The free trade agreement between Australia and the United States

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diminish the drive for more prudent antibiotic prescription. Group level studies may be helpful, but only if known to produce convergent data with individual linked studies. Donnan et al have shown that data can be analysed at an individual level without compromising confidentiality issues. Further clarification of when and where such data provide added benefit is required.

We ignore the risks from increasing antibiotic resistance at our peril. Reduced antibiotic prescribing is beginning to occur and may be leading to reduced resistance in *Streptococcus pneumoniae*. No good evidence of harm has been produced. The drive for more appropriate prescribing of antibiotics in the community should continue.

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Undermines Australian public health and protects US interests in pharmaceuticals

On 4 March 2004 Australia and the United States released the text of a bilateral trade agreement designed to reduce trade barriers between the countries.[1] Surprisingly, the Australian pharmaceutical benefits scheme (the national drug subsidy programme operated by the federal government of Australia) was part of the deal, with Australian negotiators conceding to several US demands. These included the creation of an independent review body to examine drugs rejected by the Pharmaceutical Benefits Advisory Committee. Under existing legislation only the advisory committee can recommend listing of drugs for subsidy. However, the dissenting views of another review body, supported by publicity and lobbying, may undermine the famously tough stance of this committee concerning the cost effectiveness and prices of pharmaceutical products. In addition, Australia has agreed to changes in intellectual property protection that, among other things, increase the risk of delayed entry of generic drugs on to the Australian market. The use of the trade agreement to push the interests of US pharmaceutical companies is one in a long list of hostile moves that have included legal challenges to the decisions of the Pharmaceutical Benefits Advisory Committee to reject drugs for subsidy and political lobbying for removal of committee members.[2]

This trade agreement, however, is of wider importance. It follows a pattern of trade agreements by the United States (with Jordan, Chile, and Singapore) that contain long chapters on intellectual property. These represent a retreat from the principles espoused in the Doha declaration of the World Trade Organisation (WTO), which stated that the agreement on trade related aspects of intellectual property rights (TRIPS) should be interpreted and implemented so as "to protect public health and, in particular, to promote access to medicines for all."[3] This was a major step forward for public health and access to medicines. The bilateral trade agreements now being negotiated by the United States seem to be designed to undermine the Doha agreement and promote a particular business model for the production of medicines that is based on ever stronger patent protection.

TRIPS forms one of the pillars of the WTO. One of the most important obligations in TRIPS is the recognition of patents in any field of technology for both products and processes. This in effect globalises the patenting of pharmaceutical technologies. As the HIV/AIDS epidemic grew, and patented (but expensive) antiretroviral drugs became available in rich countries, the full implications of TRIPS for access to long term treatment by poor people became clear. The adoption of the Doha declaration in 2001 to address this problem was crucial. The declaration is really a bill for rights for the public health regulation of medicines. Lying at its core is the recognition that WTO members

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have the right to interpret and implement TRIPS in ways that places public health before trade. But large pharmaceutical companies in the United States and Europe have seen risks to their profits in the Doha declaration. With the public gaze fixed on TRIPS and the WTO they have encouraged the proliferation of bilateral trade agreements that contain intellectual property standards that are much stronger than those to be found in TRIPS.

The Australian-US agreement follows the template that US negotiators use for intellectual property in all such trade negotiations. Compulsory licensing of patents is prohibited except in three circumstances (TRIPS permits compulsory licensing in any circumstances if certain conditions are met). Provisions exist that require US standards of exclusive protection for test data that are submitted as part of the process for gaining marketing approval for pharmaceutical products (TRIPS simply requires its members to protect against unfair commercial use and does not specify a period of protection). Other provisions require parties to offer patent term extensions for pharmaceuticals (not required by TRIPS). On the important issue of parallel trade the Australian-US agreement gives the patent owners greater control over the importation or re-importation of their products. TRIPS expressly steers away from setting a standard on parallel trade.

Some of the greatest risks to Australia, however, may come from the procedures to resolve disputes. The United States and Australia could take different views of Australia's obligation to provide an "independent review" of decisions made by the Pharmaceutical Benefits Advisory Committee, because the meaning of this term has not been specified. The fate of Australia's pharmaceutical benefits scheme could come to lie in the hands of a three member trade panel set up under the trade agreement. If Australia lost and did not comply with the judgment of the panel the United States could retaliate by suspending the benefits to Australia in other sectors affected by the trade agreement, putting pressure on the Australian government to make concessions on drug listing and pricing. Noteworthy here is the fact that Australia has agreed to a procedure to resolve disputes that allows for the possibility of non-governmental persons or entities to make submissions. The US pharmaceutical industry, and its lawyers, will no doubt see an opportunity here.

The United States offers no room for negotiation on intellectual property in trade agreements. The law in the United States requires that the country's trade negotiators bring back US standards of intellectual property protection. A committee, which advises Congress on intellectual property and trade, vets the intellectual property chapter in each trade agreement. The committee's membership includes Eli Lilly, Merck, Pfizer, the Pharmaceutical Research and Manufacturers of America, and the Biotechnology Industry Organization.[4]

Bilateral trade agreements and TRIPS together provide the US pharmaceutical industry with a means of strengthening and enforcing patent monopolies globally. They are a covert form of private governance that threatens to undermine hard won public gains in health regulation around the world. The United States is currently negotiating, or is about to start negotiations, with 13 other countries. Countries entering into such arrangements are engaged in a high stakes gamble with their public health systems.

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Cervical screening

Recent changes in policy regarding age and frequency are a poor use of resources

Two expensive healthcare practices have recently been endorsed as policy in England and Wales.[1] One is continuing to invite women over 50 for cervical screening; the other is shortening the screening interval from five years to three for younger women. National decisions on single issues disregard competing needs and force local decision makers to neglect other, more pressing, problems.

To inform its decision the NHS cervical screening programme commissioned a case-control analysis.[2] The difference between three yearly and five yearly screening is too small to measure, which is why we are having to use estimates, despite a huge natural experiment involving widely differing screening intervals throughout the nation and worldwide. The analysis estimated that, for women under 40, the risk reduction is 30% with five yearly screening and 41% with three yearly screening.[2] For women aged 40-54 years it is 63% and 69% respectively. The paper mentioned that three yearly screening costs 60% to 66% more than five yearly, and harm from over-diagnosis and over-treatment increases as screening interval decreases. This seems to have had no influence on the recommendations.

What does the new guidance mean for a typical local programme? The Avon programme offers five yearly screening to 250 000 eligible women. Each year 59 000

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