Senate Public Hearing Melbourne, April 29, 2013, Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013

Dr Ken Harvey, Adjunct Associate Professor, School of Public Health, La Trobe University.

Madam Chair, Senators,

Your committee is interested in the need for regulation of pharmaceutical industry conduct with regards to interactions with the medical profession, and the appropriateness of the provisions in the bill that place restrictions on these interactions.

I'd like to start by giving a personal background to my interest in this matter.

I'm a Melbourne University medical graduate. After working in Papua New Guinea I undertook postgraduate training in Sydney in microbiology and infectious disease. On returning to work at The Royal Melbourne Hospital in the mid-1970's I was confronted with the problem of hospital-acquired infection with antibiotic-resistant micro-organisms. [1]

Antibiotic-resistant micro-organisms are a reflection of antibiotic-prescribing habits. Thus I became interested in whether antibiotics were being prescribed wisely. I can still remember a confrontation with a senior staff member when I said, "I don't think your unit is prescribing antibiotics wisely". She said, "Who are you to tell me what to do!" Which raised an important question; how **do** we judge whether prescribing is wise?

The answer in the late 1970's was to collect together a multidisciplinary group of specialists and write a small booklet titled, "Antibiotic Guidelines" outlining cost-effective antibiotic treatment recommendations for common infections. Because germs change, drugs change and knowledge changes this booklet has been updated every few years. It's now reached its 14th edition and is available in both print and electronic formats. [2]

Using this book, we could compare individual antibiotic prescriptions with peer-consensus, evidence-based recommendations. Our guidelines recommended the use of older, narrow-spectrum antibiotics wherever possible; keeping more expensive, newer antibiotics in reserve. Yet, when we audited antibiotic use we often found our colleagues were prescribing newer, more expensive, broad-spectrum antibiotics as first-line. This was not what we taught. But it **was** what pharmaceutical companies were promoting. "You can't afford to be wrong" they said, "Use blundermycin!"[3]

This got me interested in forces at work on the pen that writes the 'scrip; especially the promotional activities of the pharmaceutical industry. Since that time, I've been a member of the expert group that wrote the 1988 WHO Ethical Criteria for Medicinal Drug Promotion. I joined Health Action International. I was involved in formulating and implementing the Quality Use of Medicines plank of Australian Medicine Policy. I've been a serial complainant about unethical promotion. I've also made a number of submissions to the revision of industry self-regulatory Codes and participated in relevant government working parties on behalf of CHOICE (the Australian Consumers Association) and the Consumers Health Forum.

It's been a frustrating process; most of the recommendations put up to improve industry Codes have been ignored. While there has been incremental improvement in Codes and individual behaviour over the last 25 years there's still a long way to go.

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There's increasing research that shows that too close a relationship between physicians and therapeutic goods companies can be detrimental to the public health.

For example, funding the travel and registration of practitioners to attend conferences and payment for providing consultancies, company sponsored lectures and sitting on advisory boards can encourage conscious or unconscious reciprocity by the recipients. This can manifest itself in uncritical uptake of newer, expensive and less-well evaluated products and underutilisation of more cost-effective drugs and medical devices. The cost and safety implications of these distortions to our health system are significant.

A recent editorial in the British Medical Journal reported that a US Senate Finance Committee investigation found the medical device company Medtronic was "heavily involved in drafting, editing, and shaping the content of medical journal articles authored by its physician consultants," who were paid hundreds of millions of dollars by the company through royalties and consulting fees.

The Committee Chair, Senator Max Baucus, said Medtronic's actions had "violated" patients' trust. The president of the North American Spine Society, said, "If surgeons had known that the lead authors of the 13 original studies on the Medtronic product had received payments ranging from $1.7m to $64m from Medtronic, and that its marketing employees were co-authors and co-editors, would they have been as eager to use this product on their patients?" [4]

This is just the latest in a series of scandals that has cost the U.S. therapeutic goods industry 15 billion dollars' worth of fines by the U.S. Justice Department over the last few years. [5] The most recent is a 3 billion fine and a corporate integrity agreement for GlaxoSmithKline who will be appearing before you later this morning. Prosecutors in this case said the company had tried to win over doctors by paying for trips to Jamaica and Bermuda, as well as spa treatments and hunting excursions. [6]

In response, the U.S. Physicians Sunshine Payment Act became operational earlier this year. It requires pharmaceutical and device companies to report to the Centers for Medicare and Medicaid Services (CMS) all payments made to individual doctors and teaching hospitals that total more than US$100 (A$97) a year. Companies must begin to collect the information by 1 August this year and report it to the CMS by 31 March 2014. The information will be posted to a public website on 30 September 2014.

However, in Australia, the government believes in self-regulation.

Many consumer and health professional groups have argued that Medicines Australia (and other industry associations) should fully disclose payments made to individual healthcare professionals, both in 2009 during the 16th revision of Medicines Australia Code and again in 2012 during the 17th Code revision. A petition supporting full disclosure containing more than 450 signatures was sent to the Australian Competition and Consumer Commission (ACCC) during the authorisation process of the 17th Edition of Medicines Australia Code (appended).

Subsequently, Medicines Australia set up a Transparency Working Group charged with incorporating similar disclose provisions to the US Sunshine Act into its self-regulatory code.

If the group's recommendations are adopted member companies of Medicines Australia could start recording payments made to individual health professionals from the beginning of 2015 with public reporting starting in 2016. In contrast the Dutch are already reporting such transactions and the U.S. will report next year. The slow progress of this matter by Medicines Australia reminds me of St Augustine's famous prayer: "O Lord, give me chastity and continence, but do not give it yet!"

In addition, while Medicines Australia members might take up the group's recommendations, there is no compulsion on the other eight therapeutic goods industry associations to do so. Most importantly, non-members of industry associations escape self-regulatory codes yet they are often the worst offenders.

The bill currently before the Australian Senate would, like the US Sunshine Act, provide a compulsion to report. However, unlike the Sunshine Act, the Senate bill only applies to pharmaceutical companies and doctors. The bill also allows details of payments to be posted on a multitude of individual company web sites. This would make it very difficult to find out how much money a doctor was receiving and from whom. Regardless, the bill has stimulated important debate.

Your committee is considering currently submissions which closed earlier this month. The majority of the 24 submissions posted (by industry associations and pharmaceutical companies) oppose the bill and support industry self-regulation. Their submissions remind me of Paul Keating's quotation (from Jack Lang), "In the race of life, always back self-interest".

Assoc Prof Ian Haines and the Consumers' Health Forum supported the bill (albeit the latter wanted it broadened to include all health professionals and all therapeutic goods companies). Dr Mary Osborne and I pointed out the limitations, both of the bill and self-regulation, and asked for broader debate about different models of ensuring ethical relationships between health professionals and therapeutic goods companies.

A late submission from the Department of Health and Ageing (DoHA) reinforced the government's preference for self-regulation but failed to address its limitations.

Both the AMA and DoHA's submission cite the Health Practitioner Regulation National Law Act 2009 overseen by the Australian Health Practitioner Regulation Agency (AHPRA) and in particular its Code of Conduct for health professionals which includes,

> "...8.11.6. Not asking for or accepting any inducement, gift or hospitality of more than trivial value, from companies that sell or market drugs or appliances that may affect, or be seen to affect, the way you prescribe for, treat or refer patients".

The AMA and DoHA should be asked about the apparent contradiction between this provision of the Code and the $30 million dollars or more that healthcare professionals receive from drug companies each year for attending so-called "educational events". [7] attached

I could also expand on major problems I have found when complaints about health professionals ethical conduct are sent to AHPRA.

In conclusion, self-regulation cannot be effective unless legislation is introduced to make compliance with codes of conduct a condition of obtaining marketing approval for therapeutic goods.

Four submissions (Medicines Australia, MTAA, IVD and my own), reiterated the need for recommendation 5 of the Working Group on Promotion of Therapeutic Products to be implemented; that each company which registers a product on the Australian Register of Therapeutic Goods nominate a relevant industry code with which it agrees to adhere, as a condition of registration.

It is my understanding that there is a precedent for this in that sponsors of prescription generic medicines must agree to comply with certain parts of Medicines Australia Code when they sign the TGA letter of marketing approval.

I suggest that this matter be discussed with DoHA witnesses when they appear later this morning. They could also be asked why they believe yet another Codes of Conduct Advisory Group, dominated by self-interested stakeholders, is likely to achieve a level playing field from nine disparate therapeutic industry associations, how can it address the problem of non-members and how it will achieve the desired single, public repository of transfers of value from all therapeutic goods companies to health professionals?

I welcome questions on these matters.

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Postscript: The Federal Treasurer recently announced plans to cap self-education tax deductions at $2000 from July 2014 which could see doctors paying thousands in tax for their continuing education (or being driven further into the hands of the pharmaceutical industry).

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Petition to ACCC on Medicines Australia Code Authorisation

Petition published by Ken Harvey on Nov 07, 2012 — 451 Signatures

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Target: Australian Competition and Consumer Commission (ACCC)

Region: Australia

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Petition Background (Preamble):

While collaborations between industry and health professionals are desirable, widespread financial ties bring significant risks of undue influence on professional judgements, potentially jeopardizing the integrity of medical research, education, clinical practice and public trust in medicine, according to a landmark 2009 report from the National Academies of Science in the United States.

This report made a number of important recommendations including:

> Recommendation 3.4 The U.S. Congress should create a national program that requires pharmaceutical, medical device, and biotechnology companies and their foundations to publicly report payments to physicians and other prescribers, biomedical researchers, health care institutions, professional societies, patient advocacy and disease-specific groups, providers of continuing medical education, and foundations created by any of these entities. Until the Congress acts, companies should voluntarily adopt such reporting.

The resulting Physicians Payment Sunshine Act has set a new benchmark in transparency, mandating full public disclosure of these relationships in the United States with data collection commencing January 1, 2013.

Meanwhile, several multinational pharmaceutical companies have already been disclosing the dollar amounts they pay to health professionals.

http://www.gopetition.com/petitions/petition-to-accc-on-medicines-australia-code-authorisat.html

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Petition:

We the undersigned believe comprehensive disclosure similar to the U.S. Physicians Payment Sunshine Act is required in Australia.

We commend the Australian Competition and Consumer Commission (ACCC) for its ground-breaking 2007 requirement for disclosure of industry-sponsored educational events, but respectfully urge the ACCC to require full disclosure of all benefits from industry to health professionals, including but not limited to hospitality, speaking fees, consultancies, sponsored education, accommodation and travel.

This action was requested in many submissions sent to Medicines Australia about their Code review, in the report of the consumer workshops held, and in submissions made to the ACCC. However, Medicines Australia was successful in convincing the ACCC not to make full disclosure a "condition" of authorising the Code by setting up a Medicines Australia Transparency Working Party to further consider these issues.

We note that the ACCC is holding a pre-decision conference on 12 November 2012 in relation to its draft determination proposing to grant authorisation to the 17th Edition of Medicines Australia Code of Conduct for the next three years.

We ask the ACCC to make the following changes to its draft determination.

1. Reduce the period of authorization of the Code of Conduct to one year (2013).
2. Request Medicines Australia to submit a revised Code to include arrangements covering transparency of relationships between the pharmaceutical industry and individual health professionals for authorization at the end of 2013.
3. Request Medicines Australia to increase the number of informed critics of their current Code regarding transparency matters on the transparency working group.

We also call on Australia's elected representatives to consider introducing legislation similar to the Sunshine Act, to bring Australia into line with international benchmarks on transparency in healthcare.

Sign the petition

The Petition to ACCC on Medicines Australia Code Authorisation petition to Australian Competition and Consumer Commission (ACCC) was written by Ken Harvey and is in the category Health at GoPetition. Contact author here. Petition tags: accc, medicines australia, physicians payment sunshine act

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Pharmaceutical companies spends $30m wining, dining doctors

BY:NATASHA BITA, CONSUMER EDITOR | The Australian | August 10, 2012

http://www.theaustralian.com.au/news/health-science/pharmaceutical-companies-spends-30m-wining-dining-doctors/story-e6frg8y6-1226447086707

DRUG companies are spending $30 million a year wining and dining doctors and healthcare workers, and are subsidising nurse wages in some GP clinics.

Australia's $22 billion pharmaceutical industry is sponsoring nurses to work free in doctors' surgeries as "diabetes educators", and to show asthmatics how to use their inhalers.

Medicines Australia chief executive Brendan Shaw said yesterday the industry's code of conduct allowed "support for medical practice activities".

He said companies often recruited and trained the nurses, who then worked for free or for subsidised wages at GP clinics.

"There cannot be any interference with the independence of the doctors' care of their patients," he said. "There must not be any incentive to doctors to prescribe a company's product."

Medicines Australia revealed yesterday that its members spent $29.4m on "hospitality" for medical professionals in the year to March. The industry code bans them from providing "entertainment" for healthcare workers but allows hospitality at "educational events".

A register of events sponsored by 37 companies, at a total cost of $23.7m in the six months to March, shows that half the money was spent on hospitality for 385,871 health professionals.

Sanofi-Aventis spent $54,348 on a weekend training session for 80 neurologists at the Rendevous Hotel in Melbourne - including $24,683 on flights, $15,480 on hotel rooms and $13,184 on meals.

Pfizer spent $192,924 hosting 104 GPs for a weekend meeting at the five-star Sofitel Hotel on the Gold Coast.

A one-day meeting at the luxurious Grand Hyatt Hotel in Melbourne for 113 anaesthetists and pain and rehabilitation specialists cost $265,945 - including $101,719 on hospitality.

And Pfizer's one-day meeting of 221 GPs at the Sheraton on the Park in Sydney cost $614,962 - including $56,736 for hotel rooms and $48,316 for flights.

Drug companies also paid hospitals and clinics to organise their own training sessions: St Andrew's War Memorial Hospital received $7272 from Pfizer to send 100 GPs to the Hyatt Sanctuary Cove luxury resort on the Gold Coast for a meeting on "mental health presentation".

And nine oncologists drank $560 worth of beverages at a meeting lasting 90 minutes at the Iceworks Lounge in Brisbane, paid for by Sanofi-Aventis.

Australian Medical Association president Steve Hambleton said yesterday doctors should be cynical about accepting hospitality or nursing staff from drug companies.

"I've heard of nurses who will come along to your practice to find patients with diabetes, with a view to try to see if there is optimal therapy," he said. "I haven't used them, for the express purpose that their ultimate aim in life is to get the dose of whatever is prescribed (increased). That is a conflict of interest."

Dr Hambleton said educational sessions were a "marketing exercise" for drug companies.