Responding to Fraud in the Australian Health, Pharmaceuticals and Medical Devices Sectors: Lessons from overseas models

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Fraud within the Australian health, pharmaceuticals and medical devices sectors is likely to be significant but more effective regulatory responses than currently exist may be required. This paper reviews overseas models, concentrating on enhanced whistleblower protections, the qui tam litigation mechanism in the United States, United Kingdom reforms establishing a national centre for the investigation and prosecution of fraud, and the potential for similar reforms to be introduced in Australia.

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

1. Introduction

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. Government expenditure on health, pharmaceuticals and medical devices is one 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. This paper evaluates existing mechanisms within the Australian legal framework to detect and recover public fraud in the pharmaceutical and medical device industries, and investigates potential strategies for development. The latter include enhanced whistleblower protections, the qui tam litigation mechanism in the United States, United Kingdom reforms establishing a national centre for the investigation and prosecution of fraud, and the potential for similar reforms to be introduced in Australia.

2. Literature Review

Fraud control in the health, pharmaceuticals and medical devices sectors in Australia falls within the jurisdiction of a number of agencies, including Medicare Australia (Medicare), the Australian Competition and Consumer Commission (ACCC) and Medicines Australia (Medicines Australia). However, there are few prosecutions or recovery proceedings for fraud, misappropriation or over-charging in health services, at least as compared with the

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numbers of such proceedings in countries such as the United States (Faunce et al 2010). One explanation may lie in the absence of effective whistleblower protections extending to the private sector, and *qui tam* litigation mechanism, in Australia (Faunce et al 2011). The latter allows an insider such as a corporate whistleblower to receive a substantial share of fraud recovery monies obtained by the government under the US federal and state False Claims Acts (Skillen 2008; Haron et al 2009). Adoption of a *qui tam* mechanism in Australia has been briefly considered by the Parliament (House of Representatives 2009). In the United Kingdom, a National Fraud Strategic Authority (NFSA) and National Fraud Reporting Centre (NFRC) were established in 2007, with the NFSA providing strategic authority and monitoring anti-fraud performance, and the NFRC accepting reports of fraud, providing data on the scale of fraudulent activity, referring fraud to the most appropriate body for prosecution, undertaking analytical work to identify trends and modus operandi, and providing intelligence to enable the government to deal with fraud more effectively in the future (NFSA 2009). The literature suggests that a combination of improved whistleblower protections, a US-style *qui tam* litigation mechanism, and more coordinated fraud response and reporting bodies would be an effective reform option for Australia to consider.

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 (ARC) Discovery Project. 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.

4. The findings

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 corporate whistleblowers to receive a substantial share of fraud recovery monies obtained by the government, has resulted in recoveries of billions of dollars (Faunce et al 2010). Australia has limited whistleblower protections for public sector officials, but these do not extend to private sector employees who may be able to bring information of fraudulent practices to the attention of regulatory authorities. The case for introducing strengthened whistleblower protections along with other reforms, including a US-style *qui tam* litigation mechanism, into the Australian system is persuasive.

5. Summary and Conclusions

A review of overseas models including enhanced whistleblower protections, the *qui tam* litigation mechanism in the United States, United Kingdom reforms establishing a national centre for the investigation and prosecution of fraud, suggests significant potential for similar reforms to be introduced in Australia. This would be a significant regulatory reform in the response to fraud within the health, pharmaceuticals and medical devices sectors.
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