on healthcare claims made against the Commonwealth, and civil penalty provisions may apply to service providers making illegitimate claims. The Chief Executive Officer of Medicare Australia has the power to carry out compliance, investigation and enforcement activities related to the provision of services; recover overpayments and other amounts due to the Commonwealth in connection with the provision of services; and conduct litigation or proceedings related to the provision of the services. Under the *Medicare Australia Act 1973* (Cth), renamed in 2011 as the *Human Services (Medicare) Act 1973* (Cth), an authorised officer may require a person to give information or produce a document, if there are reasonable grounds for believing that a relevant offence or civil contravention has been or is being committed, and the information or document is relevant. In addition, the Act provides the power to enter premises and conduct searches.

Medicare has acknowledged that it carries out a range of intelligence and auditing activities. It applies the Australian Government's Fraud Control Policy, which is designed to 'protect public money and property, protect the integrity, security and reputation of our public institutions, and maintain a high level of services to the community' (Medicare Australia n.d.). Random compliance audits of payments made through the Pharmaceutical Benefits Scheme are made by Medicare to verify services with patients, specialist and general medical practitioners and pharmacists. Medicare's National Compliance Plan 2009-2010 highlights areas of concern with key stakeholders. Medicare states that its data analysis and data-mining activities include 'assessing tip-offs from members of the public, and government departments and agencies' (Medicare Australia 2009). Medicare's Compliance Plan is focused on specialist and general medical practitioners and pharmacists. In the Australian legal framework, Medicare has not been given the express power to investigate and prosecute major fraud by pharmaceutical companies, and it does not appear that it currently has the capacity to undertake this role. However, it does solicit public reporting of fraud in the healthcare sector and is able to refer complaints for further

## Urbas, Faunce, Skillen & Smith

investigation and possible prosecution by other agencies (Medicare Australia: Report Fraud n.d.).

The Therapeutic Goods Association, a regulatory authority operating under the Commonwealth Department of Health and Ageing (TGA n.d.), administers the *Therapeutic Goods Act 1989* (Cth), which contains both criminal and civil liability provisions for breaches of standards regulating the supply of medicines, therapeutic goods and medical devices. For example, s14 creates offences of import, export and supply of therapeutic goods that do not comply with specified regulatory standards and threaten or cause harm to public health, punishable by imprisonment for 5 years or 4000 penalty units or both. The civil penalty for this conduct, but without reference to resulting harm, is specified in s14A to be 5000 penalty units for an individual and 50,000 penalty units for a corporation. Under s42YB, which refers to s4AA of the *Crimes Act 1914* (Cth), a penalty unit represents A\$110. The Secretary of the Department of Health may pursue civil penalties in the Federal Court (s42Y), and may authorise officers to conduct search and seizure, but the Department does not itself prosecute criminal offences under the Act.

Prosecution of crimes against the laws of the Commonwealth of Australia is usually undertaken by the Commonwealth Director of Public Prosecutions, including on referral from police and regulatory agencies (CDPP n.d.). In its most recent annual report, the agency recorded 93 summary and 3 indictable offences prosecuted under the *Health Insurance Act 1973* (Cth), but no further detail of the offences involved is provided (CDPP 2011). The key offences under this legislation include asking for or providing prohibited pathology or diagnostic services benefits, punishable by civil penalties (Faunce, Urbas & Skillen 2010). The monitoring of healthcare services has been strengthened with the *Healthcare Identifiers Act 2010* (Cth), which includes an offence of unauthorised use or disclosure of healthcare identifiers. Fraud in the health sector may also be prosecuted under general criminal offences, such as obtaining a benefit by deception or making false or misleading statements, for example, under Part 4.7 of the *Criminal Code Act 1995* (Cth).

There are provisions relating to fraudulent and anti-competitive conduct in other Australian legislation such as the *Competition and Consumer Act 2010* (Cth), with penalties for serious cartel conduct not exceeding \$10 million for each offence or 3 times total benefits obtained that can be reasonably attributed to the commission of the offence (ss 44ZZRF and 44ZZRG). These provisions, yet to be tested in court as only recently enacted, could apply to activities such as price fixing by pharmaceutical or medical devices suppliers. The federal body with responsibility for consumer and competition protection is the Australian Competition and Consumer Commission (ACCC n.d.). The ACCC currently accepts information from whistleblowers, and whilst not providing compensation, has some capacity to grant immunity under the existing legal framework. The relevant eligibility criteria for immunity 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 on-going assistance are provided to the ACCC. In line with these reforms, the Commonwealth Director of Public Prosecutions (CDPP) reportedly changed its prosecution policy and created an exception for disclosures of cartel behaviour, enabling whistleblowers to apply to the ACCC for both civil and criminal immunity. On application, the ACCC will examine a case and decide whether it meets its conditions. If it does, the ACCC will recommend to the CDPP that criminal immunity be granted (Berkovic 2008).

## Urbas, Faunce, Skillen & Smith

Australian government agencies are encouraged to institute their own fraud control policies in line with the Commonwealth Fraud Control Policy (ANAO 2004). This includes reference to whistleblower protection requirements, which should include:

- a clear statement of the entity's commitment to comply with applicable laws and practices;
- a statement that the purpose of the policy is to encourage the reporting of reportable conduct;
- an explanation of the benefits and importance to the entity of having a whistleblower program;
- a clear mechanism by which whistleblower complaints can be made and a statement that all reports will be kept confidential and secure;
- a guarantee that whistleblowers will receive feedback; and
- should stipulate the entity is committed to protecting whistleblowers.

It should be noted, however, that such policies apply to whistleblowers who are government employees, rather than corporate insiders or other individuals. Australian legislation protecting whistleblowers in the private sector is limited to particular industry sectors, such as banking, finance and telecommunications providers. Federal legislation in the form of a Public Interest Disclosures Bill has been drafted but not yet brought into law (Brown 2008).

Industry self-regulation also plays a role in responding to fraud. Medicines Australia is a representative body that serves the interests of the prescription medicines industry in Australia, and provides a Code of Conduct for the industry (Medicines Australia n.d.). The issues that are covered most extensively by the Medicines Australia Code include: claims made in marketing, conduct of company representatives, and relationships with healthcare professionals. The provisions of the Code provide for fines of up to \$200,000 and orders to cease conduct. In the most recent reporting year, the majority of the fines imposed were under \$75,000, with one fine in the \$75,000 - \$99,999 bracket and two fines in the \$150,000 - \$200,000 bracket, both relating to marketing of pharmaceuticals (Medicines Australia 2011). Given the important role that prescription pharmaceuticals play in the Australian health care system and the amount of money invested in this sector by the government, these fines arguably represent relatively small amounts (Faunce, Urbas & Skillen 2010).

The current Australian monitoring and compliance regime does not appear to extend to some practices around the marketing of pharmaceuticals in Australia (ABC Radio National 2011) that would arguably fall within the scope of anti-kickback laws in the United States. Also, while there have been some occurrences of whistleblowers bringing information to the attention of Medicare Australia, these have been isolated and not within a general fraud response context (Flynn 2004). What is therefore needed, we suggest, is a more effective regulatory regime that includes protections for whistleblowers in both the public and private sectors.

## 2.2 United States

The health care system in the United States operates at federal, state and local levels. Federal statutes 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*

## Urbas, Faunce, Skillen & Smith

*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 (Faunce, Urbas & Skillen 2010). Of particular interest in its treatment of corporate insiders and others with knowledge of fraud on the government as whistleblowers is the False Claims Act (in existence in various forms since the American Civil War and sometimes referred to as “Lincoln’s Law”), which deals generally with false claims for payment made against the government (Boese 2011; Haron et al. 2009). Variants of the False Claims Act have been introduced by many US states and a few large cities (James et al. 2005; Skillen 2008).

At the heart of the False Claims Act is the *qui tam* mechanism, which allows a private citizen to initiate civil proceedings for the recovery of fraudulently paid government monies, standing in for the government as a “relator”. The government may join in the action or decline to do so. If successful, the relator is entitled to a share, in the typical case between 15% and 30% of total funds recovered, while the government gets the remainder in addition to any fines or criminal penalties imposed. The government’s role in *qui tam* litigation is managed by the Department of Justice, while the relator is usually represented by a plaintiff lawyer specialising in *qui tam* whistleblower law. Such litigation is relatively complex and protracted, and relators for the most part lack financial resources, so these lawyers usually work on a contingency payment basis and provide an important gatekeeper to weed out frivolous cases (Elmer and Cone 2010). The reward mechanism for whistleblowers is important because it provides an incentive for them to come forward with information of wrongdoing that the government would otherwise be unlikely to acquire on its own or through public channels, and this reward also serves to compensate whistleblowers such as corporate insiders for the likely professional and financial harm that they will suffer (Boese 2011; Haron et al. 2009; Faunce, Urbas & Skillen 2010; Faunce, Urbas & Skillen 2011).

The relator’s complaint of misconduct is filed under seal and the defendant is not immediately notified while the Department of Justice examines the allegations and decides whether to join in the action (Department of Justice n.d.). Professional conduct rules for private lawyers acting for relators and the oversight of government lawyers in the Department of justice assist in ensuring that frivolous or unmeritorious claims are filtered out, and courts have not generally upheld blanket claims of privilege or contractual obligations which would frustrate the intent of the legislation in encouraging whistleblowers to bring information to the government (Elmer and Cone 2010). The effect of the False Claims Act (FCA), particularly in the health industry, appears to have been to force companies to improve their compliance (Snyder 1995; Rhoad and Fornataro 2009).

The success of the *qui tam* approach is evident in the increasing size of recoveries in the United States, including from pharmaceutical manufacturers and providers. For example, recoveries of fraudulently paid monies due to off-label promotions (i.e., marketing of drugs for unapproved uses), kickbacks to physicians and other malpractice have exceeded USD 2 billion in an individual recent case and at least 11 billion in the last decade (Faunce, Urbas & Skillen 2010; Faunce, Urbas & Skillen 2011). These recoveries are often the result of settlements rather than litigation. At a recent celebration hosted by the US Department of Justice marking the 25<sup>th</sup> Anniversary of the modern False Claims Act, senior departmental officials, including the Attorney General and the head of the Civil Division, and prominent politicians praised the statute as the government’s most effective anti-fraud enforcement tool ever. Noting that USD 6.6 billion had been recovered in health

care fraud cases in the past two years alone, officials referred to the “unprecedented level of success” achieved by the statute (Murphy 2012).

### 3. The Methodology and Model

The authors have conducted research on current anti-fraud measures in Australia and the United States, and have interviewed a variety of health litigation professionals in both countries as part of an Australian Research Council Discovery Project (ARC Discovery Grant DP 1092584). Analysis of both the dimensions of fraud in the health, pharmaceuticals and medical devices sectors (quantitative) and related anti-fraud policies and regulatory mechanisms (qualitative) provides a framework for the formulation of reform proposals for Australian regulators. As mentioned, the hypothesis we are seeking to investigate is that there is nothing intrinsic to the Australian legal system that would prevent key aspects of the US False Claims system from applying here.

Qualitative interviews with US-based litigators were conducted in mid-2010, focussing on private legal practitioners on the western seaboard while attending at *False Claims Act and Qui Tam Litigation* workshop in San Francisco in late April, and in Seattle the following week, and later in Washington DC while attending the American Bar Association National Institute on Civil False Claims Act and Qui Tam Enforcement conference in early June, New York and Boston. The interviewees included *qui tam* and whistleblower lawyers who typically have an employment law practice specialisation, defence lawyers who represent corporations against whom allegations of misconduct are made, and government lawyers from the Department of Justice. Interviews were conducted on the basis that confidentiality requests will be respected and that only de-identified data will be published. Comparative interviews have also been conducted in Australia during 2011, involving law firms that handle analogous legal issues in Sydney, Melbourne, Brisbane and Perth. Because of differences in the overall experience of United States and Australian lawyers working in the area of health care fraud, the conversations with the former focussed on the actual operation of the False Claims Act and *qui tam* litigation, while the latter asked what impediments might stand in the way of introducing a similar regime in Australia.

Our research hypothesis, based on information obtained about the United States experience, is that the *qui tam* litigation model would be an effective way of improving the anti-fraud measures available in the Australia regulatory system governing health care expenditure. However, we recognise that there are legal, structural and cultural differences between the two countries that will require consideration and further research before a concrete proposal can be formulated.

### 4. The Findings

Background research by the authors to date indicates that a significant fraud problem in the Australian health, pharmaceuticals and medical devices sectors probably exists, but that existing anti-fraud measures are less effective than some overseas models. In particular, the US *qui tam* litigation mechanism, which allows whistleblowers to receive a share of fraud recovery monies obtained by the government, has resulted in recoveries of more than USD 20 billion in the past 25 years, not including related criminal fines (Department of Justice 2011).

## Urbas, Faunce, Skillen & Smith

The interviews conducted in the United States and Australia revealed a detailed picture of the complexities of this area of regulatory reform. For example, some of the American lawyers work only with the federal version of the False Claims Act as their state has no counterpart Act, while others work with both state and federal laws. Most take cases only on a contingency basis, and will expect a case to take several years to complete. The process involves working closely with the client whistleblower to prepare the information that has to be taken to the Department of Justice for its consideration, which then decides whether to intervene in the case and whether to institute parallel criminal proceedings. The informant continues in the civil litigation in the capacity of 'relator'. The case is kept under seal for an initial period, ranging from several months to several years, after which the case is disclosed to the defendant corporation and negotiations towards settlement may occur. Where the action is successful in recovering wrongly paid or claimed amounts of money, the relator is entitled in the typical case to get a 15-30% share of the recovery amounts. This provides a strong incentive to bring information of corporate misconduct to the public authorities in the first place, and to continue with the litigation despite the professional and financial harm that will often be suffered by the whistleblower as a result. Relator lawyers generally stressed the importance of a good working relationship with the Department of Justice, often facilitated by personal connections from previous professional contact. This view was reciprocated by the government lawyers, though there were concerns expressed that the payout figures were sometimes too high, and that not enough time was available to investigate particularly complex cases.

In Australia, while several law firms expressed interest in the *qui tam* litigation model, some barriers to its introduction were identified. These included the lack of a legislative basis for such actions, inadequate and disjointed legal provisions for whistleblowers, and a much less developed contingency fee practice for litigation. Few Australian firms would be a position to take large, complex fraud cases on a contingency basis, and civil damages awards in Australia are typically much lower than in the United States. While there is an evolving litigation funding sector, including the publicly listed company IMF(Australia) which will consider cases involving more than \$5 million in claims (IMF(Australia) n.d.), some changes in the practice of mainstream law firms would need to take place, with appropriate legislative reforms, in order for a *qui tam* mechanism to be viable in Australia. Australia presently has limited whistleblower protections for public sector officials, but these do not extend to all private sector employees who may be able to bring information of fraudulent practices to the attention of regulatory authorities. Therefore, a strengthening of overall whistleblower protections may be required. As recognised in a recent Australian parliamentary inquiry into whistleblower protection, while Commonwealth legislation does not currently provide overall coverage: "In principle, any person who provides information to assist with the detection of wrongdoing should be granted legal protection" (Parliament of Australia 2009 at 3.11).

Additionally, most Australian lawyers consulted were unable to nominate a suitable counterpart to the United States Department of Justice, which could handle both civil and criminal aspects of false claims recovery. In Australia, criminal prosecutions are mostly taken by the Director of Public Prosecutions in each jurisdiction (Commonwealth, State and Territory), with a few agencies also empowered to prosecute in taxation, securities and investments and social security matters; while civil recovery on behalf of the government is usually undertaken under the auspices of the Solicitor-General. What is somewhat lacking is recognition of the appropriate agency to receive complaints and whistleblower disclosures, with powers to act on them by commencing or joining in civil litigation, with authority to prosecute criminal cases or to refer such matters to prosecution

## Urbas, Faunce, Skillen & Smith

authorities. Whether such an agency would be better contemplated for all sectors, or more likely for the health, pharmaceuticals and medical devices sectors separately, is open to argument.

Thus, our research appears to confirm for the first time that the barriers to the implementation of a *qui tam* mechanism in Australia may be more cultural than institutional. Even in the United States, some academics and policy makers have expressed reservations about the wisdom of rewarding whistleblowers, arguing that they should be motivated by altruistic desires (Carson et al. 2008). Such arguments can usually be countered by reference to the necessity of providing incentives to bring information forward and the need to encourage whistleblowers to seek out private counsel to supplement the government's scarce resources (Sawyer et al. 2006). Even where the record of *qui tam* litigation in recovering government expenditure in healthcare is acknowledged, its public policy justification may require further explanation (Broderick 2007). Interestingly, it appears that countries such as Canada, The United Kingdom and India have had similar discussions about the possible introduction of a *qui tam* litigation mechanism to combat fraud (Brockman 2005; May 2006; Walker 2007; Sharma 2012).

In Australia, a 1989 federal parliamentary committee considered a *qui tam* mechanism but summarily dismissed it as 'incompatible with accepted practice in the Australian legal system' (Faunce, Urbas & Skillen 2011). That may have been then, but this is now. Developments in whistleblower protections and anti-fraud policies over the last two decades suggest that such cultural barriers may be on the retreat and that the time for a reform of Australian law incorporating such a mechanism is right.

## 5. Summary and Conclusions

This paper has explored the hypothesis that key aspects of the United States' False Claims Act system such as the *qui tam* mechanism can apply in Australia. It has done this by critically analysing existing measures against fraud and anti-competitive practices in the health, pharmaceuticals and medical devices sectors, both in Australia and the United States. While there are differences, the two countries are broadly comparable in terms of their health care and legal systems. However, particularly as regards the protection and incentives for whistleblowers in the private sector to come forward with information of fraud or anti-competitive practices that relate to government payments, Australia does not have an equivalent of the *qui tam* litigation mechanism that allows such whistleblowers to share in the proceeds of funds recovered. While some institutional and legal reforms may be required in order to introduce such a mechanism, and some cultural barriers may exist, this would be a significant regulatory reform in the response to fraud within the Australian health, pharmaceuticals and medical devices sectors.

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## Urbas, Faunce, Skillen & Smith

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