Dr Peter J. Gordon
Sunday, 15 March 2015

To: **Sigrid Robinson**
Assistant Clerk
Public Petitions Committee
The Scottish Parliament

Dear Ms Robinson
Scottish Parliament Public Petition PE1493 on a Sunshine Act for Scotland

Thank you for informing me that my petition is to be considered by the Public Petitions Committee at its meeting on Tuesday 31st March 2015.

You suggested that I might like to make a written submission for the meeting of the Committee informing me that this would be published online with the other evidence that the Committee have gathered for **Petition PE1493.** Since my last submission to the committee I have received a letter from the Scottish Government dated 24th February 2015 [included below in the annexe] which asks my views as petitioner on a number of specific matters. With the permission of Gordon Clark, Scottish Government, I thought it would be sensible to offer my views in a single letter copied to all.

My preference has always been to keep letters to the committee to one page, but unfortunately on this occasion, given the number of questions asked by the Scottish Government, this letter requires to be longer. I will begin this letter with a current summary of my position as petitioner for a **Sunshine Act** and then, in the second half of my letter, do my best to answer the questions asked by the Scottish Government.

My summary position as petitioner for a Sunshine Act:
Gathering evidence and necessary research to support this petition has led me to conclude that the pharmaceutical industry has had significant control within Scotland's health sector and that this has been met with very little opposition or even analysis.

> *"HDL (2003) 62 made it clear that all Health Boards should establish a register of interests for all NHS employees and primary care contractors. In addition, healthcare professionals will continue to be bound by the codes and standards of their regulators and professions. Consequently, we have no plans to put in place a sunshine clause at the present time."*
>
> Alex Neil, Cabinet Minister for Health & Wellbeing, 31st October 2013,

The Scottish Government has since confirmed that across Scotland its own guidance, **HDL 62**, has been widely ignored.

> *"In moving forward, Scottish Government would wish to seek wider views from the people of Scotland, particularly patients and their families, on what they think a robust, transparent and proportionate response to this issue should look like in 2015 and beyond. We feel it is important to do this in the context of the existing legislation, the role of professional and regulatory bodies and the significant progress towards voluntary registers by the pharmaceutical industry."*
>
> Scottish Government letter to the Petitioner, ref 2014/36604, 2nd February 2015

The Scottish Government position states that we should consider *"existing legislation"*.

The Scottish Government are of the view that we have two safeguards: (1) professional bodies and (2) "*the significant progress towards voluntary registers by the pharmaceutical industry."*

Considering these in turn:

Firstly, regarding professional and regulatory bodies:
Niall Dickson, the Chief Executive Officer for the **General Medical Council (GMC)**, the professional regulatory body for doctors, has recently stated that *"Parliament has not given us powers"*. This was the official GMC response to Fiona Godlee[1], Editor in Chief of the BMJ who stated in her recent BMJ editorial that *"the profession must take the lead to protect patients and maintain public trust. The GMC should act, and a public register of UK doctors' financial interests is long overdue."*

I have been in communication with the **Royal College of Psychiatrists**, the additional "regulatory body" of which I am a member. This recent communication, with the Royal College of Psychiatrists, relevant to this petition, can be read here http://wp.me/p3fTIB-1zi . In summary the Royal College of Psychiatrists guidance again refers to local registers, as in HDL 62, which we know are not being maintained.

Secondly, the *"significant progress towards voluntary registers by the pharmaceutical industry."* (Scot Gov statement)
It is the case that the **Association of British Pharmaceutical Industries (ABPI)** have led on setting up what they have termed as a "Central Platform". From 2016, this platform will gather individual payments and record these in an open, central, searchable database. However, it is the case that any healthcare professional **can opt-out of any disclosure of any financial payments** made to them on this platform.

The Scottish Government, in a letter to me dated 24th February 2015, [see annexe] asked my views as petitioner on **nine separate points**. What follows are my responses as given under each Scottish Government question:

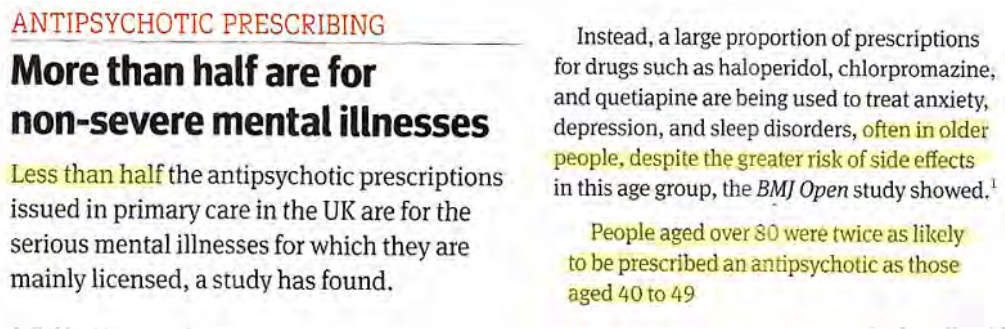
1. **Is your primary concern around ensuring appropriate prescribing?**
   This is my primary concern.

   This is a longstanding concern based on the ethical principle ***primum non nocere*** *"above all first do no harm".* My view, as petitioner, is that appropriate prescribing must try to achieve maximum benefit and minimum harm: a ratio crucial at both individual and population level. Evidence has repeatedly revealed that harm and/or

[1] Godlee, F. **Medical corruption in the UK**. 29 Jan 2015 http://www.bmj.com/content/350/bmj.h506

risks associated with prescribing may emerge *only after* the pharmaceutical industry has made its money. My view, as petitioner, is that "appropriate prescribing" in Scotland should follow evidence-based science that is free from financial conflicts of interest. Prescribing should be based upon scientific objectivity alone. Prescribing should not be determined by market forces.

One of my original motivations for raising this petition for a Sunshine Act was an appreciation that pharmaceutical companies use paid speakers, consultants and researchers to promote the **off-label use of drugs** in Scotland**:**



ANTIPSYCHOTIC PRESCRIBING

More than half are for non-severe mental illnesses

Less than half the antipsychotic prescriptions issued in primary care in the UK are for the serious mental illnesses for which they are mainly licensed, a study has found.

Instead, a large proportion of prescriptions for drugs such as haloperidol, chlorpromazine, and quetiapine are being used to treat anxiety, depression, and sleep disorders, often in older people, despite the greater risk of side effects in this age group, the *BMJ Open* study showed.[1]

People aged over 80 were twice as likely to be prescribed an antipsychotic as those aged 40 to 49

This is just one example of evidence that this happening. I covered a range of other examples in my original submission to the committee:
http://www.scottish.parliament.uk/parliamentarybusiness/28862.aspx?r=8896&mode=pdf

2. **Who should have responsibility for keeping and updating information on payments (including payments in kind) received?**

   I would like to see an *independent body* that is set up to maintain a central, single, open, searchable register that is updated on a planned and scheduled basis and which is tied to professional accountability and governance. Such a register should include not just doctors, but pharmacists, academics, nurses, allied health professionals and indeed advisors to charities.

3. **What should happen in the event of non-compliance?**

   It is my view that any system that is developed to replace **HDL 62** must include meaningful sanctions to be used in the event of non-compliance. There is always the potential for litigation following any harms caused.

   From a practical point of view, enforcement would be likely to involve a number of different approaches. Failure to follow legislation may involve regulatory bodies. For example, in the case of doctors this would be with the **General Medical Council**.

> *"All doctors have yearly appraisals that must include domains of probity and maintaining trust. Commercial interests, payments from drug and device manufacturers and other funding as well as adequate indemnity has to be declared. Not declaring such fiduciary inducements will be a probity issue and may lead to a failure to revalidate."*
>
> S. Musheer Hussain, Lead Appraiser and Associate Medical Director for Professional Governance at NHS Tayside, 31 January 2015:

"Non compliance" also has a dimension that may be beyond the employed individual. At least two NHS Boards in Scotland, NHS Lothian and NHS Forth Valley, have confirmed that they have zero budget to **support** medical education. The financial support of this education is thus solely through commercial arrangements. The details of this are covered here http://wp.me/p3fTIB-1n

4. **Which professions and groups should be covered?**

This should include not just doctors (both at primary and secondary care), but also pharmacists, nurses, academics, allied health professionals and indeed advisors to charities. It should also apply to any commissioners of healthcare services in Scotland including all those involved in improvement work.

As petitioner, part of my research confirmed in November 2013 that 44 separate **Scottish Intercollegiate Guidelines (SIGN)** guidelines had no records of declarations of interest. This concerns me greatly as does the limited governance of the experts involved in the **Scottish Medicines Consortium.**

> *"Those of us who thought we had seen an end to guidelines drawn up among vested interests behind closed doors will be disappointed…"*
>
> How Guidelines can fail us, The BMJ, 6 September 2014:

5. **Who/what should be covered by the terms 'industry and commerce'?**

The approach taken in France to legislation appears to be a reasonable model. The USA has also introduced Sunshine legislation. As petitioner, I would suggest that there is much to be learned from the approaches taken in France and the USA.

"Industry and commerce" might include: the pharmaceutical industry; device and implement manufacturers; and commercial enterprises involved in diagnostics, nutritional supplements and digital technologies. As petitioner, I would also suggest that academics, patient groups and charities are included. In France, disclosure of financial support to patient organisations has been a legal obligation since 2009.

6. **Should there be a threshold for providing information on payments (including payments in kind) and if so what should that be?**

I think this a matter that should be open to consultation. I would suggest a similar framework to that used by this voluntary database:
http://www.whopaysthisdoctor.org/

7. **If registers of payments (including payments in kind) were established what should the status of these registers be?**

A national register requires legislation to be put in place to make it meaningful, robust and properly transparent. Timescales for submissions would be clearly defined. This register should be open to all with a link placed obviously on each NHS Board homepage.

All medical educational conferences held in Scotland should have a homepage link to this single, open, searchable database. Thus duplication of recording would no longer be an issue.


BMJ

Published 11 June 2014

WHO PAYS THIS DOCTOR?

Who pays for this conference? It's time patients and doctors knew

8. Do you have experience of concerns raised by patients about these issues that you can share?

My experience of patients is that they trust NHS staff to be acting solely in their best interests. Sadly evidence demonstrates that this is not the case:

> *"I spent months researching this and building up a relationship of trust amongst several doctors. Generally, however, only retired or soon-to-be retired doctors were prepared to talk to me. Clearly, many are afraid of ruining their career. Many know about this behaviour yet say nothing. I had many reactions to the article, both from the public and from doctors. Readers said 'finally someone is looking at this', but doctors reacted differently. Most defended their occupation, did not acknowledge the problem, or felt personally attacked. I had to answer them that the examples I had written about were in my opinion not isolated cases, rather were just the tip of the iceberg."*

Otto Hostettler, New Swiss Guidelines aim to curb Big Pharma's Influence, the Lancet, Feb 2013

9. Generally, what is your view on what a robust, transparent and proportionate response would look like fit for 2015 and beyond?

I hope that I have given an indication of my perspective on this. I am most grateful to the Scottish Government for seeking my views as petitioner. I wondered if it might be helpful to conclude this letter with a range of views of some others who have also considered this area:


NO HOLDS BARRED **Margaret McCartney**

Who pays this doctor? It's time patients knew

If my MP wanted to build a motorway, it would be reasonable for constituents to know whether he had shares in the construction company appointed, or indeed in the land that had now become valuable. And it's easy to find out: all UK MPs have to make declarations on the publicly available register of members' interests.[1]

But if I am a patient, I am unfairly ignorant. I don't know whether my doctor is a chosen key opinion leader, paid by a drug company to increase prescribing of a drug. When my doctor recommends an intervention,

What would you be embarrassed by if someone else pointed it out first?

being recommended. Yet we know that even small gifts create changes in doctors' behaviour.[2]

Such ignorance extends much further than drug companies. If a doctor recommends a food or food supplement in an interview to a newspaper, we should surely also know if that doctor is acting as a paid public relations representative of the brand. Similarly, it's only fair that readers should know if a doctor who recommends an intervention also owns its patent. If a general practitioner on a commissioning board advocates a

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Dr McCartney, General practitioner in Glasgow, BMJ Columnist, Broadcaster and Medical Author

"We welcome the Association of the British Pharmaceutical Industry's move to publish public statements of fees paid to individual doctors for their time in promoting or marketing products, as it has been shown widely that payments directly influence prescribing habits. However, we feel that this does not go far enough."

Dr Emily M Ward, Doctor in training, Dundee, 29 July 2014

"Would you be comfortable declaring your competing interests on a central database?"

Yes: 417 **(81%)**
No: 98 **(19%)**

BMJ Poll 2014

Closing statement:
When politicians are held to higher standards than doctors, it is my view that it is time for tighter regulation of conflicts of interest in healthcare in Scotland.

Scottish Government guidance, **HDL 62,** has relied on self regulation and this clearly has not worked.

Moves by the drug industry are welcome but will encounter the same issues as **HDL 62**.

As a scientist as well as a student of humanities, my view is that Scotland's wellbeing, reputation and worldwide standing would all benefit from taking a leading approach in this area.

I hope this update is of some assistance to the Committee ahead of the 31st March 2015.

Yours sincerely,

Full details of all evidence I have collected for this petition, including my writings, publications and films, can be accessed from this one page: http://wp.me/P3fTIB-1zA

CC. **Gordon Clark,** The Scottish Government, Healthcare Quality and Strategy Directorate, Pharmacy and Medicines Division.

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The Scottish Government
Riaghaltas na h-Alba

LEGACY 2014
XX COMMONWEALTH GAMES
SCOTLAND

Dr Peter Gordon

24 February 2015

Dear Dr Gordon,

Thank you for your e-mail of 2 February in response to my letter of the same date.

We welcome your support for wider public engagement on the issues raised by your petition. It might be helpful if I confirm that it is not our intention that this will be limited to medical education. Your petition was broad in scope and covered all payments (including payments in kind) to NHSScotland healthcare workers from industry and commerce. We would therefore intend, subject to any further comments or suggestions from you on scope, that public engagement is on the broader issues raised by your petition.

In my letters of 5 August and 2 February I mentioned that we would be happy to hear your views on who might be covered by "healthcare workers" (we are aware from your evidence to the Committee that you did not think this would include pharmacists at this stage and possibly not GPs) and your views on where best practice exists. In our response to the Public Petitions Committee of 25 January we highlighted some of the other areas where there is no consensus in the views given to the Committee. We would like to understand your position on these points.

Specifically, we would welcome your views on the following points:

- Is your primary concern around ensuring appropriate prescribing?
- Who should have responsibility for keeping and updating information on payments (including payments in kind) received?
- What should happen in the event of non-compliance?
- Which professions and groups should be covered?
- Who/what should be covered by the terms 'industry and commerce'?
- Should there be a threshold for providing information on payments (including payments in kind) and if so what should that be?
- If registers of payments (including payments in kind) were established what should the status of these registers be?
- Do you have experience of concerns raised by patients about these issues that you can share?
- Generally, what is your view on what a robust, transparent and proportionate response would look like fit for 2015 and beyond?

I look forward to hearing from you.

Yours sincerely
GORDON CLARK