

‘Whose bread I eat, his song I sing’

Transcript of keynote address given by **Julian Burnside, QC** on May 28th 2009 at the **Royal Australian and New Zealand College of Psychiatrists Congress**, held at Adelaide Convention Centre, South Australia.

James Hundertmark, The Chair of the Programme Committee for this meeting. We are very happy to have debate within the College of Psychiatrists and I think Julian Burnside is an example of a man who has spent his life engaged in very vigorous debate and has contributed very significantly to a number of causes. Julian Burnside is a Barrister based in Melbourne, he joined the Bar in 1976 and took silk in 1989. He's acted for quite an interesting diverse range of people. He's acted for the Ocktete natives, he's acted for the Maritime Union of Australia in the well known waterfront dispute of 1989, he's been the senior counsel assisting the Australian Broadcasting Authority in the cash for comment enquiry and acted for Liberty Victoria in the TAMPA litigation. Interestingly he has also acted for Alan Bond in ford trials and for Rose Porteous, so there is quite a range of interests there.

Now I just wanted to do one other thing in introducing him and read to you from his book 'Watching Brief' and this is about his school days at Melbourne Grammar and I will try and get through this paragraph reasonably quickly. 'On my last day at school when the glittering prizes were being strewn among the chosen I was awarded colours in each of my sports, but I was awarded only 2nd colours because they were only 2nd colour sports. I still remember the stinging injustice of it. That a good footballer received the ultimate accolade of 1st colours for playing a season for the school and yet after representing the school for years as a swimmer in diving and rugby I got 2nd best. If I were to speculate on the origin of my concern about justice I would settle for that day. Even though it has faded in vividness and has ceased to hold any fear or pain for me, I still think of it with a clinical detachment and recognise that trivial events can have long consequences.' So it's a very great pleasure to introduce Julian Burnside to the microphone this morning.

Thank you very much. I must say I am a little puzzled to be here. I am a Barrister as you know, not a Psychiatrist and as such I inhabit the shadowy fringes of intellectual life whilst you are all clustered at the centre. In addition unlike Psychiatrists I have never understood people. They still puzzle me utterly, and my knowledge of the RANZCP is limited, although having said that I do admire the College for the position it took in connection with the mistreatment of asylum seekers in Australia during the Howard years. It joined the professional alliance for the health of asylum seekers and their

children and it also made a candid and powerful submission to the constitutional references committee into the operation and administration of the Migration Act, and that's all to the good.

I wasn't altogether surprised to be contacted by Jon Jureidini about I guess 18 months ago to be invited to give a talk at this Conference, not surprised because of any natural fit between me and it but because Jon had done some really great work in connection with cases that I had been involved in in the refugee area and more recently in the stolen generation case that ran in the Supreme Court of this state, but I accepted because Jon's a good bloke and he had been very helpful in some of my cases. It was a surprise to get an email from him a while later in March of last year in which he said 'I am writing to let you know that the Conference Convenor, Malcolm Battersby and several others, including me this week resigned from the Congress Organising Committee. Malcolm had taken on the Convenor role on the explicit understanding that the Congress would be free of drug company sponsorship, the College Council has decided that this is unacceptable. Shortly afterwards on the 1st of April last year the Australian newspaper carried a report of Malcolm Battersby's resignation. The report said in part that:

“...a senior member of the RANZCP resigned as Convenor of the 2009 Congress after his peers unanimously voted down a proposal to dump drug company sponsorship. The College was forced last week to appoint two co-convenors to replace Malcolm Battersby a fellow of the College.”

Of course this was quite exciting to me as I could see a fight brewing. The report went on:

“RANZCP President Ken Kirkby said yesterday the Colleges more than 20 Counsellors were not given enough reason to change a Policy that complied with the pharmaceutical industries code of conduct on sponsorships.”

It also said

“The clash highlights the debate about the scale and implications of the industries influence over doctors whose prescribing patterns affect not only patient care but the viability of taxpayer funded schemes subsidising drugs”

and for those from New Zealand, I should say that in Australia we have the pharmaceutical benefits scheme which is an extremely good scheme but it is quite expensive to the taxpayer, and pharmaceutical companies do have some influence on what that scheme costs us. The article went on to mention that in the second half of last year, that is to say the second half of 2007, 42 drug companies spent a total of 31 million dollars paying for educational events for health care professionals, mostly doctors.

In due time I received a letter from the new co-convenors, asking me to confirm that I had agreed to speak and asking me to notify them of my topic in due time. On reflection I was probably not being given a clear opportunity to say no I would not be speaking, and frankly in the same position I wouldn't have given myself that opportunity. I didn't mind that, but it did get me thinking and so after having confirmed that I would speak I emailed saying that my topic would be 'Whose bread I eat song I sing'.

Now I don't know whether the new co-convenors quite understood me or whether they even noticed what topic I was going to address, and if they notice it whether they understood the implications of it. If they did, then all the more credit to them because I imagine most of you have worked it out.

Let me start with a little bit of history, especially for those of you from New Zealand. There is an ABC television program called Media Watch which keeps an eye on what happens in Australian media. In 1999 Richard Ackland was the anchor of the program. He drew attention to something which had been happening on the John Laws Radio Program. (John Laws for those of you from the back blocks or New Zealand was a shock jock until he retired very recently. He dominated the Sydney and rural airwaves with talk back radio.) John Laws was famous amongst other things for his relentless beating up of Australian banks, but Richard Ackland drew attention to the fact that, recently, John Laws had stopped beating up on the banks and had started saying quite nice things about them. He had started telling good news stories about them. In a subsequent episode of Media Watch, Richard Ackland revealed that John Laws had reached a sponsorship arrangement with the Australian Bankers Association worth 500,000 dollars a year. The quid pro quo was that he would run a number of spots on his show called The Whole Story in which he would tell interesting little historical anecdotes which would be known in part and then he would tell you the balance of story, giving you the whole story. He would accompany that with a parallel yarn about how we have only heard half the story about the banks, and these stories placed the banks in a very favourable light. This approach managed to negate a great deal of the beating up of the banks that he had previously engaged in.

Richard got quite excited about this as it seemed quite odd that John Laws would take money from the banks and then start embracing their views. The Australian Broadcasting Authority decided to hold an enquiry into this and its initial investigations into the matter revealed the fact that the other king of talkback radio station, Alan Jones, was also on the drip with a few companies to whom he had recently been relatively benign. Now let me tell you, both Alan Jones and John Laws can be fairly ferocious if they are on your case, so it was a fascinating novelty to see them treating people very nicely, and to note that they were receiving hundreds of thousands of dollars on the quiet from those same people.

I was briefed to act for the Australian Broadcasting Authority in the public hearings into the matter. During my opening remarks at the hearing, I spoke of the old Irish aphorism: Whose bread I eat, his song I sing.

The enquiry uncovered amongst other things that Jones had a \$500,000 a year contract with Optus, \$433,000 a year contract with the Colonial State Bank, \$250,000 a year contract with the Walker Corporation and a swag of others. John Laws was getting \$895,000 a year from Optus – incidentally, it provoked a bit of rivalry between them when each discovered what the other was getting. Laws was getting \$300,000 a year from Foxtel, a couple of hundred thousand a year from Qantas plus 6 first class tickets to any destination in the world and a handful of others. Both of them doing incredibly well.

John Laws gave evidence at the hearing that he wasn't paid to be influenced or to change his mind but the recorded fact is that he stopped beating up on the banks. What conclusion you can draw from that is a matter for you. They both insisted from first to last that their comments on air and off air were completely unaffected by the sponsorships of the sorts that were revealed. Alan Jones said, among other things

“I want to say emphatically that those arrangements have never influenced what I have or have not said and John Laws said there was nothing sinister, dishonest or untoward about my arrangements with the banks. I was paid to speak my mind, not to change my mind, however with most people if the knowledge of my facts changes I change my mind, hopefully this is not an uncommon trait. Contrary to the way I am portrayed in the media I do not have a set of rigid unchangeable opinions, instead I regard myself as reasonably intelligent and a person who listens to others and who can be persuaded by new information or recent arguments.”

So that defined the fighting ground, and when you think about it the response of each of them was perfectly understandable, probably genuine, probably sincerely held, probably the sort of reaction that every person in this room would hold when asked in some form or another: Would pharmaceutical company sponsorship influence the way you see things? Of course you would say you know it wouldn't change your mind, if it brought light new facts then this would make you change my mind perhaps.

Before moving on to the real point of this I can't resist telling you a couple of very entertaining moments. It was one of those hearings that every barrister would give his right arm for: it was terrific fun. John Fordham, John Laws' Manager, was giving very enthusiastic evidence about what a powerful voice John Laws had, how influential he was. He was asked:

Question: "Would you agree with the proposition that his, Laws' voice on radio is immensely powerful in the sense that he can persuade a lot of people to agree with him."

Answer: "Absolutely"

Question: 'Was there an example of that in relation to a proposed Nashville Tour for Qantas.

Answer: "Yes. I think the year was 1997. John Laws has got a long association with country music and we came up with an idea to promote a country music tour to Nashville for their annual fanfare. Nashville is the Tamworth of the United States."

Alan Jones when being asked about one of his contracts, and he said:

"I want to say emphatically that those arrangements never influenced what I have or have not said. I am not driven by these things. I accepted a commitment to Walker Corporation because it was a new developer with a magnificent finish and terrific product and they needed someone to be identified with that product and wherever there was a Walker product or launch I was there. I would spend the morning on my hands and knees inspecting piles."

Later he gave evidence that he had entirely put out of his mind the fact that one of his contracts gave him a flat fee plus an additional fee depending on increases in the sponsor's share price. He was then shown a letter he had written to his business manager, Harry M Miller:

"Dear Harry, I notice the press release from Walker Corporation about the net profit before tax of 18.6 million, an increase of 107%. They are boasting about all of that – are we being paid enough? Lets face it, they wouldn't be in the public place without moi ! Tell me what you think?"

Question: "Do you say that you did not have in mind the terms of that agreement when you wrote that memo? "

Answer: "Well I think you can gather by the exclamation marks and the peculiar language that I was jesting. ..."

Well I mean, and of course we all understood.

Now everything has a background and in 2007 I heard a wonderful Ockham's Razor on Radio National, given by Christopher Nordin on the influence of pharmaceutical company sponsorship. It got me thinking about pharmaceutical company's sponsorship, which is something I haven't really attended to before.

More recently I have been involved in some really exciting litigation against Merck Pharmaceuticals in relation to their drug, Vioxx, which I might mention a little later on. One thing becomes clear, and that is that big pharma spends a lot of money to influence your thinking.

Now some facts. The pharmaceutical industry is very profitable. The combined profits of the top 10 drug companies on the Fortune 500 list is 35.9 billion US dollars. That is more in total than profits of all of the remaining 490 companies in the Fortune 500. Those 10 pharmaceutical companies make more between them than the other 490 on the list. They have research and development that amounts to about 11% of their budget but their marketing amounts to 36% of their budget. In 2001, a United States pharmaceutical company spent more than \$4.8 billion on sales personnel targeting medical practitioners. They spent more than \$2 billion US on conferences, seminars and other practitioner-oriented events. They spent more than \$10 billion providing drug samples free of charge to physicians.

In Australia although the scale is smaller, a study of Australian practitioners revealed that 96% of practitioners had received offers of food from pharmaceutical companies, not food handouts but nice dinners. 94% of them received products they could use in their office, 51% of them received personal gifts. 50% received journals or textbooks. Between 75% and 85% of them were invited to product launches, symposia or other “educational events”. More than half of them received offers of free travel to conferences and typically those offers would include free transport for the partner of the practitioner, gift tickets to sporting events and other entertainment.

Nevertheless, reports in learned journals indicate that physicians deny or are unaware that they are influenced in any way by pharmaceutical spending. The effects of sponsorship however are at the heart of the issue.

Drug companies sponsor a great deal of research, and no doubt that a good deal of that research has very useful outcomes. Nevertheless the reports show that the drug company sponsored research is four times as likely to have an outcome favourable to the sponsor than research that is independent.

Authors of company sponsored research are more than five times more likely to recommend the drug company's products than are independent authors. Researchers with industry connections are more likely to favour the products of the company that sponsor them. An Australian survey revealed that over 12% reported that industry staff wrote the first draft of articles published under the names of the medical specialists. Between 5 and 7% reported that unfavourable findings were either delayed or censored out of the reports, which were supposedly written by the authors. A smaller number reported complete concealment of adverse results.

Another area of influence, which must be particularly difficult to resist, is the use of Key Opinion Leaders. My involvement in the Merck trial introduced me

to this notion. Apparently this is a common thing in the medical profession. Some people are perceived as Key Opinion Leaders, and what they say seems to have great effect. I don't think we have anything equivalent in the legal profession, unless it is judges, but there are pragmatic and doctrinal reasons for following what judges say. I really don't think we have anything like Key Opinion Leaders in the legal profession, and certainly I am not aware of law book publishers exploiting key opinion leaders in the legal profession in order to influence others.

Key Opinion Leaders are the medical profession's equivalent of talk back radio hosts. They are the people whose voices are powerful and there is no doubt whatsoever that the pharmaceutical industry courts them, flatters them, coaxes them and nourishes them with feelings of goodness and virtue expecting that they will pass on favourable messages about the sponsor's products. The amounts which they spend on this are enormous, and one can only assume that they do it because they think it works.

Key Opinion Leaders might reflect on this question: why do you imagine you are being flattered and groomed by pharmaceutical companies? Ad when you pass on good messages about their products, are you confident that it is your view that you are passing on, or have you been influenced to some extent by the flattery and the money, the travel and all the perks? I don't have a view about whether or not people are able to withstand completely the blandishments that Key Opinion Leaders are subject to. I rather doubt it, as I come from a much frailer area of humanity than you do.

Equally I would be fascinated to know from you, especially as psychiatrists, why it is that we can all see these things and yet Key Opinion Leaders continue to be Key Opinion Leaders. If everyone knows that these things happen, why does anyone listen to the people they think are necessarily affected by a drug company's sponsorship? Why are they opinion leaders at all, if you have the sense they are just peddling drug company's products, albeit unwittingly?

Another source of influence that is an indirect way of drug company's influencing opinion at the grass roots is the learned journal. The New England Journal of Medicine for a long time had a stringent policy restricting or declaring possible conflicts of interest of authors in the journal. For 12 years it had a policy which precluded anyone with financial ties to the pharmaceutical industry from writing editorials or reviews. In about 2002 they scrapped this policy because it was too difficult to find anyone to write editorials. They could not find enough authors without ties to the pharmaceutical industry. That fact alone tells you something remarkable about how pervasive is the influence of the industry.

Richard Smith, Editor of the British Medical Journal in an article titled 'Medical Journals and Pharmaceutical Companies – Uneasy Bedfellows' wrote in 2003 "How did we reach a point that so many

doctors will not attend an educational meeting unless it is accompanied by free food and a bag of goodies? Something is wrong and medical journals are a part of what is wrong.”

“The industry dominates healthcare and most doctors have been wined and dined by it.”

I wonder, is there anyone in this room who has not been wined and dined, at least once by a pharmaceutical company. He also said that the randomised clinical trial is being debased for marketing reasons. He went on to suggest ways the pharmaceutical companies influence clinical trials and achieve the results that they want from clinical trials. First test your drug against a treatment known to be inferior. Next test your drugs against two lower doses of a competitor drug. Alternatively test it against two higher doses of an alternative drug to make your drug seem less toxic. Conduct trials that are too small to show differences from competitor drugs. Select for publication those end points that give favourable results and select for publication results from centres that are favourable and information those subgroup analyses that are favourable.

All of this I think can be seen if you look hard enough at the way clinical trials have been conducted and reported. I am not saying this is a universal truth but it is sufficiently widespread that you need to be alert to it. And the matter goes one layer deeper, when it was revealed during the Merck litigation that an apparently respectable, apparently independent, apparently learned peer review journal, The Australasian Journal of Bone and Joint Medicine was wholly produced by Merck and only ran articles and reviews that ran directly or indirectly in favour of Merck products. In addition it had listed as its editorial board a number of people, Merck’s own advisory board, who didn’t realise they were on the editorial board of the Journal. There was an email exchange between one of the Merck people and someone at Elsevier, who were the publishers of the Journal, in which the Merck person said “We own the journal” and yet this was a journal to all outwards appearances entirely independent of any pharmaceutical company.

Whether there are other examples of the same phenomenon, it is difficult to know. I guess you need to be on the look out.

Christopher Nordin’s Ockham’s Razor speech included this comment:

“Over prescribing makes a major contribution to the 6 billion dollars now being spent on pharmaceutical companies in Australia. How is it done. Well the immediate pressure on the medical profession comes from the travelling reps who seek and obtain regular interviews with General Practitioners and Specialists. At these sessions Reps talk up and provide reprints on published sponsored randomised controlled trials which have become the gold standard in assessing pharmaceuticals. These trials offer international scope and run into

thousands and are often financed so generously that the funding places the investigator under an obligation. I have myself held several small grants from pharmaceutical companies and am aware that this might influence my prescribing habits and my freedom to speak out. I recall the relief I felt at a meeting in Melbourne some time ago when I realised I could talk freely about the product because the grant I had received had just expired.”

Let me tell you briefly about the Merck litigation. Merck produced a drug called Vioxx, Vioxx is supposed to be very good for relief of arthritis pain. In 1999 and 2000 Merck had run a randomised controlled trial of Vioxx versus Naproxen. Naproxen was a traditional NSAID which was associated with fairly bad gastric upsets as many NSAIDs are. The point of the trial was to demonstrate that Vioxx was free of gastrointestinal problems. It was a big trial, well conducted and the results were exactly what Merck wanted, at least in part, because it showed that patients on Vioxx had far fewer gastrointestinal problems than people on Naproxen.

There was a flip side however and that was that people on Vioxx had 5 times as many myocardial infarctions as people on Naproxen. Now that was rather inconvenient and there was a flurry of activity within Merck in March of 2000 and they eventually released the report of the trials that said that Vioxx is brilliant for gastrointestinal problems, it reduces them dramatically and Naproxen subjects had fewer myocardial infarctions because of Naproxen's potent anti-platelet effect.

For the next 4 years Vioxx was sold on the footing that it did not cause adverse cardiovascular outcomes because the trial results were explained by the powerful anti-platelet or anti-thrombotic effect of Naproxen. This attributed to Naproxen a cardio protective effect even greater than that of Aspirin. The wheels fell off when a later placebo controlled study showed that Vioxx was actually producing twice as many heart attacks and other cardiovascular events than placebo.

Now what is interesting about this was that the Naproxen explanation was run as the explanation, it was pounded into the heads of the Key Opinion Leaders who were sent out like willing troops to convey the message and Les Cleland from this city was vilified and scorned when he came out with the heresy that Naproxen could not possibly be as cardio protective as was necessary to explain the results in the clinical trials. He was one of the very few dissenting voices.

After the results of the placebo-controlled trial, Vioxx was voluntarily withdrawn worldwide. A US senate enquiry was held and Senator Waxman who ran it later wrote an article about it in the New England Journal of Medicine which included these observations:

“On 7 February 2001 the arthritis drugs advisory committee of the FDA met to discuss VIGOR (the Naproxen trial). Merck argued that the significant increase in myocardial infarctions which was five fold was explained by the effect of Naproxen. The medical reviewers voted unanimously that these cardiovascular adverse events had to be reported to Physicians. The next day Merck sent a bulletin to its Vioxx sales force of more than 3,000 Reps ordering them do not initiate discussions on the FDA Arthritis Advisory Committee or the results of the VIGOR Study. They then produced a cardiovascular card which was given to all their Reps, the point of which was to say there is no cardiovascular risk with Vioxx, the results of VIGOR are explained completely by Naproxen’s powerful anti platelet effect.”

That was something about which the manufacturer’s of Naproxen had never heard, and something that which would have been immensely beneficial for them because it showed Naproxen to be twice as effective in cardio protection as low dose aspirin. The only people in the world to think Naproxen was cardio effective was Merck and their Key Opinion Leaders and it kept Vioxx on the market for the next 4 years.

Waxman also reported that the pharmaceutical industry in America spends more each year marketing its drugs than all American Medical Schools together spend educating doctors. It is a very striking fact. It seems to me that people who receive support from pharmaceutical companies are very likely to be influenced, unconsciously or not, by the levels of support they get, and the greater the support, the greater the degree of influence. The question arises: are the pharmaceutical companies doing this out of altruism or are they doing it for plain commercial motives?

One document produced in a Merck trial, passing between senior people within Merck, is an email with a subject line ‘Physicians to neutralize’:

“As we discussed attached is the list of problem Physicians that we must at a minimum neutralize. We’ve had many opportunities to get these individuals involved in the following possibilities research, national consultants meetings, grants, CME program faculty training, medical school grants, personal contacts, peer to peer interactions, spend a day at our Headquarters and other consulting activities. We will keep these individuals top of mind for any upcoming programs and activities.”

If you are offered a grant, it may be that you are regarded as someone who needs to be neutralized, at the very least pharmaceutical companies are willing to offer grants to people who they think need to be neutralized or brought on-side. Big pharma obviously think that this approach works. If they think it works and they spend so much money on it then you need to be a bit more alert perhaps than you might have been

Ultimately, the question is: Are they fooling themselves or are they fooling you? They are selling; are you buying?

I started with an Irish proverb, let me finish with an Arab proverb: “The camel driver has his projects, the camel has *his* projects.” If the pharmaceutical company is the camel and you are the camel driver, you must ask is it right to accept their sponsorship. Thank you.

THE END