Confronting our Diseased Healthcare System: some causes and cures

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ABSTRACT:

Introduction: The purpose of this paper is threefold; (i) to assess how healthy most Australians are as measured by recent national figures, (ii) to review a detailed analysis of why health systems in many advanced countries are "unwell", and (iii) to suggest possible action that could be taken to treat the cause of this modern "disease".

Method: Data from the Australian Institute of Health and Welfare and the Australian Bureau of Statistics are analysed. As well, the most comprehensive assessment of the impact of multinational pharmaceutical companies on modern health systems is reviewed. Recommendations are developed from these data.

Results: Data reveal that the average Australian is afflicted by at least one chronic disease, including a concerning 40% of young Australians. Australians are living longer but less healthy lives, and the economic burden is growing. Intentional strategies by multinational pharmaceutical companies are shown to be a significant cause of this problem. Their actions are often unethical, motivated by objectives which conflict with the goal of good health for all citizens.

Discussion: This analysis focuses on the harm many medicines cause. Other factors can affect our health including poor food, toxins in our environment, stress at work and at home and financial pressures. However, deliberate, unethical behaviour which causes harm to individuals, and which adds considerably to the cost burden which our national health system imposes on all citizens, needs to be exposed and dealt with by our parliaments.

Conclusions: The Australian health system is not broken and has many commendable features especially in acute and emergency medicine, but it is not preventing the growing rate of chronic illness among citizens, or an increasing burden on our budget. This can be corrected if our politicians so choose, possibly encouraged by demands from better informed citizens. One significant factor is unethical behaviour by multinational pharmaceutical companies, and more specifically by individuals who oversee the actions of these companies. They must be held to account, and this egregious waste of resources and unnecessary lowering of the quality of life of many must be stopped.

Introduction

This paper is presented in three parts. The first part presents recent data describing how "well" our national health system is as measured by the overall health of Australians.

The second part suggests a probable cause of our national wellness malaise, being the influence of international pharmaceutical interests on every aspect of our health system. The most comprehensive study of PhRMA ethics was undertaken through Harvard University Law School, and their findings will be reviewed. NOTE: PhRMA is the acronym for the *Pharmaceutical Research and Manufacturers of America* and was used throughout the Harvard study. It is used here in that context, but also in the wider meaning of "pharma" meaning large pharmaceutical companies (internationally) as a group.

The third part suggests some possible solutions to help turn around the decline in the health of average Australians.

PART 1: How Healthy are Australians?

We are regularly told that Australia has a world class health system[1], and the media constantly carries articles about impending medical breakthroughs, and interviews with people whose lives have been extended by new drugs and a variety of new surgical and analytical methods. Many wonderful doctors and nurses do great work, especially in emergency and acute care. Some Australian scientists lead world-first research projects in medicine.

But overall, is our health system as good as suggested? Considerable resources are expended on saving or improving the lives of relatively few people with rare conditions, but how well is the "average" Australian? Is saving the lives of a few done at the expense of the majority? In a utopian health system with unlimited resources everyone could be helped, but do we have the balance right in our system where health budgets are nearing maximum limits?

The Australian Institute of Health and Welfare (AIHW) released a 2018 report titled *Australia's Health 2018*.[2]

AIHW stated that: on an **average day** in our health system

- **$467 million** is spent on health ($19 per person)
- **406,000** visits are made to a general practitioner (GP)
- **777,000** prescriptions are filled under the Pharmaceutical Benefits Scheme (PBS)
- **21,400** presentations are made to public hospital emergency departments
- **17,300** hospitalisations are in public hospitals
- **11,800** hospitalisations are in private hospitals
- **91,500** services are provided in public hospital outpatient clinics
- **6,000** elective surgeries are performed
- **26,000** specialised community mental health care services are provided.[3]

An SBS television news summary of the AIHW report highlighted that:

"- Two-thirds of adult Australians are overweight
- More than one-quarter of children are overweight or obese
- More than 99 per cent of children and 96 per cent of adults do not eat the recommended amount of vegetables
- Australians do not exercise enough, with 92 per cent of teenagers not doing the recommended amount for their age
- On an average day there are 850 births, 440 deaths, 380 cancer diagnoses and 170 heart attacks"[4]

One of the AIHW summaries noted that **"Half of us have a chronic condition …** One in 2 (50%) Australians are estimated to have at least 1 of 8 selected common chronic conditions: cancer, cardiovascular disease, mental health conditions, arthritis, back pain and problems, chronic obstructive pulmonary disease, asthma and diabetes. Nearly 1 in 4 (23%) Australians are estimated to have two or more of these conditions."[5]

The Australian Bureau of Statistics used to provide reports on Chronic Disease in Australia roughly every 12 years, although the material is now apparently no longer produced in the format shown in Table 1 covering 1977-78 to 2004-05. It is highly unlikely that the trend has suddenly improved.

Table 1: The Incidence of Chronic Disease in Australia – 1977-78 to 2004-05

Age	1977-78 %	1989-90 %	2004-05 %
0 - 14	24.5	36.9	41.0
15 - 24	32.4	55.5	65.8
25 - 44	47.3	67.7	79.3
45 - 64	65.9	89.6	96.8
65 +	77.6	95.1	99.7
Average	**45.1%**	**66.2%**	**76.7%**

Source: Australian Bureau of Statistics. Australian Health Surveys 1977/78; 1989/90; 2004/05 Canberra, 1980, 1992, 2006.

We are living longer, but we are living with more chronic illness. We are not overall a "healthy" group of people as the figures above clearly show. When 40% of our children have at least once chronic condition the situation is not likely to improve without an informed fundamental change in attitudes and actions of politicians, health bureaucrats, medical personnel and citizens. Such a change is unlikely to occur until the true cause of Australia's epidemic of chronic disease is publicly identified and corrected by informed politicians acting in a bipartisan way to make Australia a truly healthy nation.

PART 2: The Real Cause of an Unhealthy Health System

In general, the subject of chronic illness in Australia is ignored by a media that is captured by advertising dollars and hype generated by the technically brilliant self-promotion of modern medicine. When failings are discussed a variety of theories are advanced as to why the average Australian has health issues, and most conclude that more money will fix the problem – more research, more new drugs covered by the PBS system. The real cause of the epidemic of chronic illness is ignored. The need for a *health system* rather than our current *disease management system* is avoided not addressed.

The following analysis will question whether the root cause of our underperforming health system is the extraordinary influence exerted on every aspect of our system by the pharmaceutical industry (PhRMA).

PhRMA profits are maximised when infant mortality is reduced, when life expectancy is increased, and when the general population suffers high levels of chronic illness. This fact is the key to uncovering the true cause of the current epidemic of chronic illness.

Lowering infant mortality is commendable. Extending life expectancy is good provided quality of life is maintained. Increasing chronic illness has zero benefits to individuals or governments, yet this is exactly what is happening in Australia and in most developed countries. We need to ask – is that a fortunate coincidence for PhRMA, or is it the result of an expertly executed business plan rolled out over decades around the world?

The most thorough review of the influence of PhRMA on every aspect of the orthodox health system in the USA, with direct application in other developed countries such as Australia, was undertaken by Fellows of the Edmond J. Safra Center for Ethics at Harvard University Law School. The published analysis (2013) took five years.

This analysis has been ignored by national newspapers and television stations. Whilst "investigative journalists" are prepared to reveal corruption in many areas of society, corruption involving our national health system is apparently off limits. There is a genuine need to make every Australian aware of what the Harvard analysis uncovered. It should be required reading for every politician, as well as every medical student in Australia.

This massive work will now be summarised.

The Harvard Reviews of Pharmaceutical Ethics: A Summary

The Harvard analysis comprised a symposium on **Institutional Corruption and Pharmaceutical Policy** published in the *Journal of Law, Medicine & Ethics*, Vol. 41, No. 3 (2013). All symposium articles are accessible through the Edmond J. Safra Center for Ethics website through the following link: http://www.ethics.harvard.edu/lab/featured/325-jlme-symposium , or summarised at https://ethics.harvard.edu/news/jlme-issue-institutional-corruption-and-pharmaceutical-industry

Sixteen articles were published analysing different sources of PhRMA corruption, how it occurs and what is corrupted. The articles were grouped under five topics: (1) systemic problems, (2) medical research, (3) medical knowledge and practice, (4) marketing, and (5) patient advocacy organizations, as shown in Table 2.

Table2: Articles Published by the Harvard University Review of PhRMA Corruption

INTRODUCTION
Marc Rodwin, *Institutional Corruption and Pharmaceutical Policy*
Lawrence Lessig, *Foreword: 'Institutional Corruption' Defined*Gregg Fields, *Parallel Problems: Applying Institutional Corruption Analysis of Congress to Big PhRMA*
1. SYSTEMIC PROBLEMS
Paul D. Jorgensen, *Pharmaceuticals, Political Money, and Public Policy: A Theoretical and Empirical Agenda*
Marc-André Gagnon, *Corruption of Pharmaceutical Markets: Addressing the Misalignment of Financial Incentives and Public Health*
Marc A. Rodwin, *Five Un-Easy Pieces of Pharmaceutical Policy Reform*
Donald W. Light, Joel Lexchin, Jonathan J. Darrow, *Institutional Corruption of Pharmaceuticals and the Myth of Safe and Effective Drugs*
Jennifer E. Miller, *From Bad Pharma to Good Pharma: Aligning Market Forces with Good and Trustworthy Practices Through Accreditation, Certification, and Rating*
2. MEDICAL RESEARCH
Abigail B. Brown, *Understanding Pharmaceutical Research Manipulation in the Context of Accounting Manipulation*
Yuval Feldman, Rebecca L. Gauthier, and Troy H. Schuler, *Curbing Misconduct in the Pharmaceutical Industry: Insights from Behavioral Ethics and the Behavioral Approach to Law*
Garry C. Gray, *The Ethics of Pharmaceutical Research Funding: A Social Organization Approach*
3. MEDICAL KNOWLEDGE AND PRACTICE
Sergio Sismondo, *Key Opinion Leaders and the Corruption of Medical Knowledge: What the Sunshine Act Will and Won't Cast Light On*
Lisa Cosgrove and Emily E. Wheeler, *Drug Firms, the Codification of Diagnostic Categories, and Bias in Clinical Guidelines*
Marc A. Rodwin, *Rooting Out Institutional Corruption to Manage Inappropriate Off-Label Drug Use*
4. MARKETING
Sunita Sah and Adriane Fugh-Berman, *Physicians Under the Influence: Social Psychology and Industry Marketing Strategies*
Amy Snow Landa and Carl Elliott, *From Community to Commodity: The Ethics of Pharma-Funded Social Networking Sites for Physicians*
5. PATIENT ADVOCATES
Susannah L. Rose, *Patient Advocacy Organizations: Institutional Conflicts of Interest, Trust, and Trustworthiness*

The team leader, Marc Rodwin, defined institutional corruption as “widespread or systemic practices, usually legal, that undermine an institution’s objectives or integrity.” He also identified the following four major themes that ran through the 16 presentations. The key points come from the articles shown in Table 2.

Theme 1: Individuals and corporations become financially dependent on PhRMA

Key individuals and organizations modify their behaviour to satisfy the demands of pharmaceutical firms that help pay their bills.

- Politicians (especially in the US) have become dependent on drug company campaign contributions and other resources, and produce legislation that benefits pharmaceutical firms. Political party policies also benefit drug companies.
- The Food and Drug Administration (FDA, the USA regulator) is financially dependent on PhRMA user fees and focuses on rapidly reviewing new drug applications instead of focussing on ensuring drug safety. NOTE: Because FDA approval is significant in other markets, this impacts Australia and not just the USA.
- Doctors, politicians and the public have become dependent on drug firms for the production of knowledge about drugs, and to honestly report clinical trial results when they have incentives to manipulate data. Dependence on corporate funding for research can challenge scientific norms of independence and research integrity.
- Pharmaceutical firms create dependence when marketing their products, such as dependence on advertising revenues.
- Even though they claim they can recognise and ignore influence, gifts make doctors psychologically as well as financially dependent on pharmaceutical firms so that they will reciprocate by prescribing a particular drug.
- Physicians depend on on-line networks that are also used by PhRMA for marketing.
- Patient advocacy group are financially dependent on pharmaceutical firms, which can bias an advocacy organization's policy stance and the services it provides.

Theme 2: Misalignment of incentives and markets as a source of corruption

The financial incentives for drug firms are often inconsistent with public policy goals of better public health, so that firms can prosper without advancing the public's health.

- The pharmaceutical industry has a business model that relies on developing and aggressively marketing incremental modifications of existing drugs ("me-too" drugs) that are not only more expensive without providing much more—or any more—benefit, but in some cases are even harmful.
- Firms have a strong incentive to market drugs for "off-label"[6] uses that the regulator has not approved, even when there is a lack of significant evidence that such uses are safe or effective.
- The incentive for firms and managers to get drugs approved by the regulator can be so strong that it encourages the manipulation of research data.
- Financial deterrents are inadequate. Prosecution of executives is needed. The use of accreditation, certification, and rating systems that evaluate corporate ethical performance may help. Changing the way we reimburse drug firms may create stronger incentives to develop truly innovative drugs.

Theme 3: Marketing distorts medical practice and ethics

Drug marketing can corrupt medical practice, against patient welfare and the creed to "first do no harm".

- Sophisticated pharmaceutical marketing draws on knowledge of psychology and social science to sway physicians' decisions. Physicians believe they can "see through" such marketing, but research proves most cannot.
- Doctors trust other doctors, so drug firms boost sales by targeting key opinion leaders and use them to control information.
- Drug firms have an incentive to market drugs for uses ("off label") that conflict with good medical practice.
- Online physician networks have become marketing tools for PhRMA.
- Marketing priorities distort decisions about what R&D to conduct.

Theme 4: The limits of financial disclosure as a remedy

The conventional wisdom is that disclosure of financial ties is always desirable, and is sufficient to cure conflicts of interest. However, the limits of disclosure have been known for decades, especially the view that once disclosure is made any action is acceptable.

- Reporting payments and gifts to physicians does not address key problems of dependency, reciprocation, and a belief that disclosure means the physician can now act with impunity.
- Disclosure of conflicts of interest can similarly create a moral license for individuals to pursue their self-interest even when it is inappropriate.
- Even though disclosure of drug company funding to patient advocacy organizations can be beneficial, it has limitations. The fact that funding is known does not itself remove the influence on decisions created by the funding.

This remarkable analysis in no way lessens the great value of some orthodox medicines and procedures. But it does highlight that the evidence base of *evidence-based medicine* is significantly compromised and often simply wrong.

This report is focussed on problems with the functioning of our health system. Many other factors can cause chronic ill health in citizens; poor nutrition (cross shareholdings between pharmaceutical companies of food companies was not examined in the Harvard review), environmental chemical toxicity (the recent takeover of Monsanto by Bauer shows links between chemical manufacturers), work and domestic stress, financial pressures, and so on. But intentional, unethical actions by wealthy individuals should not be allowed to compromise the wellbeing of citizens and correcting this cause should be a bipartisan political priority.

The Australian Experience

The Harvard Analysis focussed on the actions of PhRMA in the USA. A few contemporary examples can show that Australia is not exempted from PhRMA influence. For example:

a) PhRMA companies donate millions to all sides of Australian politics. "Big pharmaceuticals have a significant financial stake in the way government behaves, particularly in decisions or policy affecting medicine pricing or approval processes for new drugs. A former federal health department secretary, Stephen Duckett, now a leading health researcher at the Grattan Institute, said the pharmaceutical industry was "extremely powerful" and exerted significant influence on government."[7]
b) Oxfam claims pharmaceutical companies are avoiding $215m a year in Australian tax. "An Oxfam report claims the amount of tax avoided by local pharmaceutical companies is equivalent to 'almost the full cost of Medicare's urgent after-hours home visits service in 2015–2016'"[8]
c) The Grattan Institute finds Australian drug prices remain almost twice those in the UK and 3.1 times higher than New Zealand's.[9]
d) Dr Quin Grundy from the University of Sydney found Australian nurses attended thousands of drug industry sponsored events.[10]
e) "Pharmaceutical companies gave Australian doctors, nurses and pharmacists almost $12m in fees and expenses to attend conferences and give talks between November 2016 and April 2017."[11]

PART 3: Suggestions for Change

Australian governments, both Federal and State, could potentially improve the quality of health for most citizens and reduce health care costs by undertaking radical reform. There would be immense resistance from a variety of stakeholders, including politicians themselves. Not all resistance will be because individuals have been directly "corrupted" by PhRMA, as their methods are usually more subtle, but as the Harvard analysis made clear, the entire health system has been corrupted, including most individuals working within the system, to a greater or lesser extent.

Some suggestions to improve the quality of our system would include.

- Instruct the Advisory Committee on Medicines (ACM) to closely examine "me too" drugs on the PBS. If supporting evidence was based on trial comparisons with placebo rather than with existing alternatives (causing the true incremental benefit of the drug to be concealed), then either cause an appropriate re-analysis to be undertaken (at PhRMA expense), or benchmark government subsidies on the cheapest equivalent.

- Establish a new drug testing Institute with no links to PhRMA or compromised institutions such as the NHMRC. Require new drugs, whenever the initial testing was not independent, i.e. was funded by PhRMA and undertaken by contract clinical trial firms, before they are placed on our PBS to be retested by this Institute (at PhRMA expense)

- Overhaul the major medical Institutes in Australia. Establish a national register of employees and contractors working in these Institutes, and in Universities, who have ties to PhRMA. In organisations under government control, adopt employment policies where people on the register are not employed in areas where there may be a potentially damaging conflict of interest.

- Establish a new Agency, totally independent of the NHMRC but funded by a modest percentage of the NHMRC budget, to take responsibility for the analysis of the potential cost-benefits to the nation, as well as national budgetary implications. from using established natural therapies.

- Ensure that the Department of Health releases regular and simply written report cards which are carried in national media to inform all Australians of the true state of health of all citizens and of our health system. Encourage politically bipartisan action to improve all aspects of our health system, starting with appropriate education about health in primary and secondary schools. Generations of parents literally have no idea how to create a naturally healthy lifestyle, so governments must accept responsibility for this education.

- Enact legislation that will hold the top executives and Board members of pharmaceutical companies, and researchers, personally liable for deliberate actions which harm individuals and/or national health goals.

- Elect to State and the Federal parliaments people who will champion the inclusion of appropriate natural therapies into our health system and will highlight to other parliamentarians and the public the true influence of PhRMA on our health system, and how this influence can be lessened, for the benefit of all.

- Carefully evaluate incentives and dis-incentives to be used to encourage food manufacturers to offer healthy food at reasonable prices, thus reducing sugar content, unhealthy trans-fats, excessive saturated fats, and highly refined foods. Expose links between large food manufacturers and PhRMA.

Conclusion

Evidence gathered by government agencies shows that on average Australians are not particularly healthy, and that the incidence of chronic disease has reached epidemic proportions in Australia.

Evidence assembled by specialists at Harvard University Law School examining all aspects of the conduct of multinational pharmaceutical companies has found that unethical behaviour within these corporations has influenced directly or indirectly the actions of other corporations and institutions, as well as individuals who work within the health sector. This influence has contributed to the growing burden of chronic illness and associated suffering

and cost in America and elsewhere. In fact, the PhRMA business model means that higher levels of chronic disease directly translate into higher profits.

It is essential that individuals within corporations be held personally liable for unethical actions. Fining immensely wealthy corporations has not corrected the problem. Occasionally, when efforts are made to pursue a company, one director is sacrificed for the sake of the corporation. All Directors and senior managers must be made personally accountable. The Harvard review argued that legislation might alter this loophole.

If our current disease-management system is not changed into a health-creation system, and if the pervading influence of PhRMA is not exposed and eliminated, the majority of Australians will be destined to living longer but less healthy lives at even greater cost to health budgets.

Change will be difficult and will face immense opposition from the many people and organisations directly or indirectly aligned with international PhRMA. But as the saying goes – *sunlight is a great disinfectant* - we must inject light (truth) into the darkness created by PhRMA and make our health system well again.

References

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[5] Ibid. https://www.aihw.gov.au/reports/australias-health/australias-health-2018-in-brief/contents/how-healthy-are-we (accessed 17.8.18).

[6]" 'Off-label' prescribing occurs when a drug is prescribed for an indication, a route of administration, or a patient group that is not included in the approved product information document for that drug." https://www.nps.org.au/australian-prescriber/articles/off-label-prescribing-6 (accessed 18.9.18).

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