Productivity Commission inquiry into data availability and use: submission

Over a career in using a variety of publicly generated data, I have found many situations where relevant data have not been available. These include PBS data prior to 1998, the number of registered Patent Attorneys by year, beneficiaries of the R&D tax concession scheme (including by year so longitudinal analysis can be done), names of recipients of the Export Market Development grants scheme, ASX price data for corporate bonds and floating notes, regular data on median weekly earnings. In other situations some data have been available, but only useable after significant cleaning work.

Over time there have certainly been improvements in this situation and recent efforts to move towards a more open environment for data access are to be commended. These include, but are not limited to, open access initiatives for government data and requirements by the Australian Research Council (ARC) for open access to the results of publicly funded research. Even here, however there could be improvements. We could, for example, follow the US example and simply make provision for no copyright restrictions on any government document. The government's (any government, both sides do it) use of "commercial-in-confidence" as an excuse for hiding data from public scrutiny is excessive. Where a firm or other entity receives taxpayer money then citizens have a right to substantial data on how those funds are being used. Hurdles for exemption from the new ARC requirements should be robust, high and applied consistently.

I spent part of my career working on labour market research. In regard to tracking the average level of wage income, the ABS continues to publish only average weekly earnings data, rather than the more valid measure of central tendency – median weekly earnings. It is well known that where a distribution is skewed to the right, then the mean will be consistently greater than the median. Australians cope easily with median data on housing. Yet public policy reliance on average income data is more important, and continues to be based on the deficient measure of the mean rather than the median. Indeed getting median data is only possible if one does one’s own calculations.

Another part of my career has been spent on policy-oriented research into industrial innovation and small enterprises. At that time (the early 1990s) there were few time-series data available. As a consequence I developed a proposal for a longitudinal survey of small businesses and this was funded in the 1996 budget. Subsequently an improved approach has been developed and the ABS now uses Australian Business Numbers (ABNs) to link firms across different data collection series. Having manually tried to clean data for 1990-2002 patent grant data to identify the number of patents owned by each firm I can attest to the importance of using ABNs. There also needs to be a publicly-funded and publicly available configuration database to track mergers and take-overs.

As an investor I have appreciated the public availability of Australian Stock Exchange (ASX) data. The fact that these data are only available after a short (twenty minute) interval is not a problem as all trading platforms offer immediate data. However, since the privatisation of the ASX, one set of data has been withdrawn from the market – data on prices for company bonds, floating rate notes, hybrid data etc. These data were previously available on the same basis as data for listed companies. This is no longer the case, and these data are now only available for an additional fee from selected companies. This is very questionable. The ASX has been allowed to withdraw public

data for its own commercial benefit. Trading platforms have these data, but provide them to their users only for the current/last trading day. Were any questions asked before access to these important public data were restricted? Who approved this?

Earlier in my career I worked as a demographer and was appalled, when I migrated to Australia, to find out that all our census forms are destroyed shortly after collection. This was explained to me as being due to such a strong distrust of ABS systems that any other course of action would substantially reduce compliance. Although privacy groups are again raising such concerns, the world has shifted substantially. A very large proportion of the population now distribute personal information widely through various social networking media. An increasing segment of the population is taking an active interest in researching their own family history. Census data provide an excellent source for tracking relatives more broadly. For example, I accessed the relevant household records from the 1911 UK census to identify residents in a friend's grandmother's house. This inquiry raises an excellent opportunity to create a new public discussion about the importance of keeping census forms for future historic and family history research.

As a consumer I have not found it possible to access data on consumer complaints by company/product, even in condensed form of number of complaints. Given that formal consumer complaint mechanisms exist, surely consumers should be able to draw on such data to ensure they are buying reliable products from reputable companies?

Given all these experiences I welcome this inquiry. In the remainder of this submission I touch in a little more depth on some specific data availability issues that have arisen for me over recent years.

Health: Phase III and Phase IV clinical trial data

Phase III clinical trial data are required by public authorities for public purposes (assessing the safety and efficacy of new medicines). Despite this they are deemed to be the private property of the company producing the medicine and are not available for other researchers to use. This perspective is questionable. It also creates substantial problems.

Firstly, because clinical trials are not defined as public, companies are able to withhold trial data with adverse outcomes (Goldacre, 2012).

Secondly, lobbyists have been able to persuade governments to agree, in "trade" treaties, to prevent, for specified periods of time, the use of these trial data to approve market entry for generic medicines. This is despite the fact that it would be both unethical and inefficient to undertake clinical trials where the outcome is already known, as is the case with generics. This policy is known as data protection or data exclusivity (Harris *et al.*, 2013: 155), and is closely related to patent policy.[1]

[1] Data exclusivity is a relatively new form of government-granted monopoly. It was first introduced in 1984 in the USA as part of the Hatch-Waxman Act. That statute was motivated by the need to overturn a CAFC decision (*Roche Products Inc. v. Bolar Pharmaceuticals Co. Inc*. 733 F.2d 858 (1984)) deeming that the traditional experimental use exemption to patent infringement did not apply to preparations for marketing approval of generic versions of a product.[1] This decision effectively extended the market exclusivity period substantially. It was swiftly overturned by the Congress. The Hatch-Waxman Act introduced a package of reforms to ensure that generic companies could use patent data to prepare for market entry as soon as possible after patent expiry – this exemption from patent infringement is widely known as the *Bolar exception*. The statute also included the first provisions limiting the ability of third parties to use clinical and other data required by regulatory agencies for the market approval of new medicines. Such use was precluded for 5 years. Thus the origin of the data protection/ exclusivity policy was political horse trading in the Congress.

Thirdly, such data remain perpetually confidential despite their value in developing a better understanding of the use of the medicine thus contributing to better health outcomes.

Australia agreed such a data protection period of five years in the Australia-US Free Trade Agreement (AUSFTA).[2] In the USA lobbyists have achieved a 12 year limitation period for newer more expensive "biological" medicines. Although the US President had indicated an intent to reduce this period to seven years, in the Trans-Pacific Partnership Agreement (TPPA) negotiations the US Trade Representative (USTR) demanded a period of 12 years, before finally settling for eight.

These "data protection" policies can delay the entry of generic drugs into the market thus increasing the cost of pharmaceuticals to taxpayers and consumers. While there are, as yet, no examples of this occurring in Australia, there are examples from overseas markets.[3]

The 2012-13 Pharmaceutical Patent Review (PPR) considered the data protection issue, and reported that in 98% of new medicine cases,[4] the effective life of the underlying patent exceeded the data protection period by two or more years (p 159). The PPR Panel reported research showing no relationship between data protection and investment by the pharmaceutical industry.[5] The Panel concluded there was a lack of evidence that data protection limitations had reduced the availability of pharmaceuticals in the Australian market. The Panel further noted that the protected data were not released to the public following the period of data protection, but remained confidential indefinitely, inhibiting "the development of other pharmaceuticals and research directed towards a better understanding of complex medical conditions and responses to drugs" (PPR: 167). The PPR Panel concluded that

> "Opening these data for further research … could provide a substantial public health benefit. It thus makes sense, in principle, that these data should be publicly available." (PPR: 167)

The PPR Panel considered that it would be necessary for such a move to be co-ordinated internationally, to avoid risks of non-supply of a medicine in countries where marketing approval had not yet been granted. But the panel also concluded that Australia should work with the European Medicines Agency (EMA) to develop an appropriate protocol for making clinical trial data publicly available (p. 169).

The recent Johannesburg Declaration – a civil society declaration made in the context of the UN Secretary-General's High-Level Panel on Access to Medicines[6] – has also called for full accessibility to clinical trial data:

> "Clinical trials to test the safety and efficacy of medical technologies should be independently evaluated and conducted to ensure proper research design,

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[2] The major pharmaceutical producing countries (USA, European Union, Switzerland and Japan) all have strong data protection policies, and countries with post-TRIPS trade agreements with the USA all have data protection policies. TRIPS is the Trade-Related Intellectual Property Agreement, part of the Single Undertaking suite of World Trade Organization (WTO) treaties.

[3] In Jordan an Oxfam study found that since 2001 medicine prices in Jordan had increased by 20%, and data protection has delayed generic entry for 79% of medicines newly launched between 2002 and 2006 (Oxfam International, 2007). Shaffer and Brenner found prices to be substantially higher in Guatemala for medicines with data protection and that this also delayed generic entry (Shaffer and Brenner, 2009).

[4] Cases that had received an extension of the patent term.

[5] PPR Final Report, p. 161 citing Palmedo, 2013.

[6] See http://www.unsgaccessmeds.org/#homepage-1. The final report was due in June 2016, but is still being finalised. One member of the Panel was retired High Court Judge Michael Kirby.

> objective weighing of evidence and transparency. Subject to measures to protect the privacy of patients, the results of all clinical trials should be accessible to researchers and the public, in order to expand access to knowledge and enable the data to be evaluated by others."

Phase IV data

Although clinical trials have reasonably large samples, it is an accepted fact that these samples are not large enough to identify all situations where a medicine is contra-indicated. As a result Phase IV trials are critical to good health outcomes. Phase IV "trials" refers to analysis of the data that emerges after a medicine has been approved for the market.

My understanding is that current arrangements are aimed at ensuring that any adverse outcomes are reported to the originator company, and in turn originator companies must report these data to the relevant public authorities.[7] There are many examples where medicines have been removed from the market following the assessment of such data.[8] The TGA makes their adverse event reports database available for public searching.

What is less clear is whether there are proper incentives for fuller post-marketing studies by independent researchers allowing comparisons of the effectiveness and safety of alternative medicines.[9]

New medicine are only assessed in terms of safety and efficacy compared to a placebo. Thus the 60th low dose oral contraceptive pill is only assessed against a placebo not against already approved medicines in this class. The same holds true of the numerous statins on the market. This seems a very poor approach, form a health perspective, and does not allow adequate information about the comparative effectiveness of similar medicines.

In countries where there is public subsidy of pharmaceuticals there is a strong case for health and prescription data to be used automatically – that is without any need to individual patient consent – to compare similar pharmaceuticals to determine which are more effective in which circumstances. Goldacre makes a compelling case, for the UK, for using National Health Service data to randomly prescribe two well-regarded statins to determine whether and when there is any difference in outcomes. Now that Australia has built the infrastructure for linking health data, there should also be a requirement that anyone benefitting from PBS-listed medicines be deemed to have given consent for data on health outcomes from that drug to be used for Phase IV assessments. This should include – where needed – random assignment of a medicine where two or more alternatives are equally indicated and their relative efficacy is unknown. Such data should be made available for research purposes. Their analysis would add substantial to public knowledge of health treatments and health outcomes.

Patent data / ability to analyse industrial innovation

The government grants over 17,000 standard patents a year yet collects no data on how these monopoly rights are used. This is despite the then government having accepted a

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[7] The Therapeutic Goods Administration (TGA) reports that most adverse events are reported by the originator company or its licensee (the sponsor in TGA terms) (https://www.tga.gov.au/medicines-and-vaccines-post-market-vigilance-statistics-2014).

[8] See https://en.wikipedia.org/wiki/List_of_withdrawn_drugs.

[9] One cannot rely on companies to do this. For example, desvenlafaxine is the major metabolite of venlafaxine and performs the same function. It has been deemed equivalent for prescribing purposes. Nonetheless its owner, Pfizer, has never released any comparative data. Pfizer has undertaken clinical trials involving both medicines, but the research protocols were not designed for comparison purposes.

1984 recommendation to do so. The recently produced IPGOD database is a marked improvement over previously available data. I provided some comments on the availability of data on patents and innovation in my submission to the inquiry on intellectual property arrangements and repeat these here.

Extract:

> To properly evaluate the impact of granted patents, specific patent data need to be linked to the owner firm, with appropriate economic variables about that firm. Some elements of that have recently been put in place with the new IPGOD database (Man, 2014). …[T]his new database … [finally] implements the 1984 IPAC recommendation on industry data – albeit at a very high level of abstraction. I also note that it builds on the firm linkage capacities developed by the ABS as a result of the experimental three-year Business Longitudinal Survey.
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> A number of variables about the patent need to be added, most particularly data about how the patent is used. Given the strength of the "powerful exclusive right" it seems reasonable to require the owner to advise IP Australia whenever a patent is used. This is particularly needed for any legal uses, whether it be a simple solicitor's letter or a full-blown litigation matter. Responding to solicitor's letters takes real time and effort, diverting resources in the threatened business from their own priorities. It takes time to search for the evidence that such patents are likely invalid. Including the name of the party sued or threatened would allow researchers to link information about those who benefit and those who pay. It is improbable that a legal threat of infringement would be made against any firm but an innovating firm.
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> Beyond this, regular in-depth research into particular industry sectors where Australia has an apparent or potential competitive strength would not only allow a deeper understanding of innovation and commercialisation, but would also provide a basis for comparing the full range of government programs and policies which support innovating firms. Such studies would allow the role of patents to be seen in the perspective of the broader taxpayer-funded innovations incentives. If such studies were repeated at intervals a real depth of knowledge could be built. This would provide a sound basis for policy advice about the patent system and other innovation supports.
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> For a number of years IP Australia funded the Intellectual Property Research Institute of Australia (IPRIA), which allowed this small group of University of Melbourne researchers to develop a real depth of knowledge and systematically address a number of policy-related issues. The basis on which IP Australia withdrew this funding, in favour of internal economic expertise is unknown. Certainly it is the case that IPRIA had academic independence, while IP Australia's economists do not. One positive outcome of the move has been IPGOD, but this is a high price to pay for the lack of sound funding for independent analysis.
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> The national innovation surveys that first made their appearance in the 1990s have provided some limited information useful for evidence-based policies. These surveys were, however, developed by science and technology specialists (the Oslo and Frascati manuals), so paid limited attention to patents. From the Yale and Carnegie Mellon surveys we know of important questions that can and should be added to the national innovation surveys. As a priority we need to know more about when innovating firms are blocked in their R&D and commercialisation plans because of the patents held by others. We also need much clearer information as to the relative importance of a patent in inducing an innovation.

> The second major gap in policy-relevant evidence is the cost and speed of copying. {Such data] needs to pay attention to the relative quality of the original and copied product as this will impact on the size of the market for the original innovator. Data on Chinese and Indian capacities in this area are particularly needed.
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> Measuring the height of the inventive step in terms of expert assessment of the new knowledge contributed by granted patents would be of considerable value. Proposals along these lines were made to the 2009 Senate Community Affairs Committee Inquiry into Gene Patents. Such independent audits would help IP Australia to maintain balance in their examination work.
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> I would also like to see at least basic annual data on the number of Patent Attorneys licensed to operate in Australia each year. I tried to obtain such data in 2007 but was told it was "too hard". Given that these professional groups have protected status – never evaluated – under the patent act, regular reporting of basic data to the public and parliament seems a minimal return.

Confidence and trust in data: the Centrelink case

The submission to this inquiry by the Department of Social Services (submission 10, p.10) states that "In the social security portfolio alone, there was almost $3.5 billion of social welfare debt as at 30 June 2016." It then goes on to discuss a 'tell us once' approach. A 'tell us once' approach is essential for increasing confidence and trust in government in respect of the systems it administers and the data it requires. Other agencies have similar problems. The multiple databases in the then Department of Immigration, and the fact that these could not be linked, became public knowledge in the aftermath of the Cornelia Rau (aka Anna Brotmeyer) case in 2004.

Perhaps the Department of Social Security (DSS) could start by implementing a 'tell us once' approach for all pensions and benefits. It is my understanding that much of the "social welfare debt" – though there is little clear reporting on this issue because clients have to report the same information multiple times – is due to overpayments caused by the requirement for multiple reporting of the same data. If clients do not report the same data multiple times they incur a debt. It is shocking that people on very low incomes are forced into debt because of the poor design of social security systems. Indeed there is a strong case that over-payment debts created by the inadequacy of systems should be forgiven. Instead, large amounts of money are invested in recovering the "debts" rather than fixing the system deficiencies that create them. The 'tell us once' approach, apparently inspired by a 2011 UK births, deaths and marriages initiative, is an admirable goal, but it remains to be implemented. In the meantime DSS should report regularly to parliament on the proportion of debt caused by pensioners and beneficiaries having to report the same facts more than once, and the cost of fixing the consequent debt issues.

Privacy

It is often assumed that consumers have choice and if they dislike the terms and conditions of one supplier they can use another. However, in many markets, there is little variation in what is offered. A prime example is telecommunications. I believe all companies in Australia offering pre-paid mobile phone services, include that if funds are left at the end of a period (often only 30 days), then they will disappear if no new funds are added. This is clearly a form of theft (money taken in exchange for no benefit), but the only way a consumer can prevent this is to pay new money. Similarly with cookies. If one wants to use a service – such as buying a plane or train ticket on-line – then cookies are compulsory. Yes, in theory, one can refuse to allow cookies, but

then there is no way to buy the product. This is rather like banks' "privacy policies" which are as much about telling you how they will use your data to market to you as they are about how they will protect your data from misuse. In one recent transaction where I was buying an organised tour of an overseas country, the fine print included the ability of the tour operator to share my credit card data with whomsoever they chose.

Consumers have little ability to buy the goods and services they want without being forced into such compulsory data disclosures. There have been some efforts to provide safeguards. For example in telecommunications there is a Customer Service Guarantee. But if a provider deems the telephone element of a package (e.g. a VOIP service) to be provided free as part of a bundle of services, then they can make waiving the Customer Service Guarantee a condition for selling the package.

I do not believe that privacy protections are strong enough to over-ride companies' excessive uses of personal data for marketing purposes – whether through cookies, analysis of cash register data or other means. I would welcome stronger arrangements through which such practices can be challenged and removed.

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