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Dealing Drugs with the Bush

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The past year in bioethics in Australia has been relatively predictable. We continue to struggle with rising healthcare costs, though thankfully not on par with numerous other countries due to a relatively positive economic outlook. We are still fighting difficulties associated with higher medical indemnity costs, which have again caused many physicians to leave private practice, particularly in high-risk and specialty practice areas. In response, the federal government (following a shuffle of ministerial positions including that of the federal health minister) delayed the imposition of the medical indemnity levy for physicians until mid 2005.[1] In May, the Australian Law Reform Commission and the Australian Health Ethics Commission issued their final joint report on genetic testing entitled "Essentially Yours"[2] and endorsed use of genetic tests by insurance companies, despite the concerns of some geneticists and many members of the public about their scientific reliability.[3] However, they also advocated the establishment of the Human Genetics Commission of Australia (HGCA) to oversee such uses of genetic tests in terms of both scientific and actuarial reliability, and debates continue over the implementation of this and a number of their other recommendations. And state governments continue to phase in smoking bans in public places, with most implementing full bans in enclosed restaurants and cafes and planning to require provision of nonsmoking areas in all pubs within the next year.

But perhaps the most intriguing development of the year was the economic assault on Australian health by the United States, not well covered even in the Australian media except as an occasional aside in longer discussions on U.S.-Aussie relations. In this case, the target is control over the costs of pharmaceuticals as provided under Australia's Pharmaceutical Benefits Scheme (PBS), which is part of the public health insurance system. The U.S. pharmaceutical industry was relatively successful in defeating price controls over prescription drugs in the United States during 2003, and legislation recently passed by Congress as part of the Medicare prescription drug benefit package specifically prohibits the government from attempting to negotiate lower drug prices. So now they have turned their sights on Australia, with assistance from the Bush administration under the auspices of an ongoing free-trade negotiation.[4] Ultimately, this negotiation is an attack on the public health insurance system that delivers decent care to all Australians, for roughly half what Americans pay under their private system (in terms of percentage GDP) but

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on a par with what other developed countries with public health insurance schemes pay.

The PBS has operated in some form in Australia for over 50 years, evolving from a service to provide a limited number of "lifesaving and disease-preventing drugs" free of charge to the community, into a broader subsidized scheme around 1960 for access to generic drugs available in different forms and marketed under different brand names.[5] The PBS in its current form was established in part to achieve the objective of "securing a reliable supply of pharmaceutical products at the most reasonable cost to Australian taxpayers and consumers."[6] It involves a system of regulated prices and per-unit subsidies on many prescription medicines (2,500 in total are currently on the formulary). The maximum cost for a pharmaceutical benefit item on the PBS is currently AU$23.10 for general patients and $3.70 for concessional patients (e.g., pensioners, disabled and unemployed persons); nearly 80% of the total expenditure goes toward prescriptions for concession card holders.[7] On average for every dollar people spend out of pocket at the chemist on PBS-subsidized medicines, the government contributes $5. In 2001–2002, the total subsidy amounted to 0.6% of GDP and 15% of total federal health expenditure.[8] Predictions are that this system is unsustainable in its current form for several reasons: increasing costs (due to new, increasingly more expensive drugs being listed), overprescribing, leakage (drugs with more than one indication having differential cost-benefit ratios; see below for more detail), consumer demands, an aging population, and, not least of all, aggressive marketing by the pharmaceutical industry.

To be listed on the PBS in Australia, a drug must be assessed for its safety, quality, and efficacy by a committee under the auspices of the Therapeutic Goods Administration (TGA), and application must then be made to the Pharmaceutical Benefits Advisory Committee (PBAC) for listing on the PBS. Applications are generally made by pharmaceutical companies but can also be put forward by professional medical bodies, health professionals, private individuals, and their representatives. The PBAC assesses the evidence for the drug's effectiveness, including its cost-effectiveness, and makes a recommendation to the Minister for Health and Ageing as to whether the drug should be listed. If the Minister accepts the recommendation, the drug is then referred to a pricing authority that negotiates with manufacturers on the price at which the drug will be listed. This process establishes whether the drug is cost-effective—that is, "whether at the agreed price it yields an additional unit of health benefit at less cost than the next best alternative drug."[9] There is also negotiation over how much of the additional net health benefit that would be created by regulating the drug via the PBS should be transferred back to the pharmaceutical firm via the agreed price paid by the patient (as discussed earlier, some "leakage" can occur here if the drug has more than one indication, or a different indication emerges later). Of course, pharmaceutical companies that produce drugs in the same therapeutic class compete with each other to maximize these tradeoffs.

As persuasively argued by Sydney economist Donald Wright, there are options available to pharmaceutical companies outside the PBS—that is, they can choose not to invest in the process of applying to the PBAC and engaging in the bargaining process, if the amount they will receive should the drug become PBS-listed would not produce a profit. In fact, Wright shows (using a

Nash bargaining model) that a regulated pharmaceutical firm (one whose drug goes through the PBS negotiation process) is unambiguously better off than it would be in an unregulated environment. Even though the agreed price between the government and the pharmaceutical company for a PBS-listed drug is less than for the same drug on the "open market," the total profit is a function also of the quantity of the drug sold at the regulated price, which is considerably more than would be sold at an unregulated, or non-PBS subsidized, price, particularly in a competitive drug class.[10]

By way of comparison, consider other countries with universal eligibility for public pharmaceutical subsidies within public health insurance schemes, such as Sweden, France, Spain, New Zealand, and the United Kingdom. Manufacturer prices for top-selling pharmaceuticals in Australia are similar in pricing to France, Spain, and New Zealand, although prices are around 50% higher in Sweden and the United Kingdom. For new pharmaceuticals, the gap is even less, with similar prices in all of these comparison countries except the United Kingdom, where the price is 54% higher. On the other hand, prices for top-selling drugs in the United States are at least 162% higher (and still 84% higher when discounts are taken into account) than in Australia, and 104% higher on new or innovative drugs considered alone.[11] Clearly, there is a gap, but in which system, and along which sociopolitical as well as economic axis?

Against this historical and economic backdrop, the multinational pharmaceutical companies approached the U.S. Congress in 2003. In retrospect, we Australians received subtle warning cues from our government about anticipated threats to the system around mid 2003, in the form of enhanced public education campaigns about PBS and its structure, and new labeling that details the full cost of drugs, not just the patient contribution. The recent U.S. Medicare reform bill explicitly requires further examination of "free trade" and competition within the international pharmaceutical market[12] and, according to the *New York Times*, "requires the Bush administration to apprise Congress on progress toward opening Australia's drug pricing system"[13] as part of a more general challenge being mounted against foreign government "price controls," notably those used in Canada. This negotiation is part of a broader one with Australia over agricultural exports and imports of other types of American goods.[14]

Although the attempts by big pharma to bring Australian prices more in line with those of the United States are understandable in terms of propping up their bottom line, they are not defensible ethically. Spokespersons for various pharmaceutical companies have claimed that the negotiations are justified because other countries do not pay for their "share" of pharmaceutical research,[15] but adequate evidence has not been presented to support this claim, particularly for developed countries such as Australia that do have large federally funded medical research programs (and commit monies to some types of innovative research that are less strongly supported in the United States—for instance, in reproductive technologies and stem cell therapies). If such a gap indeed exists in terms of contributions to development and research of pharmaceuticals in relation to population, per capita income, and so on, the Australian system already allows pharmaceutical companies to negotiate their prices accordingly or choose instead to offer their products to consumers outside the PBS, as many (often more expensive) drugs are currently supplied. Ethical questions may be raised if access to the most appropriate drug for a

particular patient or disease condition becomes wholly unavailable through the PBS and economically unaffordable out of pocket, but so far the system has worked quite well.

Australia is playing the big pharma game, negotiating rather effectively to further its ideals of providing high-quality healthcare for all at reasonable prices in a relatively efficient manner, though admittedly the system sometimes falls short as might be expected. As of early February 2004, an agreed text for the Australia–United States Free Trade Agreement had been formulated. Australian negotiators have stated publicly that they do not consider the PBS to be negotiable: "The Government remains committed to ensuring access to affordable medicines through a sustainable PBS, and negotiation of an FTA with the U.S. will not compromise these commitments."[16] Perhaps the bottom line was best summarized by Mark Vaile, the Australian Minister for Trade, when he was quoted as saying, "It is different in Australia. We are a differently structured society."[17] And at least when it comes to our PBS and our public health insurance system, we'd like to keep it that way.

Notes

1. Radio National. The medical indemnity dispute. *Australia Talks Back* 7 Oct 2003. Available at: http://www.abc.net.au/rn/talks/austback/stories/s961268.htm.
2. Australian Law Reform Commission. *ALRC Report 96: Essentially Yours: The Protection of Human Genetic Information in Australia*. Sydney: Australian Law Reform Commission; 2003. Available at: http://www.austlii.edu.auauother/alrc/publications/reports/96/.
3. See, e.g., Salleh A. Gene tests: too unreliable for insurance? *ABC Science Online* 29 Aug 2003. Available at: http://abc.net.au/science/news/health/HealthRepublish_934272.htm.
4. Becker E. Drug industry seeks to sway prices overseas. *New York Times* 27 Nov 2003:A1 (late ed.).
5. Biggs A. *The Pharmaceutical Benefits Scheme: an overview*. Canberra: Department of the Parliamentary Library, Parliament of Australia; last updated 2 Jan 2003. Available at: http://www.aph.gov.au/library/intguide/SP/pbs.htm. See also: Sloan C. *A History of the Pharmaceutical Benefits Scheme 1947–1992*. Canberra: Department of Human Services and Health; 1995.
6. Prescription Benefits Pricing Authority. *Annual Report for the Year Ended 30 June 2000*. Available at: http://www.health.gov.au/pbs/general/pricing/pbparpt.htm.
7. Full details on the PBS are available at: http://www.health.gov.au/pbs/index.htm.
8. Wright DJ. Profitability and leakage under the PBS. *The Drawing Board: Australian Review of Public Affairs* 8 Dec 2003. Available at: http://www.drawingboard.info.
9. See note 8, Wright 2003.
10. See note 8, Wright 2003.
11. Statistics drawn from Biggs; see note 5, Biggs 2003.
12. Available at: http://www.cms.hhs.gov/medicarereform/, last viewed 16 March 04.
13. See note 4, Becker 2003.
14. On the Australian point of view on the free-trade negotiation, see: Australian Department of Foreign Affairs and Trade. Available at: http://www.dfat.gov.au/trade/negotiations/us.html, last viewed 16 March 04.
15. See note 4, Becker 2003. For evidence to the contrary, see: Light DW, Lexchin J, Will lower drug prices jeopardize drug research? A policy fact sheet. The *American Journal of Bioethics* 2004;4(1): W3–W6.
16. Australian Department of Foreign Affairs and Trade. *AUSFTA Briefing No. 4, 2003*. Available at: http://www.dfat.gov.au/trade/negotiations/us_fta/newsletter/ausfta_4_03.html. Last viewed 16 March 04.
17. See note 4.