Submission No 5

INQUIRY INTO OFF-PROTOCOL PRESCRIBING OF CHEMOTHERAPY IN NSW

Name: Dr Leong-Fook Ng

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4 Oct 2016

Legislative Council Select Committee on off-protocol prescribing of chemotherapy in NSW
Parliament of NSW,
Sydney 2000

Dear Honorable Ministers,

Inquiry into off-protocol prescribing of chemotherapy in New South Wales

I thank the Committee for allowing me this submission.

With pleasure and chilling concern, I wish to submit as an AHPRA registered specialist medical oncologist and an ex employee of NSW Health.

Yours sincerely,

Leong-Fook Ng
Registered Specialist Medical Practitioner in Medical Oncology (Malaysia, UK and Australia)

NSW PARLIAMENT

An Inquiry into off-protocol prescribing of chemotherapy in New South Wales

A Personal Submission

by

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Acknowledgment: This is humbly submitted from the land of the oppressed Kaurna peoples, respecting their Ancestors, Elders, the culture and heritage

Co-submitted as a Protected Disclosure under Commonwealth Law as 'correspondence' to the Community Affairs Committee of the Australian Senate (Upper House) inquiring "Medical Complaints in Australia"

and to the

COAG Health Ministers' Council Meeting of 7 Oct 2016

Disclosure:

In 1992, I was Dr Grygiel's trainee Registrar at the Department of Medical Oncology, Royal Prince Alfred Hospital, Camperdown, NSW. I have also published a laboratory research letter in the Medical Journal of Australia with him the year before where we cross discussed a patient with a rare tumour and some novel laboratory based research whilst at the Department of Cancer Medicine, University of Sydney. From 2006, I have been a previous victim of NSW Health's unfair mendacity – which relied on falsities created elsewhere by other parties. I am a Foundation Member of the Health Professionals Australia Reform Association, and Subcommittee Member of the Honest Peer Review Group. I have previously had the privilege of working as a General Medical Oncologist in SE Asia and the Kingdom of Saudi Arabia where Head and Neck tumours are "endemic". I do not and will not accept any remuneration or benefits in kind by making this submission – except for assisting to seek justice for Dr Grygiel, others and myself. I write without fear or favour with additionally, an applied-for Commonwealth protected disclosure.

Terms of reference (ToR)

1. That a select committee be established to inquire into and report on off-protocol prescribing of chemotherapy in NSW including at St Vincent's Hospital, St George Hospital, Sutherland Hospital, Macquarie University Hospital and clinics at Orange and Bathurst, and in particular:

(a) the efficacy of electronic prescribing systems, and their capacity to stop or limit off-protocol prescribing of chemotherapy,

(b) the value of a potential new patient information sheet on dose adjustment for patients and caregivers information,

(c) the process and systems around informed consent for all medical interventions, including chemotherapy,

(d) the capacity of the NSW Health system to have all notifiable cancer patients in New South Wales overseen by a Multidisciplinary Cancer Care Teams, and if this may prevent off-protocol prescribing,

(e) St Vincent's Hospital capability to comply with relevant NSW Health Policy Directives and Guidelines, particularly Open Disclosure Policy (PD2014_028) and Incident Management Policy (PD2014_004),

(f) the NSW Health Code of Conduct and specific programmes within NSW Health and St Vincent's Hospital, in relation to staff raising concerns about the practice of clinicians, and other breaches of the Code of Conduct.

Introduction – a historical (unresolved) case

In May 2006, I was appointed as a Level 1 Staff Specialist in Oncology at the Tweed Hospital in Northern NSW. I had just completed a repeat peer review practice which I had been unhappy about as this was based on a false set of reviews on me, accompanied by bullying by both the Ballarat Health Services (BHS) and by the Royal Australasian College of Physicians (RACP) culminating in a confidential deed of release. The details are obtainable elsewhere in the next paragraph.

Whilst 'gagged' I was unable disclose to my past Australian employers the whole truth about what BHS and their collaborators had done to me. I honoured this till Dec 2015 after I had obtained a Protected Disclosure by writing to the Victorian Ombudsman [1i, 1ii , 2]

When I commenced clinical practice at the Tweed, after 2 weeks, Medicare investigators incessantly interrupted my clinics, claiming that I was 'defrauding' the Commonwealth government. I requested them to photocopy what I had purportedly sent to them and send these to me in a sealed envelope. When I received this, I opened the envelope in front of another consultant colleague and we both initialled and dated all the documents.

Immediately, I consulted the Australian Medical Association NSW which instigated me to discuss this with the Independent Commission Against Corruption (ICAC). I also discovered that the Australian Salaried Medical Officers Federation in NSW was a different entity, so I joined them. My discussion with ICAC led to a protected disclosure and despite my informing the CEO of the North Coast Area Health Service (as it was then called) at a later date, he ignored it. The finer details are set out in another NSW Parliamentary Inquiry [3] and also a confidential submission and confidential witness interview with Mr Peter Garling, SC, who held the Garling Inquiry in 2008 [4].

To this day, and despite voluminous inculpatory evidence, ICAC has repeatedly dismissed my complaint as have other responsible 'authorities'. I give consent for these to be accessed by the Committee and higher authorities.

In this submission, I shall present evidence (following the ToR, attached confidentially because of privacy reasons) of my intentional use of palliative intent chemotherapy on a patient with metastatic colorectal cancer (mCRC) in 2006, where the dose was altered to the original (higher) dose by a third party, logging into the clinical electronic notes 24 hours before I was stood down by the CEO.

This was discovered surreptitiously during my self-audit in preparation for my defence during an internal investigative interview. This was co-sighted and signed off by a Justice of Peace whom I located in the Medical Records Department of The Tweed Hospital, when I was doing the audit. This was also raised with Ms , the Lead Investigator but she ignored it.

Despite my frequent written protests about the false risk rating, this was sustained by the then CEO of the North Coast Area Health Service, Mr C Crawford – and compulsorily reported to the NSW Medical Board.

After the investigative interview, the flawed report also described the nurses, led by the Clinical Nurse Consultant, , RN, 'prescribing' (and altering) chemotherapy. Both investigators, Ms and Professor (Co-investigator) described this practice as 'unacceptable' [5i]

The effort was led by the same nurse who filed false allegations about me during the period when the then Manager, Ms (presently CEO of Private Hospital, had ordered summary disciplinary action against me by the Director of Medical Services (19 Jul 2006). There were no written warnings about 'complaints'. Independent reports of her mendacious conduct are available from other RNs who have been 'ejected' (or bullied) from the Tweed Hospital as recent as 2015.

In the case of 'substantiated' complaints about myself, a patient and the partner of a then deceased patient offered NSW Statutory declarations that they had never complained about me and that what was concluded in the internal Investigative Report was false[5ii] .

In 2015, I made a Fair Work Application under Federal Law. This application was shared with the Press and reported [5iii]

A week later, I withdrew the application after a private conversation with the Deputy President of the FWC in Sydney, NSW because the requirement to remit an application to the Federal Court jurisdiction did not require a FWC certificate of termination as per erroneous information then implied on the FWC website.

Details of the Current Case
ToR 1a, 1b, 1c, 1d, 1e, 1f

As regards to Professor J Grygiel [6i], (subsequently reffered to as Dr Grygiel) a 'final report' by 'external investigators' stated that there was/were

i. no record of the meeting of the Executive with Dr Grygiel, neither was it stated what was discussed
ii. no record of whom or which persons raising concerns of 'flat dose' chemotherapy and whether there was clarification from Dr Grygiel what proportion of the patients were treated with palliative intent and who had multiple co-morbitities or their clinical staging of the disease
iii. no record of whom the 'internal investigators' were and their qualifications
iv. no detailed record of the nature of the 'Internal Report' and who crafted it
v. no record of which how many cycles of chemo-irradiation therapy were used for each patient evaluated for 'flat' doses
vi. a record of the request for inculpatory evidence from the hospital without a record of any opportunity to Dr Grygiel to provide exculpatory evidence (which is by convention but, in my view, unnecessary)
vii. conflicting accounts of implementing EviQ or no discussion
viii. no record of Dr Grygiel being given access to notes for 'personal audit'
ix. signs of prematurely informing patients and the media of this 'incident' and swiftly labelling it as an 'error' on Dr Grygiel's part
x. no record of what the clinical notes recording system was before 'Mosaic' was implemented and which data entry methods were used and by whom e.g. how many data entry clerks or persons
xi. the demographics of the patients without the staging of disease and intents of therapy
xii. past cases were purportedly entered into "Mosaic" which was then relied on for 'analyses', No data was available on 'exclusions' or non entry or the reliability of the data entry.
xiii. records of other single studies showing an intended benefit of 'personalised chemotherapy' were selected rather than that of meta-anlayses – no attempts were made to prevent bias

xiv. errors in statements like in point 30 “that the dose of chemotherapy is personalised” – they were not – hence this inquiry.

xv. no measureable differences in overall survival of a cohort of patients treated with cisplatin versus carboplatin (as it was too early) but did not clearly state how many patients were ‘frail’ or who were treated with a ‘curative intent’. The Inquiry confirms this in item 60.

xvi. misleading conduct in speculation that patients who received a lower dose of a radiosensitiser as part of chemoirradiatioin protocol “would suffer from a higher chance of recurrence”. No such data exists in the literature or at St Vincent’s – at least for head and neck tumours. The all cause mortality appears not affected or it would have been detected and published elsewhere from other centres.

xvii. that Dr Grygiel’s “off-protocol practice” was not ‘overseen by a HREC’.

Additionally,

xviii. Item 30 states the opposite for chemo-irradiation when there are multiple co-morbidities. The chemo-irradiation dose is usually fixed by convention unless the intent of therapy is curative (low number of patients).

xix. item 60 claims that only “2 out of 103” patients treated were treated with a ‘palliative intent’. This needs to be validated as it may be in error or that unrealistic clinical treatment intents had been proposed by Dr Grygiel’s colleagues in the “Multidisciplinary Team” or other colleagues i.e. non clinical bureaucrats. The majority of Head and Neck cancer patients being treated with chemo-irradiation in most institutions globally are those with palliative intent therapy. Approximately 60% of all squamous cell (SCC) patients have Stage III or IV disease*

xx. Item 63 criticises that there is no ‘research data’ available and yet admits that there is “no perfect way of dosing platinum-based chemotherapy”

xxi. Item 68 retrospectively criticises Dr Grygiel for not ‘contextualising this decision to use carboplatin on a flat dose’

xxii. Items 70 and 71 discuss something completely different: that of chemotherapy and not chemo-irradiation.

xxiii. Item 74 is completely out of context for a matter which is common day practice outside clinical trials

xxiv. Item 76 offers some solutions for something which is good clinical judgment/practice rather than for something “wrong”.

xxv. Item 79 discusses and comments on “failures” of the internal investigation

xxvi. Item 80 accepts that content experts in medical and radiation oncologist was not sought

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** Cleveland Clinic Center for Continuing Education 2010*
http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/hematology-oncology/head-and-neck-cancer/

xxvii. Item 82 further elaborates on the scope of Dr Grygiel's prescribing practices in a negative and non neutral way.

xxviii. Item 84 confidently reassures the public that 'no patients appeared to have suffered any negative impact as a result of the dosage issue'

Comment: An irregularity documented in any one or a combination of these above elements in a review can be termed serious error and/or a lack of natural justice and/or due process – i.e. a Sham Peer Review **

i. The first goal in clinical patient care is '*primum non nocere'* – "first do no harm" in the treatment of any patient. The WHO Staging of Head and Neck cancers *** show that Stage II upwards is classified as 'locally advanced'. Treatment intents can be anywhere from 'curative' to 'aggressive palliative' to 'palliative' depending on co-morbidities, which are frequent: one is dealing with an extremely heterogenous group, most of which are 'locally advanced' with no good treatment data for specific groups. Australian data are sparse and anecdotal.

ii. HRECs are formed to explore research and ethics and not "to supervise" or police clinicians on off-protocol patients

iii. There is no need to contextualise the use of carboplatin for patients who have multiple-comorbidities. It is a matter of prudent clinical judgment and not protocol. This is widely accepted in non trial (off protocol) clinical practice globally, not only in oncology but all of medicine.

iv. None of the NSW Cancer Institute 'expert' panel including the Chief Cancer Officer of NSW, had medical or radiation oncology qualifications

v. Item 84 elaborates no tangible short term outcomes: this means the Jury is out and Dr Grygiel cannot be proclaimed guilty at this time – as his practice has not harmed any patient. The basic principles of the rule of law have been severely maligned [6ii].

vi. As this investigation is, in my view, fundamentally flawed in both natural justice and in scientific medical content, no comments will be made on the Recommendations of the Final Report

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*** Chalifoux, R. So what is a sham peer review? Medscape Web Article 2005.*
http://www.medscape.com/viewarticle/515862
Westhues, K. Sham Peer Review in Medicine http://www.kwesthues.com/mob-sham-htm
Huntoon, L. 2016 Sham Peer Review: Disaster Preparedness and Defense. JPANDS 16; 2-6
http://www jpands.org/vol16no1/huntoon.pdf
**** WHO Overview on Staging of Head & Neck Cancer*
http://emedicine.medscape.com/article/2007181-overview

Similarities to my case:

On 15 Aug 2006, I was stood down from my position as Level 1 Staff Specialist. I never performed any work that day. I was to attend a scheduled internal investigative interview at a later date, with a timeline for report back etc. I was given access to the Medical Records office to prepare for my interview. During electronic audit I discovered an entry of an escalated dose of chemotherapy [6iii] on a patient I had treated and in addition, other unauthorised entries. I never inserted this entry on 14 Aug 2006 – after having made a clinical decision to do dose reduction on 31 July 2006.

I also spotted "entries" by the other oncologist, the Director of Oncology of the Tweed Hospital at times where he was absent from the country, with no remote access to the server and notes. If required, I have audited details and dates of all allegedly unlawful logins.

EviQ was in its infancy and not implemented. There were no protocols in place for the full range of tumours. I was 'criticised' during a complaint for 'not adhering to protocols' for which there were none. The missing protocols were in the head of the then Clinical Nurse Consultant (CNC).

Surely, the public must be 'protected'.

There are four (or more) issues here

1. The third party had made unlawful multiple entries in my name. [The same could have been said of "instructed" data clerks at St Vincent's with the introduction of Mosaic in Dr Grygiel's case]

2. Only one party knew the login password for the notes: the CNC who created it and disclosed it to me. She is , RN - or her delegate(s). [reading the commentary suggests that there were initially no electronic notes]

3. My said patient could have perished and the protocol-adherent alteration led-outcome ascribed to myself; with the allegation being 'clinical incompetence' in not reducing it. One does not know what happened subsequently.

4. I was 'dismissed' by NSW Health but had to apply (not on my decision but at the strong insistence of my initial lawyer) to the Industrial Relations Commission for a determination[6iii]. I was 'not dismissed' but "had dismissed" myself - in an awkward opaque and transforming situation (allegedly misled by NSW Health and mismanaged by my initial lawyer) and, in my view, having to deal with an evolving scenario, a subsequently biased determination by the Deputy President [6iv]. A final appeal before a Full Bench was settled out of court with each side disbursing its own costs with no public record of this. Further falsities

subsequently discovered remain uncorrected. The cost of seeking justice had been financially high to me and I continue to pursue this.

General Comment:

1. The late CJ Gibbs of the High Court of Australia (HCA) gave a precedent judgment that 'the government has no lawful authority in interfering with a doctor-patient relationship" [7i] According to M Lemming, QC, (presently a NSW Supreme Court Judge) in "Resolving conflicts in Law" [7ii], there is a hierarchy of courts – in this case of Dr Grygiel, a HCA precedent prevails over the National Law [8] (and its antecedent statutes) which NSW Health fully relies on together with a domestic law on co-regulation with the Health Care Complaints Commission.

2. EviQ [9] , though run by the NSW Cancer Institute are guidelines set up by a private consortium of volunteers who may be 'experts' or who purport to be 'experts'. I had previously considered being a 'volunteer' writer but then decided against this. This database cannot be the "be all and end all" of all medical oncology practice though many Australian oncology centres regard it as 'gospel'. Much better international cancer protocols exist - like the ESMO (Europe), ASCO (USA), NICE (England & Wales), SIGN (Scotland) and NCCN (USA) Guidelines from which EviQ is generally 'developed from'. Some discuss a 'minimum standard' in order to reduce rigidity in adherence. There are no data that this is harmful. D Dahm, an accountant and qualified medical practice manager, has recently proposed that international standards[10] as opposed to 'local standards' be adopted, to reduce poor outcomes. Examples are the historical positive reforms of the insurance and civil aviation industries.

3. An individual clinician's dealing with his or her patients is based on mutual trust and the overall medical conditions of the patients. This relationship is private, mysterious and sacrosanct and is best between that doctor and his/her patient with no or minimal third party interference. I do not believe that any normal reasonable medical practitioner will betray this trust or not to have the best interests of his or her patients at heart. The patients Dr Grygiel treated were generally over 60 years of age and had good relationships with him. The current debacle on falsities has sadly turned most of them and the authorities against him and his practice. The point about my isolated case was not about the reduced dose but about a third party, unlawfully altering the chemotherapy dosage in a NSW Health public hospital using vulnerable computer systems in an alleged criminal way. This technology challenge was also independently pointed out by Mr Garling, SC, during his visit to the Tweed Hospital.

4. Most of Head & Neck patients treated in oncology units where systemic and local non surgical therapy (e.g. irradiation) are already in advanced disease stage and are being treated palliatively. The greatest

experience comes from India, SE Asia and the Middle East – which I believe none of the Australian "arm-chair" experts had experience from. Indeed a local Australian private oncologist wrote a well balanced and well research piece in The Conversation[11]

5. Many locally advanced patients are treated with either chemotherapy (palliative intent) alone or with chemo-irradiation where chemotherapy is used only as a radio-sensitiser, not as a cytotoxic agent *per se.* The essential questions to ask are i. how many patients were treated with a palliative intent with carboplatin as a *radiosensitiser* ii. how many of these had multiple comorbidities and what they were

6. The group investigating Dr Grygiel and other 'experts' do not come with additional expertise in Head and Neck Medical and Radiation Oncology. None of this panel[12] who issued the final report had any qualifications, local or overseas, in the clinical practice of medical or radiation oncology let alone having experience in Asia, India or the Middle East where the disease is endemic. It appears the Australian cases are a heterogenous group and low in number - of mainly squamous cell carcinomas termed 'aerodigestive tumours' by our US colleagues and associated with past chronic smoking and/or alcohol intake. This has to be validated.

7. A similar resource depleting case has already happened with the widely publicised Queensland Health Vega Vega case of 20l5[13]

8. To date, my matter in NSW Health's mendacity remains unresolved and this appears another emboldened attempt to attack another practitioner for whatever reason. Both the Premier (2015) and the Health Minister (2016) have been put on notice to attempt to settle it amicably.

9. In the meantime other possible sham peer reviews[14,15,16] have emerged (noting that sham peer reviews can be used to attack or protect[17]). We have a national systemic problem.

10. In my view, a not improbable alternative hypothesis is that this *fracas* had been used to distract and conceal Medicare irregularities by the establishment – e.g. double dipping and cost shifting to the patients and the Commonwealth. The field of multidisciplinary oncology has the potential to generate a huge amount of non evidence-based service turnover in developed countries and many irregular or "pretend" players mingle with real and ethical oncologists in Australia (and the USA).

Recommendations

In my view, the case appears to be one of error and ignorance on the part of the 'authorities' or it may have been a not-so-sophisticated sham peer review.

In any case, in my view, it was a 'storm in a teacup' with the credibility of NSW Health in question.

Numerous past inquiries have unearthed widespread cultures of bullying and torment in NSW Health and also nationally. In my view, malfeasant public servants must be specifically identified and individual action taken, as this is not the first time it has occurred within NSW Health or nationally. The law allows this.

The results of this NSW Health commissioned external inquiry are constitutionally unlawful and procedurally and administratively flawed: it must be cross referred to the Senate Inquiry into Medical Bullying[17] and the COAG Health Minister's Council and comments requested.

Process wise for Dr Grygiel, the error (or malice) has now progressed to professional sanctions and uncalled for reputational damage.

If a Royal Commission is announced, this is the correct and ideal platform of inquiry.

False registrant complainants may be prosecuted using s136 of the National Law. Higher authorities will also need to transparently debate which is nobler: the creation of a false belief (a criminal act) versus 'protecting the public'.

References

1.

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1ii Charlotte King 2015 ABC http://www.abc.net.au/news/2015-12-28/accusations-of-bullying-at--ballarat-hospital-surface/7056372

2. Coutts, R 2016 "Workplace Cultural Reviews" http://bhs.org.au/node/607 and associated links

3. Leong Ng 2013 NSW Parliament Submission no. 8 "The promotion of false or misleading health related information or practices" https://www.parliament.nsw.gov.au/committees/DBAssets/InquirySubmission/Summary/37311/Submission%20No%208%20-%20Dr%20Leong-Fook%20Ng.pdf

4. Garling Inquiry Summary 2008 http://www.dpc.nsw.gov.au/__data/assets/pdf_file/0003/34194/Overview_-_Special_Commission_Of_Inquiry_Into_Acute_Care_Services_In_New_South_Wales_Public_Hospitals.pdf

5.

5i, Stow, W 2006 NSW Health Internal Document: Confidential Report: "Report on the Investigation on allegations against Dr Leong-Fook Ng" independently obtainable form Archival files of The Tweed Hospital (but note different versions supplied to the NSWMB and myself and also comments by my initial lawyer in response)

5ii. Statutory Declarations by a patient (now deceased) and a carer of a deceased patient (surnames blanked out)

5ii. Calcino, C 2015 Northern Star http://www.northernstar.com.au/news/doctor-accuses-health-disctrict-of-medicare-fraud/2502986/

6.

6i. NSW Health Final Report on Inquiry under s122 of the Health Services Act 1997 http://www.health.nsw.gov.au/Hospitals/Documents/section-122-final-report.pdf

6ii Ng, Leong 2015, Independent Australia "Injustice and the Rule of Law - Bingham's Rules" https://independentaustralia.net/life/life-display/unjust-ahpra-breaches-binghams-rules-of-law,8140

6iii A Justice of the Peace sighted and signed Screen Print-out of altered electronic notes in pdf (**CONFIDENTIAL** as it has patient's and other staff members' names)

6iv Ng v NCAHS 2007 NSWIRComm 173 http://www.austlii.edu.au/au/cases/nsw/NSWIRComm/2007/173.html

6v Ng v NCAHS 2007 (no 2) 2007 NSWIRComm 311 http://www.austlii.edu.au/au/cases/nsw/NSWIRComm/2007/311.html

7.

7i. Mandeleson, D 2003 "Devaluation of a constitutional guarantee : the history of section 51(xxiiiA) of the Commonwealth Constitution" http://dro.deakin.edu.au/view/DU:30038850

7ii. Lemming M 2011 "Resolving the Conflicts of Law" Federation Press ISBN 9781862878259

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9. EviQ https://www.eviq.org.au/

10. Dahm, D 2016 To reduce fatal medical errors, look to the world of accountancy https://thebusinessofhealthcare.com.au/2016/09/14/to-reduce-fatal-medical-errors-look-to-the-world-of-accountancy/

11. Haines, I 2016 The Conversation https://theconversation.com/st-vincents-scandal-whats-the-protocol-for-chemotherapy-and-are-low-doses-less-effective-63445

12. NSW Health 2016 www.**health**.**nsw**.gov.au/Hospitals/Documents/st-vincents-interim-report.pdf

13. Vega Vega v Hoyle and Ors [2015] QSC 111 http://archive.sclqld.org.au/qjudgment/2015/QSC15-111.pdf

14. ABC News 4 Aug 2016 http://www.abc.net.au/news/2016-08-04/sydney-chemo-scandal-cancer-researcher-defends-dr-kiran-phadke/7687986

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16. Penny Debelle 2016 Adelaide Now "Chemotherapy dosing bungle – what price for a life" http://www.adelaidenow.com.au/news/south-australia/chemotherapy-underdosing-bungle-what-price-for-a-life/news-story/70fbc0b0394e6af541f0fea9e1288b12

17. Leong Ng 2015 Independent Australia "Sham peer reviews and the old boys' clubs" https://independentaustralia.net/life/life-display/sham-peer-reviews--another-fashionable-modern-vice,7226

18. Senate Inquiry into "Medical Complaints Processes in Australia" 2016 http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MedicalComplaints45