Conflicts of Interest in Vaccination Science

The individuals listed below are working on the Influenza Specialist Committee (100% funded by the pharmaceutical companies) that advises the government on the best strategy for management of influenza and they are also on the ATAGI government boards and involved in designing the clinical trials for influenza vaccine funded by the pharmaceutical companies. They also work for the government TGA and were on the board that investigated the problems with the childhood influenza vaccine (Fluvax) in 2010.

Policy decisions should be made independently of manufacturers that stand to benefit from these decisions. Therefore it is of great public concern that the Influenza Specialist Group (ISG), who advisors the government on policy is fully funded by industry. The justification provided by the ISG is that 'they are helping promote public health messages, not pushing specific brands of vaccine' (1). This argument is irrelevant to this situation. The ISG provides the government with information about which strategy is best for reducing the burden of influenza in the community not which brand of vaccine is best. This public health message should be determined independently of the manufacturers who stand to gain. This is because it is in the industry's interest to advise that a vaccine should be used and to ensure it is promoted to as many people as possible. This is not always in the public interest.

The credibility of the advice is therefore questionable if it is given to the government by a body that is funded by the company that can make a profit out of the decision being made. If government regulators are not ensuring decisions are made independently of the manufacturers then they are betraying the trust the public has placed in these bodies to protect the public interest.

The COI's of Robert Booy, Terry Nolan and Peter Richmond show that whilst these researchers claim to be objective, the advisory roles they hold require them to protect two different interest groups (2). They have spent time on pharmaceutical boards whose primary interest is company profit and they are also representatives on government regulatory boards whose primary interest is protecting public health. The two roles are not compatible. The Department of Health and Aging claims that advisory board members are sourced from a 'limited pool of experts' (3), however, this does not justify individuals being on vaccine company advisory boards as well as government policy-decision making boards. If these conflicts of interest do exist then the public should be openly advised about them.

Professor's Nolan and Richmond were also investigators on the TGA enquiry into the cause of the adverse reactions to childhood influenza vaccine in 2010 (3). This investigation did not find a cause for the high number of adverse reactions to the childhood Fluvax vaccine. It also concluded that the 48 reports of febrile convulsions from the Panvax vaccine and 11 reports of possible anaphylaxis were within the expected range of side-effects (3). In other words, the panel members investigating the cause of the adverse reactions were investigating their own research: they were the same people who trialed the Panvax vaccine and coordinated the influenza program for children in WA. They were also on government advisory boards and had spent time on CSL's vaccine advisory board with various funding arrangements for conferences and nominal payments (2) (3). This arrangement contradicts the statement made by the TGA that 'post-market surveillance functions of the TGA are clearly separated from the pre-market approval process (4). This is stated to be the case in order to avoid perceived conflict of interest between officers charged with initially assessing the suitability of a product and those charged with monitoring its ongoing suitability' (4, p.10) Prof. Nolan and Prof. Richmond were involved in the approval of Panvax and Fluvax for the market and also with the post-marketing surveillance and investigation of the adverse event's (AE's) associated with these vaccines.

The TGA justifies its dual roles of licensing and monitoring drugs by claiming this arrangement makes good sense (4). They believe that it is appropriate to have the scientists that evaluate drugs for approval should also monitor their safety because they are the scientists that have the most knowledge of the pharmacological properties of these drugs. This would be acceptable if the TGA could prove that the information the scientists base their decisions upon is transparent, balanced and unbiased. At present the processes of the TGA are not transparent and funding arrangements for this body and its representatives illustrate that the information can be perceived as biased towards industry and consumers are not being properly represented in decision-making processes.

The suggestion by the TGA that the separation of licensing and monitoring functions for vaccines 'would have serious deleterious effects on the ability of health authorities to respond to emerging vaccine safety issues' is clearly inaccurate. This is the situation that occurred in 2010 when many children reacted severely to Fluvax vaccine and the TGA performed *both* roles at this time. In addition, the TGA does not have monitoring systems in place that can determine causal links between vaccines and AE's or determine the rates of specific AE's with any accuracy (5). Consumers of vaccines expect that immunization policies are based on rigorous evidence that is obtained *before* the vaccine is introduced into mass vaccination campaigns.

The fact that the TGA is essentially funded by the pharmaceutical companies and manufacturers of medical devices, as is stated in the Ministerial Review, needs to be addressed. Funding arrangements must not enable commercial interests to influence policy decisions. If the TGA is justifying this arrangement by suggesting that 'it requires commercial companies that apply for marketing approval to pay for the cost of the review of the application on a cost recovery basis' (4, p.10) then this must be addressed through the Commonwealth Department of Health and Ageing and not directly with the TGA.

The onus is on the TGA to demonstrate through transparent processes that commercial companies cannot influence policy decisions. It is not satisfactory for the TGA to state 'there is no inappropriate commercial influence over the TGA' when clear conflicts of interest exist and the statistics for policies are being provided by pharmaceutically funded clinical trials (2). The TGA must demonstrate that its processes are truly independent of stakeholder interests in order to protect the public interest.

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References:

1. Finch Gareth, Burson-Marsteller manager, as cited by Sweet M, *Crikey,* The shot of PR that could undermine public health policy. www.crikey.com.au/2010/09/29/the-shot-of-pr-that-could-undermine-public-health-policy Visited 0.8.11
2. Nolan T, McVernon J, Skeljo M, Richmond P, Wadia U, Lambert S, et al. Immunogenicity of a Monovalent 2009 Influenza Vaccine in Infants and Children: A Randomised Trial. Jama. 2010 jan 6:303 (1): 37-46: Supplementary online content.
3. Bita N, Consumer editor, 29th September 2010, A flu jab too close for comfort, *The Australian,* www.theaustralian.com.au/news/features/a-flu-jab-too-close-for-comfort/story-e6frg6z6-1225931148903
4. Australian Government, Department of Health and Ageing, Therapeutic goods Administration, November 2010, Response to the West Australian (Stokes) Review into the handling of AEFIs following 2010 seasonal flu vaccination www.tga.gov.au/safety/alerts-medicine-seasonal-flu-101018
5. CSL Package Insert Afluria (Fluvax/Enzira), Influenza Virus Vaccine, 2007-08 http://novaccine.com/pdffiles/afluria_flu_influenza_vaccine_package_insert.pdf visited September, 2011