We congratulate the Review Panel on many impressive aspects of its draft report.

We are dismayed however that the draft report ignores our evidence on the damage of pharmaceuticals patents to Australian health and government coffers. The review panel has an obligation to consider Australian health and taxpayer costs. Therefore we request that our 65 pages of evidence be integrated into the final report.

We think our evidence was ignored since it was not formatted for easy slotting into the topics to be covered in the review panel report. Now that we have the draft report, we in this April submission indicate relevant pages of that draft for slotting in our evidence, and appropriate wording for the insertions.

We are further dismayed at those sections of the draft report which treat claims in papers paid for by firms as if these claims constitute uncontroversial objective facts. The panel has a duty to protect the Australian public from implementing policies based on false industry claims. The draft report fails to mention the following.

a) **Conflicts of Interest**

The draft report omits stating that some authors cited were paid by pharmaceutical firms. Such an omission violates ethical standards for writing on pharmaceutical topics.¹

b) **Opposite Conclusions**

The draft report omits reference to research publications of independent university researchers that reach opposite conclusions to those of the financially biased authors cited.

¹ See eg the International Committee of Medical Journal Editors 2013 Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Authorship and Contributorship. Available at: http://www.icmje.org/ethical_1author.html.
We think that a) happened because the panel was not aware of how pharmaceutical firms have corrupted academic publications over the last thirty years. For the panel to appreciate how financial incentives corrupt, consider the evidence of the 2013 Grattan Report on how pharmaceutical influence has contributed to Australians paying up to 12 times more for its pharmaceuticals than our trans Tasman cousins in New Zealand. In this submission, we alert the panel to some parts of the report where it is important to revise the text to mention those conflicts of interest and conform with international medical ethical standards in the final report.

We think that b) happened because the panel was not aware of the conflicting conclusions reached by independent university researchers to those it cites reached by ones financially biased. In this April submission, we furnish the panel with a few appropriate references and summaries of the contrary conclusions. The literature with such contrary conclusions is vast. But this review panel’s report needs only to cite a few.

We request that this our April submission (providing invited feedback on the review panel’s April 2013 draft report) be lodged on the review website.

Our comments on the draft report are under four headings.

1 Evil innovations damaging health and government coffers must be distinguished from good ones, in pharmaceuticals every bit as much as in finance

2 Tax-payer and university actual losses on pharmaceuticals patents (from the transfer of university drug discoveries to firms) are mis-reported as profits
   (The draft report ignores data in publications of independent researches on this topic. It mis-reports as fact, opinions of biased industry-paid researchers)

3 Pharmaceutical innovations costs are inflated two to four-fold
   (The draft report uses costs supplied by biased industry-paid researchers, not the far lower costs calculated by independent researchers from the same industry data)

4 Ways of deterring patent applications should be proposed

1 Evil versus Good Innovation

A prime issue in our original submission, highlighted in it opening 1-page overview that we furnished to our submission is the crucial importance of distinguishing between evil innovations that damage Australian health and taxpayers and those that are beneficial. Only beneficial innovations should receive investment subsidies from the Australian federal government. We were shocked, that our submission on this matter was ignored in the draft report that virtually begins, page 6, with a declaration that

“Although there can be disagreements about the details of a patent system, there is general agreement that the system encourages investment in pharmaceutical innovation.”

Our January submission was made to alert the review panel to the necessity to distinguish between evil and good innovations. We documented the substantial medical journal literature on the evil nature of numerous pharmaceutical innovations. This failed to alert the panel.

Beginning with examples outside pharmaceuticals patents may help alert the panel and parliamentarians who must act on the report. We propose that at this early point in your final report, page 6, you insert paragraphs to the effect of those below:

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“Innovations however can be can be evil or good. The Australian government has a duty to foster good innovations that benefit the public. The Australian government has a duty to to exterminate bad innovations that damage Australian health and economic well-being.

“The innovations of firms like Enron resulting in the Dotcom bubble bust that damaged Australia and other companies were evil. They involved fraud, a negative net public benefit. Again, much of the innovation in the finance sector of the 1980s, 1990s and this millennium, has proven to be of the evil form.

“The January 2013 submission of Pope and Selten to this review documented the pronounced role of fraud in the design and conduct of clinical trials on pharmaceutical patented products. It documented that numerous pharmaceutical innovations in the form of new patented drugs damage to health, the tax base, and patients’ own finances. It documented how patented drugs have led to a wholesale distortion of health treatment and prevention as reported by the UK Royal college of Physicians. The distortion has been away from needed lifestyle and environment changes. The distortion has been to popping expensive pills that are often inefficacious and most with serious adverse side effects.

“The January 2013 submission of Pope and Selten also documented the routine violations of the law by pharmaceutical firms in withholding information on adverse effects detected in their clinical trials. It documented the modest fines (relative to their profits) imposed each time these firms are found guilty in the courts. It documented how judges bewail that drug firms regard being fined when caught breaking the law as just a cost of doing business. Without lobbying, when the associated deaths amount to statistical manslaughter, the executives would be behind bars, and the firms closed down. Minimal fines, instead of gaol and firm closure, reveal substantial capture of the justice system by these firms.

“Pope and Selten draw readers’ attention to the matter that phases 2 and 3 of clinical trials conducted by firms are evil. They document the published literature in medical journals of these trials being dishonestly conducted and reported, corrupting medical research. They document the published medical literature on the biased design of these trials. The designs are too biased to furnish the information required for physicians to assess drugs. They are conducted mainly on irrelevant populations as regards age and co-morbidities so as to make the drugs appear to be more effective with less side effects. Most are also conducted over too short a time period to detect the adverse effects.

“Pope and Selten further reported that numerous medical practitioners, medical researchers, medical editors, journalists, politicians and health ministers have campaigned against the evil innovations for decades. They have had minimal success in stopping these evil innovations, and stop them being paid for by national health systems. They fail, Pope and Selten document, for many reasons. One is because the pharmaceutical lobby proves stronger than democracy when the lobbying is allowed to occur largely behind closed doors.

“In few countries is there the opportunity, as in the 2013 Australian pharmaceuticals patents review, for democracy to break through. It is an opportunity for the public to see what is evil, as compared to good, innovation by the distinction between evil and good innovation being salient in this final review report.

This final review report gives parliamentarians and the public that opportunity. It is an opportunity that Australia missed when parliament made in 2010 a Memorandum of Understanding with drugs firms without preceding it with a review calling for public submissions.3 Then the lobbying was essentially behind closed doors. Closed doors give too little opportunity for reformers to withstand the lure of campaign contributions and

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arguments of lobbyists that are not laid out on the table – or these days public websites – for transparent objective analysis.

“Pope and Selten give numerous examples of how reformers get beaten without the backing of a parliamentary-appointed review in which all sides should lay their arguments on a public web if they wish to have democratic support. One of their examples comes from the late 1990s when Horst Seehofer, Germany’s Health Minister, was from the conservative pro-industry CSU party of Bavaria. Despite his pro-industry position, Seehofer could not in conscience condone so much evil innovation of patented drugs being supported by public health insurers. He constructed a "positive" list of pharmaceuticals. The positive list excluded evil innovations on sale in Germany. That is his positive list excluded ineffective, dangerous and exorbitantly expensive prescription drugs for which the German public health insurers were paying. His positive list however was shredded. The German drugs lobby prevented the positive list being published, prevented the German public being informed of which were evil innovations, and prevented Germans from being saved the cost of paying for these evil innovations.

At a celebratory birthday party for the head of the drugs lobby, Seehofer’s undersecretary presented to its head as his birthday gift, Seehofer’s positive list shredded. Seehofer himself was not at the party. On the shredding Seehofer then gave this interview some ten years later:

Reporter:
Does that mean that the pharma lobby was so strong that the government (reform) policy had to be withdrawn?

Horst Seehofer:
Yes. That is the case since 30 years till now. Meaningful structural changes toward a more social market economy in the German public health sector are not possible because of the resistance of confederated lobbying.

Reporter:
It cannot be that the industry is stronger than government policy. In the end government policy should say No!

Horst Seehofer:
I cannot contradict you. 4

“The Pope and Selten January 2013 submission was on the public web site of the review panel for more than the two months of February and March 2013. The pharmaceutical industry was invited in this way to comment on Pope and Selten’s documentation of evil innovation by pharmaceutical firms. No responses were received. 5 It might thus be inferred that the verdict of Pope and Selten is correct, uncontested by drug firms.

“The Australian government is in a stronger position than countries with bigger pharmaceuticals sectors like Germany to withstand evil pharmaceuticals innovations, both those imported and the minority that are home-grown. Thus Australia can gear its

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4 English translation. The German language broadcast is available on: http://www.youtube.com/watch?v=DCy1D1HGeeA as uploaded 27 September 2008 by Germany's Organisation for Truth (die Wahrheit). As Germany's Organisation for Truth said (in German) in its caption to the translated video clip above, "here Seehofer acknowledges that the confederated lobby is stronger than the people's government representative." For further details on this case and other examples from a range of countries, see the original submission of Pope and Selten to this review panel.

5 The review procedures permit non-public responses. But if there had been private objections to any of our evidence, the review panel would ask us to respond without breaching privacy by revealing who the objectors were.
innovations policy instead toward the public interest. It can gear it against evil innovation immediately in some respects, and in others, from July 2014. This is when its Memorandum of Understanding with pharmaceuticals firms expires.”

2 Taxpayer and university actual losses on pharmaceuticals patents from the transfer of university discoveries to drugs on the market through patents are mis-reported as profits

(The draft report ignores data in publications of independent researches on this topic. It mis-reports as fact opinions of biased industry-paid researchers)

We were shocked to see that on page 9, the draft report relies exclusively on a 2003 paper co-authored by Cohen,6 to reach a conclusion that biotechs and patents are great for universities. We were likewise shocked that the draft report violates the ethical code of the International Committee of Medical Journal Editors. The draft report does not mention the conflict of interest. Cohen in the year of that paper (2003) was a co-principal investigator in research paid for by a major pharmaceutical firm Eli Lilly. There are two issues here, a) Eli Lilly’s criminal and fraudulent nature; and b) the conflict of interest on this topic of universities and patents. It seems that the review panel was unaware of both a) and b).

a) Eli Lilly’s criminal and fraudulent nature

Eli Lilly has been guilty of hindering objective pharmaceutical research in many countries over many years. It is fundamental that if evidence paid for by Eli Lilly is to enter the final review report, that the report also cite findings against Eli Lilly so that parliamentarians and the public appreciate the consistent efforts of this company to expand evil innovation that damages health and government coffers. Eli Lilly corrupts medical academic research, and physician prescriptions as the following cases reveal.

It is alleged to have had the offer of a chair at the University of Toronto to David Healy reversed in 2001. After receiving the chair offer, and while with his wife searching for a house in Toronto, David Healy gave a lecture that highlighted his research findings on suicides and other adverse effects of the antidepressant Prozac. Prozac is a major revenue source for Eli Lilly. The University of Toronto in 2001 had $1.5 million grant from Eli Lilly. The University of Toronto evidently feared a continuation of such grants unless it revoked Healy’s offer. Healy’s offer was revoked.7

In 2009, Eli Lilly was found criminally guilty by the US Justice Department in its psychiatric marketing. It paid at that point the largest criminal fine of a corporation in the US, nearly $1.5 billion, for marketing one of its psychiatric medicines for uses not approved by the Food and Drug Administration.8 The next year 2010 Eli Lilly was fined by Mexico for coordinating insulin tenders,9 while the Swiss Competition Commission fined Eli Lilly for price collusion with others on erectile drugs.10 Research findings by such a criminal firm warrant corroboration by independent researchers before being taken as fact in this review report.

References:

8 CNN Money 2009 Eli Lilly fined nearly $1.5B in drug marketing case U.S. drug maker allowed 'off-label' marketing for anti-psychotic drug; to pay largest criminal fine for a corporation.
10 Competition – Switzerland (2010) Competition Commission fines Pfizer, Eli Lilly and Bayer for resale price maintenancehttp://www.internationallawoffice.com/newsletters/detail.aspx?g=0c8d778d-b0e5-4e17-a9bf-67d3885741bd
The conflict of interest in how pharmaceutical firms analyse university patents

The giant pharmaceutical firms like Eli Lilly have become massive beneficiaries of changes in patents laws since 1980. These transfer substantially the profits of patents on taxpayer-funded university research to them. The transfer process is for universities and individuals in universities to imagine that they can capture the profits. Universities have built large IP departments, and frequently go further, and run the risks and costs of startups. Those start-ups with a hint of success are often sold for a song by the university to the researcher.

In the case of biotechs (pharmaceutical start-ups), many survive phase I of human clinical trials testing are then bought up by the giant pharmaceuticals firms. Neither the university, nor the start-up, nor the giant pharmaceutical firm, typically paid anything for the research that was all done on taxpayer money. This has resulted in massive reduction in research costs for pharmaceutical firms. The reduction is a major reason that they wind down in-house research. In public announcements, these drug giants state that the universities and start-ups are more efficient, and give this as one reason for their shedding each few years more in-house research.

Reality is that in the neoliberal era, the not-for-profit universities that in the 1970s mainly stood proudly for independent research untainted by firm money have largely vanished. Instead, universities compete avidly for firm money. Whereas before in most western countries an academic discovered to be getting firm money might get fired, today promotion is difficult in most areas of academe, most especially in pharmacy, without firm backing.

The revolution has occurred without articulating coherent guidelines to safeguard tax-payer funds being used for public good, rather than efforts of universities and academics to enrich themselves at the expense of the public. Sheila Slaughter and Gary Rhoades in Academic Capitalism and the New Economy: Markets State, and higher Education, John Hopkins University Press 2004, give a blow by blow account of this progression. They identify numerous ways in which it has damaged the public and science.

Academics like Boston University’s Iain Cockburn indirectly admit to standing uneasily astride their academic calling to serve the public and their roles in numerous consulting companies. Cockburn (2005) comments on the now blurred lines between not for profit universities and their actual profit-taking ventures.11 He identifies the upsurge in pharmaceutical R&D now being undertaken in universities and biotechs. He identifies implicitly the low returns reaped by universities and biotechs in taking on the former in-house research of the pharmaceutical giants, as “less productive”.12 He fails to take the next step, and note that universities and biotechs have by and large allowed themselves to become patent-lured fools, progressively saving the giant pharmaceutical firms most of the costs of the early research stages.

Cockburn presents a moderately comforting picture of science, identifying ways in which the big pharmaceutical firms are acting more like universities in their emphasis on publications. Unobjectively, he fails however to mention the profit motives behind the drug publications, and their efforts to deceive physicians into perceiving them as objective researchers in these publications. Incidents like Merk’s imitation in Australasia of a refereed Journal of Bone and Joint Medicine to deceive physicians totally,13 is but the bottom of a situation of corruption and deceit in medical journals that has become seemingly insolubly deep as former British medical editor Dick Smith reports in his 2006 book, The Trouble with Medical Journals. London: Royal Society of Medicine Press. Cockburn does however note the lack of profits on start-ups.

13 See eg The Australian’s 9th April 2009, report on this disgraceful episode, implicating also its medical publisher, Elsevier.
Researchers however like Slaughter and Rhoades without such financial biases as Cockburn by contrast report a sorry state of affairs on the damage done to research from patents. Their case studies of the damage to research are complemented by those in many other articles and books such as Philip Mirowski Science Mart: Privatising American Science (2011). Mirowski moreover indirectly ridicules those defending the lost boundaries between research for the public good and that for private profit by pointing to the rising number of patents lodged by universities. He uses reasonable measures to identify a decline in the scientific value of the patents being lodged by US academics.

There is no evidence of universities making other than losses in the neoliberal world in which they and their academics are lured by patent gold. US University net profits on patents and from start-ups seem, with barely a handful of exceptions, solidly negative – in sofaras there could have been some, dissipated in inter-university patent litigation, or floated up to the giant pharmaceutical firms. Such losses can be inferred with varying extents of data from eg Mirowski, and Christopher Newfield’s 2008 book, The Unmaking of the Public University, Harvard University Press. Probably nobody can be dogmatic. This is because universities dodge researchers’ requests for data. University Intellectual Property divisions tend to release (and maybe only collect data) at most on gross revenues. Most universities seem too ashamed at what would be revealed. Those employed in their Intellectual Property divisions recognize that they might lose their posts if the losses on the university patent race were made public. In their publications, Slaughter, Rhoades, Mirowski, and numerous researchers not paid by firms, report also on the damage to research of the patent system.

On page 9, we request that the review panel do the following.

2.1) Document Cohen’s Eli Lilly funding at the time of the publication it cites by Walsh, Arora and Cohen reaching benign conclusions on patents and university research.

2.2) Document the history of criminal activity of Eli Lilly.

2.3) Report that the opposite conclusion to Walsh, Arora and Cohen – instead a conclusion of most universities losing money on patents and biotechs – reached by researchers who are not paid by industry such as Mirowski and Newfield.

2.4) Report the opposite conclusion to Walsh, Arora and Cohen – instead a conclusion of university science damaged by the pursuit of patents – reached by researchers who are not paid by industry such as Slaughter, Rhoades, Mirowski and Newfield.

2.5) Highlight how Australian taxpayers are funding start-up firms and giant pharmaceutical ones for using virtually cost-free discoveries of universities.

2.6) Mandate Australian universities to furnish them with data on the costs and revenues from their intellectual property sections and pharmaceuticals patents. Since these universities are tax funded, the data ought to be in a publicly available form and in sufficient detail for others to verify.

2.7) Mandate medical schools of Australian universities to provide full disclosure of their conflicts of interest. This is fundamental when lives are a stake from biases in design, conduct and assessments of drug trials and such is currently lacking in many.14

On page 15, we request the following:

2.8) Supplement the information that pharmaceutical firms are downsizing and looking to universities and smaller biotechnology companies for research with the information provided above and in our January 2013 submission and above in this section 2 of our April 2013 submission. In

summary, the additional information is that governments are now so generous in handing over free taxpayer funded discoveries that big pharmaceutical firms have less need for in-house research. Further, the evil nature of pharmaceutical innovation to public health and government costs was discussed in part 1 above. Hence governments should not be seeking to support the pharmaceutical industry in continuing bubble patent activities. Government should restrict their subsidies to R&D in industries generating good innovations that improve welfare.

3 Innovations costs are inflated two to four-fold
(The draft report uses costs supplied by biased industry-paid researchers, not the far low costs calculated by independent researchers)

We were shocked to see the draft report on page 58 gives what is in fact cost data supplied by Eli Lilly without even reporting that all 7 authors of the study, Steven M. Paul, Daniel S. Mytelka, Christopher T. Dunwiddie, Charles C. Persinger, Bernard H. Munos, Stacy R. Lindborg & Aaron L. Schacht were Eli Lilly employees. We request that the review panel insert the following.

3.1) The authors’ affiliation and the criminal and fraudulent convictions of their employer Eli Lilly. This avoids the impression that the cost data came from independent researchers or ones employed in an honorable firm fostering health and saving government and patients money when the reverse is the case.

3.2) Findings in publications of researchers not paid by pharmaceutical firms. These independent researchers also rely on firm sources, but analyse it objectively. The studies find that pharmaceutical firms and lobby groups inflate their costs 2 to 4 times by counting as research all their marketing activities. The costs provided in the review panel report should integrate the data in publications like:

2004 estimates in the book by the ex editor of the New England Journal of Medicine, Harvard University’s Marcia Angell, *The Truth About the Drug Companies: How They Deceive Us and What to Do About It*,


3.3) In graph 5.2, a note to the pharmaceuticals R&D curve.
The note must mention that checks on what is reported as pharmaceuticals research in the US uncover R&D expenses overstated by multiples. Those R&D statistics reported in lobbying governments were inflated by marketing costs (“education” of physicians to prescribe the drugs, by exaggerated capital cost imputations and so forth). Such could also be the case with R&D statistics tendered to the Australian Bureau of Statistics.

3.4) A cost disclosure recommendation for firms seeking government subsidies in the form of PBS listing of a drug.
Such firms should have their accounts on public websites, for independent economists to re-analyse their cost estimates. Government subsidies ought come only with demonstrably objective cost accounting.
4 Ways of deterring patent applications should be proposed

The case presented against patents in our original submission stands. Your draft report helpfully provides a number of ways in which Australia may mitigate the malevolent effects of its own legislation and international agreements.

We propose you extend the number of ways recommended that Australia hinders applications and use of patents. First, government lawyers ought to be employed to present the public’s interest against patents. Second, tax-payer funds ought not be squandered on educating students to become patent lawyers, or on rapid hearing of those seeking to have new patents or enforcement of existing patents.

Third, the draft report says that the cost of patent extensions was “efficient”. But efficient for whom? Australia could place very steep charges on awarding and extending patents, steep enough to deter all, without violating treaties. Our case reveals benefits to health and government coffers from deterring all. This avoids the waste of national resources on patent lawyers moreover.

For the sake of public health and government coffers we request that the review panel canvasses: 1) use of government lawyers to oppose patents; 2) reduced funding of law schools that fail to focus in patent litigation on the demerits of patents; reduced number of judges to hear patent cases; 3) massively increased costs for applications connected to patents; and 4) study India for tips on other means of inhibiting patents.