Medication Safety:
Closing the Loop – The Health Consumers’ Council Perspective

Presented by Dr Martin Whitely
• Data obtained from clinical research are primarily used to boost and support sales rather than to improve prescribing behaviour.

• Ghost-writers are employed to inflate the number of publications showing the drug in a positive light; results that would harm sales are not published (publication bias); and negative data are suppressed.

• Pharmaceutical companies consider that private-sector clinical research produces private, confidential results that are their own intellectual property.

• They are not compelled by political and health authorities to make public the data obtained in clinical trials.

Professor Marc – Andre Gagnon, ‘Corporate influence over clinical research’ Rev Prescrire April 2012. p.311
Summary of the history of the regulation of Strattera (atomoxetine hydrochloride) in Australia:

- Failed antidepressant rebadged 22 years later as an ADHD drug
- No access to old antidepressant safety data
- Study used to justify licencing to TGA
  - Conducted in house
  - Obvious conflicts of interest
  - Questionable methodology
- Marketed as a “Milder” drug
Soon after market it gets warnings for:

- Potentially fatal liver damage
- Suicidality (Boxed Warning)
- Cardiovascular risk
- No attempts to inform public
- String of disturbing adverse events
- After publicity about horrific individual reports the TGA stops making them available
- Put on PBS $101.2M over 4 years
- Privacy clause in Health Act 1953 prevents FOI access to Eli Lily’s evidence provided to PBAC
Pharmaceuticals Regulation Transparency Reforms:

1. Reforming 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.

2. Require full public disclosure of all relevant safety and efficacy data (with protections for intellectual property and commercially sensitive information) of all evidence regarding pharmaceutical products approved for market and/or subsidised in Australia.

3. Prevent cherry picking of favourable results by requiring pre-registration of all new research that may be later used to support the TGA licencing and PBS subsidisation of pharmaceutical products in Australia.

4. Strengthen Consumer Medicine Information (CMI) requirements so that:
   - Every warning currently included in information to prescribers is also on the CMI
   - It should also be mandatory to include a CMI inside medication packaging.
   - Putting a brief summary of the most serious (boxed) warnings on the outside packaging of drugs so consumers are aware of very significant risks. (Currently boxed warnings are often only highlighted on information made available to prescribers and are not seen by consumers.)

5. Make adverse drug event reporting to the TGA for a specified range of serious reactions (suicidal ideation, strokes, psychosis etc.) mandatory and regularly publish full de-identified details on the TGA website.

6. Require full public disclosure of pharmaceutical industry funding sources for clinicians, researchers, patient groups, advisory board members and members of committees involved in regulatory and policy development processes.

7. The Commonwealth Government should commission or conduct research into the incidence and impact of ‘off label’ prescribing.
Reform 1 - FOI Reform

Reform 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.
Section 135A of the *Health Act (1953)* states:

A person [public servant] 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
Reform 2 – Disclose Safety and Efficacy Data

Require full public disclosure of all relevant safety and efficacy data (with protections for intellectual property and commercially sensitive information) of all evidence regarding pharmaceutical products approved for market and/or subsidised in Australia.
Reform 3 – Establish an All Trials Register

Prevent cherry picking of favourable results by requiring pre-registration of all new research that may be later used to support the TGA licencing and PBS subsidisation of pharmaceutical products in Australia.
Reform 4 - Strengthen Consumer Medicine Information Leaflets

- Every warning currently included in information to prescribers is also on the CMI.

- It should also be mandatory to include a CMI inside medication packaging.

- Putting a brief summary of the most serious (boxed) warnings on the outside packaging of drugs so consumers are aware of very significant risks. (Currently boxed warnings are often only highlighted on information made available to prescribers and are not seen by consumers.)
Reform 5 – Mandatory Reporting of Severe Adverse Events

Make adverse drug event reporting to the TGA for a specified range of serious reactions (suicidal ideation, strokes, psychosis etc.) mandatory and regularly publish full de-identified details on the TGA website.
Reform 6 – Disclosure of Financial Relationships

Require full public disclosure of pharmaceutical industry funding sources for clinicians, researchers, patient groups, advisory board members and members of committees involved in regulatory and policy development processes.
Reform 7 – Review ‘Off Label’ Prescribing

The Commonwealth Government should commission or conduct research into the incidence and impact of ‘off label’ prescribing.

Based on the outcome of this research the Commonwealth Government may consider if over time it is worth encouraging ‘off label’ prescribing to become ‘on label’.

This could be achieved by gradually restricting PBS subsidisation of medications to those prescribed within the approved guidelines.