HEALTH CONSUMERS' COUNCIL
YOUR VOICE ON HEALTH

Health Consumers' Council submission to the Therapeutic Goods Administration consultation on the use of comparable overseas regulators for the regulation of medical devices

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Summary and Recommendations

Proposed reforms of the regulation of medical devices focus on finding faster ways of getting new products to market via streamlined processes including relying on foreign regulators. Provided they are rigorous and transparent and act only in the interest of consumers, whether the regulatory processes incorporate the work of foreign regulators or are conducted exclusively 'in house' by the Therapeutic Goods Administration (TGA) is of little concern.

Arguably given the repeated failures (outlined below) by the TGA to ensure the safety and efficacy of medical devices and medicines, increased reliance on overseas regulators with rigorous approval and ongoing safety and efficacy monitoring processes could benefit Australian consumers.

However, like the TGA, on numerous occasions comparable foreign regulators have failed to ensure the safety of consumers within their home jurisdictions. We are also concerned that the TGA has a history of relying on foreign regulators to guide it when new products are first approved for market but appears not to respond when overseas regulators place warnings on products.

The TGA document prepared for this consultation states "the purpose of this criteria is to identify regulators with similar standards to the TGA".[1] A collaborative international approach to the regulation of medical devices could work but only if the bar is raised to increase the rigour of the processes in foreign jurisdictions and Australia. Without reform product manufacturers will continue to game the system by finding the easiest way to gain approval for their products.

The Health Consumers' Council (HCC) therefore submit that rigorous mechanisms must be put in place to prevent device manufacturers 'cherry picking' not only the evidence they use to support their applications to approve products but also to prevent 'regulator shopping' to find the easiest path to market. These mechanisms must also ensure the ongoing safety monitoring of products particularly in the early years when they are first brought to market.

To achieve this, regardless of whether the TGA or another regulator undertake the initial assessment, we recommend**:**

1- Full public disclosure (with protections for intellectual property and commercially sensitive information) of all evidence regarding the safety and efficacy of medical device and pharmaceutical products when they are approved for market in Australia. Note: This may require a reform of Commonwealth Freedom of Information legislation to end the entitlement of corporations to rely on privacy provisions originally intended to protect the health records of individuals. (refer to Appendix 1 for details)
2- The TGA monitor and replicate the actions of foreign regulators who issue warnings or remove medical devices and pharmaceutical products from market for safety reasons.
3- Mandatory reporting to the TGA by medical practitioners for a specified range of serious adverse event reactions and the TGA regularly publish full de-identified details on the TGA website.
4- The TGA compel medical device manufacturers and clinicians to establish registers for all medical devices permanently implanted in patients.

Examples of Australian and International Regulatory Failure

The market for medical devices and medications is globally integrated. National safety regulators like the FDA And the TGA often rely on international research to approve both pharmaceuticals and medical devices for use by the public. A 2013 study by Australian, British and US researchers found that product manufacturers 'masterfully influenced' medicine.[2] The report found that 'the benefits of drugs and other products are often exaggerated and their potential harms are downplayed'. The researchers noted that the profits available gave industry 'power to influence every stage of the health system' including regulatory processes.

Recent examples of transnational regulatory failures in relation to medical devices that have caused significant harm to untold thousands of consumers worldwide include Transvaginal Mesh, Poly Implant Prothèse (PIP) breast implants and Articular Surface Replacement (ASR) Hips.

Transvaginal Mesh – The Australian Senate Community Affairs References Committee is currently undertaking an inquiry into the *Number of women in Australia who have had transvaginal mesh implants and related matters*.[3] Along with our equivalent organisations in other states and territories we made a joint submission to the Inquiry highlighting the failure of the TGA to protect the safety of Australia women.[4]

In 2016, long after it became clear that thousands of women in Australia are suffering severe adverse reactions, the TGA belatedly recognised the following potential harms from Transvaginal Mesh:

- punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel (these may require surgical repair)
- transitory local irritation at the wound site
- a 'foreign body response' (wound breakdown, extrusion, erosion, exposure, fistula formation and/or inflammation)
- mesh extrusion, exposure, or erosion into the vagina or other structures or organs
- as with all foreign bodies, mesh may potentiate an existing infection
- over-correction (too much tension applied to the tape) may cause temporary or permanent lower urinary tract obstruction
- acute and/or chronic pain
- voiding dysfunction
- pain during intercourse
- neuromuscular problems including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area
- recurrence of incontinence
- bleeding including haemorrhage, or haematoma
- seroma
- urge incontinence
- urinary frequency
- urinary retention
- adhesion formation
- atypical vaginal discharge
- exposed mesh may cause pain or discomfort to the patient's partner during intercourse
- mesh migration
- allergic reaction
- abscess
- swelling around the wound site
- recurrent prolapse

- vaginal contracture
- vaginal scarring
- excessive contraction or shrinkage of the tissue surrounding the mesh
- vaginal scarring, tightening and/or shortening
- constipation/defecation dysfunction
- granulation tissue formation.[5]

Mesh injured women have also reported the following additional side effects:

- Chronic debilitating pain
- Chronic ongoing infections
- Bleeding
- Recurrence of prolapse/SUI
- Tissue necrosis - necrosis cell death as a direct result of irreversible changes caused by injury or disease
- Autoimmune disorders (the mesh is made of polypropylene and releases toxins when in contact with heat)
- Disability (can't sit, stand or walk without pain)
- Sepsis
- Post-Traumatic Stress Disorder
- Anxiety disorder
- Depression
- Suicidal ideation
- Significant out of pocket expenses for reparative treatments.[6]

In belatedly recognising the dangers of these devices, the TGA has implicitly acknowledged its' own failure to ensure the safety of mesh products before they were approved for the Australian market. In August 2014, the TGA issued a press release that stated:

> While there may be a benefit in certain patients there is little evidence to support the overall effectiveness of these surgical meshes as a class of products… The TGA undertook a literature search of published materials since 2009. The overall quality of the literature was found to be poor... However, the literature did identify the known adverse outcomes associated with their use. [7]

As early as 2007 and again in 2016 the *Royal Australian and New Zealand College of Obstetricians and Gynaecologists* acknowledged there is 'very little robust information is available on the efficacy and long-term safety of polypropylene mesh kits marketed for use in the surgical management of pelvic organ prolapse'.[8] Despite this, the TGA took no action to ensure the safety and efficacy of these devices until way, way, way, too late. Given the paucity of evidence to support their safety and efficacy the obvious question is why the TGA allowed these devices to be approved for market?

The TGA is not the only national regulator to have failed to ensure the safety of mesh devices. We would encourage viewing of the five-minute YouTube video *Mesh Misery: Thousands are suffering. Where are the watchdogs?*[9] The video highlights that the US Food and Drug Administration (FDA) were similarly ineffective in protecting American Women. Similar regulatory failures occurred with mesh in other countries including Great Britain.[10]

Poly Implant Prothèse (PIP) Breast Implants - After international evidence of increased rupture rates and concerns about the toxicity of the industrial rather than medical silicon used in PIP Breast

implants manufactured in France, unused implants were recalled in Australia in 2010.[11] An estimated 300,000 women in France, Great Britain, Brazil Argentina, Germany Spain and Italy received these implants indicating a widespread international failure of product safety regulators.[12]

Over 1,000 Australian women joined a class action against Medical Vision Australia (MVA) the Australian importer of PIP Breast implants to recover 'medical care and other costs'. The class action was dropped in 2014 because MVA was in liquidation and did not take out product liability insurance. The TGA does not require product manufacturers to hold product liability insurance and the TGA has legislative immunity from its' failure to protect Australian consumers.[13] So not only did the TGA fail to ensure the safety of the PIP Breast implants prior to them being marketed, it was powerless to ensure these women had adequate support when they needed it.

Articular Surface Replacement (ASR) Hips – Widespread and repeated complaints about the deterioration of metallic ASR hips and the release of toxins into the patient's body caused DePuy to issue a worldwide recall of the hip in 2010 (following voluntarily withdraw in Australia in 2009). Prior to the withdrawal 93,000 patients worldwide, 5,500 of them Australians, had been implanted with the faulty ASR hip.[14]

Many patients implanted with the faulty hips had to undertake:

> painful and complex revision surgery to remove the faulty hip. Many, in addition, have experienced severe illness away from the hip, which some doctors and medical researchers attribute to metal poisoning from the joint…High levels of cobalt and chromium, two of the metals used in the manufacture of the joints, have been found in the blood of many patients whose DePuy ASR hips have failed…US regulator the Food and Drug Administration (FDA) wrote to manufacturers of metal-on-metal hip prostheses on May 6, demanding they study patients who have received their devices amid concerns the joints may be leeching potentially toxic metal ions.[15]

Of great concern given the plans to outsource the regulation of medical devices to foreign regulators is that:

> The DePuy ASR [hip] was approved for use here [by the TGA] on the basis of European certification by the British Standards Institute. It was never separately tested by the TGA and the resurfacing version of the device - which was approved for use in Australia by the TGA - was never approved for use in the US by the FDA.

The HCC notes that the failure of regulators internationally extends to pharmaceuticals. In 2014 a HCC submission to the Senate Select Committee on Health, *Licensing and Subsidising Pharmaceuticals in Australia - Reforms needed to deliver Transparency, Safety and Value for Money* highlighted successive failures by the TGA to protect the health and safety of Australian consumers.[16] Specific examples detailed include the TGA's failure in relation to the approval and ongoing safety monitoring of arthritis drug Vioxx, anti-coagulant drug Pradaxa and ADHD drug Strattera. The submission also detailed how internationally industry has used research as a marketing tool to advance their own interests, often at the expense of consumer safety.

Discussion and Recommendations

To date Australian consumers have been unable to rely on the Commonwealth Government via the TGA to keep them safe. In 2011 in response to these failures, the Senate Community Affairs References Committee held an *Inquiry into the Regulatory Standards for the Approval of Medical Devices in Australia*. The inquiry made specific recommendations of assistance that should be made available to recipients.[17] It also made recommendations on how the operations of the TGA could be improved to better protect the safety of medical device consumers (Recommendations 1, 2, 3, 4, 7, 8, 9, 10, 11, 13, 14 and 18). We endorse all these recommendations and would welcome a public statement by the TGA detailing if and how these recommendations have been met.

The fundamental weakness of TGA processes is that treatment proponents (both medical device and pharmaceutical manufacturers) provide the evidence that the TGA uses to licence and monitor (once brought to market) the safety and efficacy of their products. Treatment proponents are free to determine who conducts their studies, which studies they seek to publish and which are kept private.

This largely self-regulatory process delivers the worst of all outcomes for consumers. They believe that the products like transvaginal mesh, PIP breast implants and ASR hips have been through a robust independent process, however in reality the TGA has rubber stamped the treatment proponent's application. The onus has been put on those suffering adverse events to prove they have suffered, rather than on the treatment proponents to prove their products are safe and efficacious before they are approved for market. These failings of the TGA are similar to those of foreign regulators and must be addressed regardless of the jurisdiction making the determination.

Details of all research conducted on therapeutic goods (medical devices and pharmaceuticals) approved by the TGA should be provided to the relevant regulator for consideration and made available for public scrutiny. This would help to address the problem of a narrow base of selective research used to licence therapeutic goods. Regulators would have access to all related research. The public, including interested researchers and the media, would also have the opportunity to properly scrutinise the TGA and where appropriate foreign regulator decisions to ensure the rigour of product approval processes.

Recommendation 1

We recommend that full public disclosure (with protections for intellectual property and commercially sensitive information) of all evidence regarding the safety and efficacy of medical device and pharmaceutical products when they are approved for market in Australia. Note: This may require a reform of Commonwealth Freedom of Information legislation to end the entitlement of corporations to rely on privacy provisions originally intended to protect the health records of individuals. (refer to Appendix 1 for details)

The HCC are also concerned that the TGA has a long history of relying on foreign regulators to guide it when new products are first approved for market but appears not to monitor when overseas regulators place warnings on products. For example, from January to September 2005 the US FDA issued twenty black box warnings on prescription drugs sold in both the US and Australia. However, the Australian TGA issued warnings for only five of these twenty. In response to a question in a Senate committee, the TGA admitted that it did not monitor the FDA's drug warnings stating:

> The TGA does not record which drugs sold in the US, with black box warnings in the US approved prescribing information document, do not carry black box warnings in the Australian prescribing information (P1) document.[18]

Although this is old evidence of the practice of the TGA ignoring overseas evidence of the dangers of therapeutic products, we are concerned that this may still be the case.

Recommendation 2

We recommend that the TGA monitor and replicate the actions of foreign regulators who issue warnings or remove medical devices and pharmaceutical products from market for safety reasons.

Voluntary reporting means that only a tiny fraction of adverse events for medical devices and medications ever get reported. A 2008 study by Curtin University pharmacologist, Con Berbatis identified that for the prescription medications Australian General Practitioners only report two percent of adverse events.[19] The equivalent figure for medical devices is no known but it is likely there is also significant underreporting.

The Royal Australasian College of Physicians (RACP) has advocated mandatory reporting of adverse events. The RACP argues that the economic cost of an adverse event to the Australian public is considerable as the consequences can be extra visits to both GPs and hospitals.[20] The RACP also advocates remuneration for healthcare practitioners for time spent on reporting and utilising "personally controlled electronic health records as an additional means of ensuring more timely detection of product safety problems."[21]

Mandatory reporting of serious adverse events by health professionals and product manufacturers to the TGA would help build a more accurate risk profile. The TGA should then publish this data as the public has a right to know about the frequency of adverse events. Similarly, policy makers need to know so they can make informed decisions when subsidising, licencing, placing warnings on or removing from market, medical devices and medications.

The HCC notes that in 2011 a *Senate Community Affairs References Committee Inquiry into the Regulatory Standards for the Approval of Medical Devices in Australia* recommended that:

> The Department of Health and Ageing introduce mandatory reporting for health practitioners to the Therapeutic Goods Administration on relevant issues, in certain circumstances including problems with medical devices.[22]

We were disappointed with the response from the Commonwealth Government, where they undertook to consult with the Medical Board of Australia on the issue of mandatory reporting.[23] Action, not consultation was required.

This ignored recommendation is very like the recommendation on mandatory reporting made by the *Consumer Health Forum of Australia* in its' January 2015 submission to the *Review of Medicines and Medical Devices Regulation*.[24] It is also similar to a recommendation the *Health Consumers' Council WA* made in relation to pharmaceutical regulation in previous submissions being that the Commonwealth Government:

Recommendation 3

We recommend that there is mandatory reporting to the TGA by medical practitioners for a specified range of serious adverse events and the TGA regularly publish full de-identified details on the TGA website.

Many medical devices including Transvaginal Mesh, PIP breast implants and ASR hips are permanently implanted in patients. When safety issues have emerged for these three products identifying and communicating with implant recipients has been very difficult and in some cases impossible. In the case of Transvaginal mesh some women have not even aware that the product has been inserted in them and are unaware that it may be causing their unexplained medical problems. Establishing registers to facilitate communication in the case of emerging issues won't help these women but it will help prevent the problem occurring in the future.

Recommendation 4

The TGA compel medical device manufacturers and clinicians to establish registers for all medical devices permanently implanted in patients.

Conclusion

The HCC takes this opportunity to restate our core message. The TGA and many comparable foreign regulators have failed on numerous occasions in their duty to protect the safety of consumers of medical devices and medications.

Therefore, the premise of the criteria identified by the TGA in its document for feedback (identifying "regulators with similar standards to the TGA") is grossly inadequate. Instead the Commonwealth Government needs to either reform the TGA, or find a foreign regulator that does the job properly.

APPENDIX 1

Section 135A of the *Health Act (1953)* prevents anyone working for the Commonwealth Government revealing information relating to the affairs of a (legal) person. Specifically it states:

> (1) **A person shall not,** directly or indirectly, except in the performance of duties, or in the exercise of powers or functions, under this Act or for the purpose of enabling a person to perform functions under the Medicare Australia Act 1973 or the medical indemnity legislation, and while the person is, or after the person ceases to be, an officer, **divulge or communicate to any person, any information with respect to the affairs of a third person** acquired by the first-mentioned person in the performance of duties, or in the exercise of powers or functions, under this Act.
> Penalty: $5,000 or imprisonment for 2 years, or both.[25]

In November 2008 I (Martin Whitely) requested, via Freedom of Information, copies of all documents relating to the decision of the Pharmaceutical Benefits Advisory Committee (PBAC) to recommend ADHD drug Strattera's (manufactured by Eli Lilly) listing on the PBS.[26] I was particularly interested in what consideration had been given by the PBAC to Strattera's (highest possible) boxed warning for suicidal ideation and the numerous serious adverse event reports.[27] The Department of Health and Ageing (DoHA) refused to release all but a tiny percentage of heavily redacted and irrelevant documents.

In April 2010 the Administrative Appeals Tribunal (the Tribunal) heard my appeal against DoHA's refusal to release all the documents.[28] The DoHA lawyers argued successfully that they had erred in providing me with any documents because, for the purposes of the abovementioned provision, Eli Lilly was a 'person' entitled to privacy protections. This sixty year old provision appropriately protects the privacy of patients, however the 2010 decision by the Tribunal established that the same privacy protections extend to the affairs of corporations. My argument to the Tribunal, that it was in the 'public interest' to know what safety and efficacy data the PBAC had considered before recommending that Strattera be placed on the PBS, was considered irrelevant. The privacy provision of the *Health Act (1953)* trumped any consideration of the 'public interest' in the *Freedom of Information Act 1982*.

Section 135A of the *Health Act (1953)* is one of more than 65 secrecy provisions from over 28 Acts and one sub-regulation listed in schedule 3 of the *Freedom of Information Act* that are exempt from FOI requests.[29] [30] There are sound reasons for secrecy provisions in regards to personal information and issues of national security. However, Section 135A denies the public the right to know why the PBAC recommends taxpayers subsidising any drug. It also exempts all interactions of the Health Department and commercial operations from scrutiny via FOI processes. This means that the operations of the TGA are similarly exempt.

In 2010 the the Australian Law Reform Commission (ALRC) produced a report titled *Secrecy Laws and Open Government in Australia*.[31] The ALRC recommended a wholesale review of secrecy provisions in commonwealth legislation. It stated secrecy provisions should only remain 'where they are necessary and proportionate to the protection of essential public interests of sufficient importance to justify criminal sanctions'.[32]

In the case of Strattera, Eli Lilly benefited from a taxpayer funded price subsidy (worth an estimated $101.2 million over four years) for a drug that is known to increase the risks of suicidality, potentially fatal liver problems and heart attacks and strokes.[33] For drugs like Strattera it is in the public interest to know whether taxes are being well spent and if government agencies

responsible for enhancing patient wellbeing are considering relevant safety and efficacy evidence. The ‘protection of essential public interests’ requires disclosure not secrecy.

Note: Reforming FOI legislation to address this anomaly may be a necessary pre-requisite for enabling recommendation 1 discussed above.

ENDNOTES

[1] Australian Government Department of Health Therapeutic Goods Administration, Comparable overseas regulators – medical devices, Criteria and implementation version 1.0, may 2017 https://www.tga.gov.au/sites/default/files/consultation-comparable-overseas-regulators-medical-devices.pdf (accessed 23 June 2019)

[2] Emmanual Stamatakis, Richard Weiler and John PA Ioannidis, 'Undue industry influences that distort healthcare research, strategy, expenditure and practice: a review', *European Journal of Clinical Investigation*, March 2013. Available at http://onlinelibrary.wiley.com/doi/10.1111/eci.12074/abstract

[3] For details of the inquiry visit http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants

[4] A copy of the joint submission is available at http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants

[5] TGA Website, Urogynaecological surgical mesh complications TGA urges reporting of adverse events. 2 August 2016 https://www.tga.gov.au/alert/urogynaecological-surgical-mesh-complications

[6] A copy of the joint submission is available at http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants

[7] TGA Website, Results of review into urogynaecological surgical mesh implants, Behind the News, 20 august 2014. https://www.tga.gov.au/behind-news/results-review-urogynaecological-surgical-mesh-implants

[8] Royal Australian and New Zealand College of Obstetricians and Gynaecologists, College Statement C-Gyn 20 Polypropylene Vaginal Mesh Implants for Vaginal Prolapse, March 2016 available at https://www.ranzcog.edu.au/RANZCOG_SITE/media/DOCMAN-ARCHIVE/C-Gyn_20_Polypropylene_Vaginal_Mesh_Implants_for_Vaginal_Prolapse_Rewrite_UGSA%20Executive_Mar_13.pdf

[9] Available at https://www.youtube.com/watch?v=r4qAKJb1D4o

[10] See http://www.bbc.com/news/uk-scotland-27669702

[11] See https://www.tga.gov.au/alert/silicone-gel-breast-implants-manufactured-poly-implant-prothese-pip-france

[12] See http://www.reuters.com/article/us-breast-implants-idUSTRE7BM14420111224

[13] See http://theconversation.com/victims-of-faulty-breast-implants-were-let-down-by-the-tga-13074

[14] Quentin McDermott and Karen Michelmore, Patients Reveal Agony of Toxic Hip Implants, ABC Online Updated 16 May 2011, 9:20am http://www.abc.net.au/news/2011-05-16/patients-reveal-agony-of-toxic-hip-implants/2694656

[15] Quentin McDermott and Karen Michelmore, Patients Reveal Agony of Toxic Hip Implants, ABC Online Updated 16 May 2011, 9:20am http://www.abc.net.au/news/2011-05-16/patients-reveal-agony-of-toxic-hip-implants/2694656

[16] Whitely M. *Licensing and Subsidising Pharmaceuticals in Australia - Reforms needed to deliver Transparency, Safety and Value for Money* HCC 2014 http://hconc.org.au/wp-content/uploads/2015/06/hcc-senate-submission-on-pbs-tga-tranparency-reform-september-2014.pdf

[17] Australian Government Response to Senate Community Affairs References Committee Report on The Regulatory Standards for the Approval of Medical Devices in Australia August 2012 http://www.health.gov.au/internet/main/publishing.nsf/Content/3141B94933949C69CA257BF0001B750C/$File/Final%20Govt%20Response_approved%20310812.pdf

[18] Australian Parliament, Community Affairs Committee Examination of Budget Estimates 2006-2007 Additional Information Received VOLUME 2 HEALTH AND AGEING PORTFOLIO Outcomes: whole of portfolio and Outcomes 1, 2, 3 OCTOBER 2006 page 106 file:///C:/Users/User/Downloads/vol2_doha_Oct06%20(1).pdf

[19] Con Berbatis (2008), 'Primary care and Pharmacy: 4. Large contributions to national adverse reaction reporting by pharmacists in Australia', *i2P E-Magazine*, Issue 72, June 2008.

[20] The Royal Australasian College of Physicians (RACP) Budget Submission: Adverse Drug Event Reporting, The Royal Australasian College of Physicians, RACP 2013-14 Budget Submission

[21] The Royal Australasian College of Physicians (RACP) Budget Submission: Adverse Drug Event Reporting, The Royal Australasian College of Physicians, RACP 2013-14 Budget Submission

[22] Australian Government Response to Senate Community Affairs References Committee Report on The Regulatory Standards for the Approval of Medical Devices in Australia August 2012

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[23] Australian Government Response to Senate Community Affairs References Committee Report on The Regulatory Standards for the Approval of Medical Devices in Australia August 2012 http://www.health.gov.au/internet/main/publishing.nsf/Content/3141B94933949C69CA257BF0001B750C/$File/Final%20Govt%20Response_approved%20310812.pdf

[24] Consumer Health Forum of Australia, Submission to the Review of Medicines and Medical Devices Regulation, January 2015 https://chf.org.au/sites/default/files/sub-review-medicines-medical-devices-regulation.pdf

[25] ComLaw, *National Health Act 1953*, Australian Government, Canberra. Available at http://www.comlaw.gov.au/Details/C2013C00083

[26] Strattera is pharmaceutical company Eli Lilly's brand name for atomoxetine hydrochloride, a noradrenaline reuptake inhibitor. Unlike the most commonly prescribed ADHD drugs dexamphetamine and methylphenidate, Strattera is not amphetamine based and therefore has the advantage of being non-addictive and unsuitable for illicit use however it carries a black box warning for suicidality and warnings for potentially fatal liver damage and significant cardiovascular harm.

[27] Martin Whitely, Strattera's sad story – (warning it may make you want to kill yourself)', *Speed Up & Sit Still*, 30 August 2012. Available at http://speedupsitstill.com/strattera; The TGA searchable database of adverse events at http://www.tga.gov.au/daen/daen-report.aspx

[28] Administrative Appeals Tribunal of Australia, *Whitely and Department of Health and Ageing*, AATA 338, 7 May 2010. Available at http://www.austlii.edu.au/au/cases/cth/AATA/2010/338.html

[29] See http://foi-privacy.blogspot.com.au/2010/06/drug-secrecy-law-trumps-foi.html#.Uxk5GT9atnU

[30] Available at http://www.austlii.edu.au/au/legis/cth/consol_act/foia1982222/s38.html

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[32] *Secrecy Laws and Open Government in Australia*, p. 307

[33] See http://speedupsitstill.com/strattera and http://www.strattera.com/Pages/index.aspx