# CONSOLIDATING PHARMACEUTICAL REGULATION DOWN UNDER: POLICY OPTIONS AND PRACTICAL REALITIES

Frances H. Miller*

*You think countries run the fucking world? It's 'God save our multinationals' they're singing these days.* – John LeCarré, THE CONSTANT GARDENER, (2000), 401

## INTRODUCTION

Pharmaceutical regulatory agencies struggle worldwide to maintain public trust these days. Drug safety issues proliferate,[1] the costs of pharmaceuticals take increasingly larger shares of most countries' health service spending,[2] and conflicts of interest afflicting the drug approval and marketing processes capture more and more public attention.[3] The Australian and New Zealand governments are keenly aware of these problems, and have been attempting to forge a regulatory alliance to combine their respective pharmaceutical regulatory agencies, Australia's Therapeutic Goods Administration (TGA) and New Zealand's Medicines and Medical Devices Safety Authority (Medsafe), into the pending Trans Tasman Therapeutic Products Authority (ANZTPA, or TPA). If this effort succeeds, it could serve as a model of cost-effective regulatory cooperation for the rest of a transparency-seeking world to emulate. If it does not, a unique opportunity to merge national pharmaceutical regulatory operations to cope more effectively with 21st century global realities will have been lost.[4]

Writing about Australia and New Zealand's pending regulatory consolidation has its surreal aspects, particularly from afar, since as of this writing the whole venture hangs on

* Professor of Law, Boston University School of Law; Professor of Public Health, Boston University School of Public Health; & Professor of Health Care Management, Boston University School of Management. Craig Marinho, Class of 2007, Boston University School of Law, provided valuable research assistance for this article. Thanks also to Professor Vincent Banz of the University of Queensland Law Faculty, for his aid in obtaining research materials unavailable outside Australia, and to Professor Peter Davis, Department of Sociology, University of Auckland, for his helpful comments.

1 Phil B Fontarosa, Drummond Rennie and Catherine D DeAngelis, 'Postmarketing Surveillance: Lack of Vigilance, Lack of Trust' (2004) 292(21) *Journal of the American Medical Association* 2647.

2 *Drug Spending in OECD Countries Up By Nearly a Third Since 1998, According to New OECD Data* (1998) Organisation for Economic Co-operation and Development, <http://www.oecd.org/document/25/0,2340,en_2649_33929_34967193_1_1_1_1,00.html> at June 8 2005; Manfred Huber and Eva Orosz, *Health Expenditures in OECD Countries: 1990-2001* (2003) [17] <http://www.cms.hhs.gov/apps/review/03fall/03fallpg1.pdf> at 1 September 2006.

3 Jerome P Kassirer, *On The Take: How Medicine's Complicity with Big Business can Endanger Your Health* (2005); Peter Lurie, et al, 'Financial Conflict of Interest Disclosure and Voting Patterns at Food and Drug Administration Drug Advisory Committee Meetings' (2006) 295(16) *Journal of the American Medical Association* 1921; *FDA Announces Plan to Strengthen Advisory Committee Processes* (2006) US Food and Drug Administration <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01416.html> at 24 July 2006; cf Luke Timmerman and David Heath, 'Drug researchers leak secrets to Wall St', *Seattle Times*, 7 August 2005, 1.

4 Cf, eg, Alastair J J Wood, 'A Proposal for Radical Changes in the Drug Approval Process' (2006) 355(6) *New England Journal of Medicine* 618.

passage of enabling legislation still mired in distant political maneuvering.[5] Perhaps some observations about the accomplishments and shortcomings of two well-known pharmaceutical harmonization schemes from other areas of the world, both of them less comprehensive than the merger envisioned for ANZTPA, can illuminate why the pending joint venture holds so much promise for Australia and New Zealand.[6] Cooperative efforts such as those of the European Union's European Medicines Agency (formerly the European Medicines Evaluation Agency, and still known by the acronym EMEA)[7] and the International Conference on Harmonization (ICH), an inter-continental government/industry-sponsored organization dedicated to a achieving a more transparent regulatory approach among the world's three major pharmaceutical-consuming areas (the EU, the U.S. and Japan),[8] offer an illuminating preview of the problems and prospects associated with harmonizing the often-disparate national policies, cultural issues and ethical approaches inevitably involved when attempting to regulate therapeutic products in a cooperative context.[9]

## BACKGROUND

Three per cent of total world trade now consists of commerce in therapeutic products, mostly among the wealthier nations of the globe, and pharmaceuticals constitute Australia's biggest high-technology manufactured export.[10] Meanwhile, New Zealand leads the world in keeping prescription drug costs stable courtesy of PHARMAC, the government's high-profile purchasing authority, notwithstanding normal levels of drug consumption for a developed country. PHARMAC outpaces all other industrialized countries in holding down the cost of supplying prescription drugs to New Zealand's population through its strict competitive tendering rules and reference pricing processes.[11] Australian prescription drug prices are generally lower than those of other westernized nations as well — for example sometimes up to 50% or more lower than those usually found in the US[12] — thanks in part

---

[5] As of this writing, whether the New Zealand government can secure a coalition vote sufficient to pass the ANZTPA enabling legislation remained unclear.

[6] For a quick overview of the cooperative regulatory initiatives engaged in by the US Food and Drug Administration, see David Kelly and Lawrence L Bachorik, 'Promoting Public Health and Protecting Consumers in a Global Economy: An Overview of HHS/FDA's International Activities' (2005) 60 *Food and Drug Law Journal* 339.

[7] Regulation (EC) no. 2309/93 (creating European Medicines Agency); European Medicines Agency <http://www.emea.eu.int/> at 23 August 2006.

[8] The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, <http://www.ich.org/cache/compo/276-254-1.html> at 23 August 2006. See generally, Justina A Molzon, 'The International Conference on Harmonization Common Technical Document – Global Submission Format?' (2006) 60 *Food and Drug Law Journal* 447; J John Lee, 'Comment: What Is Past is Prologue: The International Conference on Harmonization and Lessons Learned from European Drug Regulations Harmonization' (2005) 26 *University of Pennsylvania Journal of International Economic Law* 151; cf, Arthur A Daemmrich, *Pharmacopolitics: Drug Regulation in the United States and Germany* (2004).

[9] See Dan Kidd, 'The International Conference on Harmonization of Pharmaceutical Regulations, The European Medicines Evaluation Agency, and the FDA: Who's Zooming Who' (1996) 4 *Indiana Journal of Global Legal Studies* 183.

[10] *World Trade Report 2005* (2005) World Trade Organisation [25] <http://www.wto.org/english/res_e/booksp_e/anrep_e/world_trade_report05_e.pdf> at 1 September 2006.

[11] *New Zealand Public Health and Disability Act 2000* (NZ) s 47.

[12] *International Pharmaceutical Price Differences – Research Report* (2001) Productivity Commission <http://www.pc.gov.au/study/pbsprices/finalreport/pbsprices.pdf> at 21 August 2006.

to the cost-effectiveness criteria the Pharmaceutical Benefits Scheme (PBS) uses in determining which medications can be covered by the government's universal health insurance.[13] Several US state governments even defiantly formed a consortium in 2005 to save their residents money by purchasing the drugs they need Down Under,[14] notwithstanding the US Food & Drug Administration's (FDA's) prohibition on importing pharmaceuticals through gray market channels[15] where counterfeit drugs can be more easily slipped into the US supply chain.[16]

Citizens of the world's poorer countries, meanwhile, often suffer needlessly for lack of the routine and relatively inexpensive medications which could ameliorate the devastating consequences of such global public health scourges as malaria, tuberculosis and HIV-AIDS.[17] Existing medications could also go a long way toward improving the health of people in poorer nations suffering from chronic conditions such as diabetes, arthritis, depression and hypertension. Unfortunately, however, such products are usually priced out of reach for impoverished patients in these countries thanks to the pharmaceutical patent monopoly.[18]

---

[13] See generally, Stephen J Duckett, 'Drug Policy Down Under: Australia's Pharmaceutical Benefits Scheme' (2004) 25(3) *Health Care Financing Review* 55: The cost-effectiveness guidelines used by PBS, provide that a drug will be listed if it is: 1) needed for preventing or treating significant medical conditions not already covered, or inadequately covered, by existing PBS drugs, and is acceptably cost-effective, 2) more effective, less toxic (or both) than a drug already listed for the same reasons, and is acceptably cost-effective, and 3) at least as safe and effective as a drug already listed for the same reasons, and shows similar or better cost-effectiveness (at 59).

[14] Samantha Zee, *Illinois to Buy Drugs in Australia, New Zealand, Governor Says* (2005) Bloomberg <http://www.i-saverx.net/assetsrx/071905_bloomberg.pdf> at 21 August 2006; The majority of US state legislative proposals to purchase less expensive drugs extra-territorially have focused on cross-border purchases from Canadian pharmacies. See generally, Aiden Hollis and Peter Ibbott, 'How Parallel Trade Affects Drug Policies and Prices in Canada and the United States' (2006) 32 *American Journal of Law and Medicine* 193; Mary Ellen Fleck Kleiman, 'State Regulation of Canadian Pharmacies: A Prescription to Violate the Supremacy Clause' 32 *American Journal of Law and Medicine* 219.

[15] 21 USC § 331; *Importing Drugs from Foreign Sources* (2006) Food and Drug Administration <http://www.fda.gov/importeddrugs/> at 18 August 2006; *Letter to Governor Kenny Guinn* (2005) Food and Drug Administration <http://www.fda.gov/oc/opacom/hottopics/importdrugs/guinn052005.html> at 20 May 2005: outlining legal framework regarding Nevada legislation to license Canadian pharmacies to import prescription medicines into Nevada.

[16] See generally, Bryan A Laing, 'Fade to Black: Importation and Counterfeit Drugs' (2006) 32 *American Journal of Law and Medicine* 279.

[17] Kevin Outterson, 'Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets' (2005) 5 *Yale Journal of Health Policy, Law and Ethics* 193; *Selection and Rational Use of Medicines* (2006) World Health Organisation <*http://www.who.int/medicines/areas/rational_use/en/*> at 21 August 2006; Lissett Ferreira, 'Access to Affordable HIV/AIDS Drugs: The Human Rights Obligations of Multinational Pharmaceutical Corporations' (2002) 71 *Fordham Law Review* 1133; Ellen 't Hoen, 'TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha' (2002) 3 *Chicago Journal of International Law* 27.

[18] Kevin Outterson, 'Patent Buy-Outs for Global Disease Innovations for Low and Middle-Income Countries' 32 *American Journal of Law and Medicine* 159; Tessa Richards, 'The great medicines scandal: New initiatives offer hope that global inequity in access to medicines will be reduced' (2006) 332 *BMJ* 1325 (editorial discussing several recent reports that helped galvanize the World Health Assembly to adopt resolution committing the World Health Organization to 'produc[e] . . . a blueprint for a new system of prioritizing and financing pharmaceutical research aimed at . . . diseases member states identify as health priorities . . . .').

Evaluating the safety and efficacy of medical products is a complex, expensive and time-consuming scientific endeavor,[19] and the approval process is permeated by both policy questions (should an eye to the cost-effectiveness or 'appropriateness' of a particular medication demonstrated to be relatively safe and effective matter in deciding the basic licensing question?)[20] and ethical dilemmas (how best should regulators be protecting the human subjects of pharmaceutical research?).[21] Many other factors – ranging from which products should be regulated (substantial opposition in New Zealand to regulating complementary medicines has held up passage of enabling legislation for ANZTPA, notwithstanding strong support for doing so from both the present and former health ministers),[22] to post-approval pharmacovigilance (which is notoriously lax, with adverse drug event reporting seriously inadequate and uncoordinated world-wide),[23] to widely variable governmental enforcement resources, will, and capacity[24] – also complicate the international regulatory picture.

In addition to those dilemmas, intellectual property questions bedevil adoption of a consolidated pharmaceutical regulatory regime from the margins. When is it ethically and legally permissible for countries to authorize manufacture of generic versions of 'foreign' drugs, if their patents have not yet expired?[25] Lingering controversies over the evergreening

---

[19] Jerry Avorn, *Powerful Medicines* (2004); Cf, Charles A Medawar & Anita Hardon, *Medicines Out of Control? Antidepressants and the Conspiracy of Goodwill* (2004).

[20] Elias Mossialos et al, 'Regulating pharmaceuticals in Europe: an overview' in Mossialos et al (eds) *Regulating Pharmaceuticals in Europe: Striving for Efficiency, Equity and Quality* (2004) 1; Cf, Peter Littlejohns and Mike Kelly, 'The changing face of NICE: the same but different' (2005) 366(9488) *The Lancet* 791 (U.K.'s National Institute of Clinical Effectiveness to take evidence of effectiveness and cost-effectiveness into account when issuing its guidances). See also, David A Henry et al, 'Drug Prices and Value for Money: The Australian Pharmaceutical Benefits Scheme' (2005) 294(20) *Journal of the American Medical Association* 2630 (contrasting the PBS with NICE).

[21] Baruch Brody, *The Ethics of Biomedical Research* (1998); Robert Gatter, 'Conflicts of Interestin International Human Drug Research and the Insufficiency of International Protections' (2006) 32 *American Journal of Law and Medicine* 351. Cf, Ganesh Suntharalingam et al, *Cytokine Storm in a Phase 1 Trial of the Anti-CD28 Monoclonal Antibody TGN1412*, <http://content.nejm.org/cgi/content/short/NEJMoa063842> at 14 August 2006.

[22] On the post-enactment saga of subjecting dietary supplements to (slightly additional) regulatory scrutiny in the U.S., See, 'Symposium Issue: The Dietary Supplement Health and Education Act: Regulation at a Crossroads' (2005) 31 American Journal of Law and Medicine, Nos 2 & 3.

[23] Frances H Miller, 'Medical Error, Adverse Drug Reactions & Patient Safety: The Precautionary Principle in the US and the EU' in *The Reality of Precaution* (Jonathan Weiner and Michael Rogers, eds. Cambridge University Press, forthcoming 2006).

[24] Mary K Olson, 'Agency Rulemaking, Political Influences, Regulation and Industry Compliance' (1999) 15 *Journal of Law, Economics and Organization* 573 (describing drop in FDA inspections accompanied by increase in reported violations); Mary K Olson, 'Substitution in Regulatory Agencies: FDA Enforcement Alternatives' 12 *Journal of Law, Economics and Organization* 376, 404 (budget cuts force FDA to switch to less resource-intensive enforcement methods); Cf, James O'Reilly, 'Can the US Food and Drug Administration Act Against Global Frauds? The Extraterritorial Effect of Food and Drug Sanctions after Small v. United States' (2005) 60 *Food and Drug Law Journal* 347 (only 13% of Phase IV clinical studies required by the FDA as a condition of marketing approval completed within five years); Larry D Sasich et al, *The Drug Industry's Performance in Finishing Postmarketing Research (Phase IV) Studies – A Public Citizen's Health Research Reports*, HRG Publication No. 1520 (2000).

[25] Article 31 of the *World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS) permits governments to authorize compulsory licenses for patented inventions in public emergency emergencies, which include public health emergencies. The Doha Declaration Amendment to TRIPS explicitly stipulates that 'the TRIPS Agreement does not and

provisions of the 2004 Australia-United States Free Trade Agreement have highlighted relevant aspects of that problem for Australia. They prompted the Australian Government to enact anti-evergreening amendments to the implementing legislation, explicitly rejecting linking generic drug licensing to the patent status of the pioneer drug.[26] Another issue concerns whether the well-being of domestic pharmaceutical manufacturers should 'count' in an international regulatory process?[27] New Zealand's complementary health medications industry has made its opposition to closer regulation of 'alternative' products through the TPA abundantly clear in its presentations on the treaty.[28] Australia's PBS explicitly takes the economic health of the country's drug industry into account in making its recommendations for reimbursement, because one of the four objectives of its National Medicines Policy is 'maintaining a responsible and viable medicines industry'.[29] On the other hand, New Zealand PHARMAC's embrace of competitive tendering and reference pricing in structuring its pharmaceutical benefits package has allegedly prompted drug companies to cut back drastically on biotech research and development in that country.[30]

Other intellectual property questions often closely or loosely associated with pharmaceutical regulation include whether a manufacturer should be permitted to cease supplying a formerly-experimental medication to a clinical trial subject in the research that was required in order for its safety and effectiveness to be demonstrated.[31] For that matter, should a manufacturer be allowed for financial (including potential liability) reasons to abandon seeking licensure for a medication on which it holds a patent, once the drug's safety

---

should not prevent Members from taking measures to protect public health'. See, *The DOHA Declaration on the TRIPS agreement and Public Health*, The World Health Organisation, http://www.who.int/medicines/areas/policy/doha_declaration/en/index.html at 21 August 2006; Carlos M Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* (2002) <http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf> at 1 September 2006; Cf, David Vaver and Shamnad Basheer, 'Popping Patented Pills: Europe and a Decade's Dose of TRIPS' (2006) *European Intellectual Property Review* 202.

[26] See, Amendments (made by USFTA implementation act of 2004) to the therapeutic goods administration act of 1989. The anti-evergreening amendments are sections 26(b), 26(c), and 26(d), available at <http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/840CB0162B421D54CA256FBF00121547/$file/TherapeuticGoods1989_WD02.pdf>. See generally, Thomas Faunce et al, 'Assessing the impact of the Australia-United States Free Trade Agreement on Australian and global medicines policy' (2005) *Globalization and Health* 1:15, available at <http://www.globalizationandhealth.com/content/1/1/15>; Ken J Harvey et al, 'Will the Australia United States Free Trade Agreement undermine the Pharmaceutical Benefits Scheme?' (2004) 181(5) *Medical Journal of Australia* 256.

[27] Cf, Danny Fortson, 'EC moves against drugs "protectionism"', *The Independent*, 18 June 2006 (citing new EC guidelines narrowing loophole permitting member states to reject drugs produced by foreign manufacturers on grounds of 'potential serious risk to public health').

[28] See, eg, 'Toward a New Regulatory Model: Harmonizing Complementary Healthcare Products', statement of John Blanchard, President of the National Nutritional Foods Association of New Zealand, CHC Summit, March 2001 (advocating continued regulation of complementary healthcare products under the Food Act rather than through ANZTPA).

[29] *National Medicines Policy* (2000) Commonwealth Department of Health and Aged Care <http://www.nmp.health.gov.au> at 1 September 2006.

[30] Edward Watson, *Pharmaceutical Research and Development in New Zealand – On the Brink of the Abyss* (2006) Report commissioned by Pfizer Pharmaceuticals <http://www.pfizer.co.nz/Media/PharmRD.pdf> at 1 September 2006.

[31] Leonard H Glantz et al, 'Research in Developing Countries: Taking "Benefit" Seriously' (1998) 28 *Hastings Court Reports* 38 (for experimental studies on people in underdeveloped countries to be ethically justifiable, the manufacturer must make the benefits – if any – identified by those investigations economically available to that country's citizens).

and efficacy profile have appeared promising from initial clinical trial results?[32] People increasingly don't know what to believe or how they feel about pharmaceuticals and their manufacturers, their value, and their associated risks, not to mention their costs. More and more often the public is invited to distrust all parties involved.[33]

At the same time these complex issues are attracting attention world wide, pharmaceutical companies themselves are consolidating and gaining more influence on a global scale.[34] Pharmaceutical distributors,[35] retail sellers,[36] and the providers who prescribe — and often sell — medications to patients are combining and becoming more powerful in many countries too.[37] Small wonder that consolidation and enhancement of costly and sophisticated regulatory agency expertise has been on the minds of governments everywhere,[38] including — far from least — those of Australia and New Zealand.[39] Pharmaceutical industry giants tend to support broad harmonization efforts too, at least in

---

[32] For example, in 2004 Amgen Inc, the world's largest biotechnology company, halted clinical trials of intraputaminal glial cell line-derived neurotropic factor ('GDNF') for the treatment of Parkinson's disease because of alleged safety and efficacy concerns. The participants in the study and their physicians, however, claimed that Amgen's GDNF infusion therapy produced dramatic benefits. They filed preliminary injunction orders in two states to force Amgen to continue access to GDNF therapy, but both courts denied the orders and dismissed the actions. *Suthers v Amgen*, 372 F Supp 2d 416 (SDNY, 2005); *Abney v Amgen*, 443 F 3d 540 (6th Cir, 2006).

[33] Marcia Angell, *The Truth About Drug Companies: How They Deceive Us and What to Do About It* (2004); Jerry Avorn, *Powerful Medicines: The Benefits, Risks and Costs of Prescription Drugs* (2004); Charles Medawar and Anita Hardon, *Medicines Out of Control?* (2004). Cf, Michael A Steinman et al, 'Narrative Review: The Promotion of Gabapentin: An Analysis of Internal Industry Documents' (2006) 145(4) *Annals of Internal Medicine* 284 (detailing drug manufacturers' promotion tactics to stimulate demand for off-label use of neurotonin, the subject of a Medicare fraud prosecution in *US ex rel David Franklin v Pfizer Inc, and Parke Davis, Division of Warner-Lambert Co*, 2003 WL 22048255 (D Mass)).

[34] For example, Pharmacia and Upjohn merged in 1995, Glaxo Wellcome and Smithkline in 2000, etc.; Nicholas Zamiska, 'China Drug Firms Consolidate', *The Wall Street Journal*, 5 August 2005, A12 (In 2004 alone, the 5,000 drug companies in China's $10 billion pharmaceutical market shrank to 3,500, mostly because of mergers and acquisitions).

[35] *Federal Trade Commission v Cardinal Health Inc*, 12 F Supp 2d 34 (DDC, 1998) (Proposed merger of two of the four largest US drug wholesalers, already controlling 80% of the wholesale market, would render market too concentrated.) The number of U.S. drug wholesalers had already declined by 64% between 1978 to 1995, mostly through acquisitions. Simon Lorne and Joy Marlene Bryan, 'Acquisitions and Mergers: Negotiated and Contested Transactions, from Mergers and Acquisitions in Regulated Markets', Ch 9, §9.31, in *Securities and Exchange Commission Acquisitions and Mergers* (updated June 2006).

[36] Dennis K Berman and Amy Merrick, 'Rite Aid Nears a Deal for Eckerd, Brooks Chains - Purchase of $3.4 Billion From Canada's Jean Coutu Would Add 1,800 Stores', *The Wall Steet Journal*, 24 August 2006, 34. By way of contrast, pharmacists are limited to owning not more than five pharmacies apiece in Australia and New Zealand. *Pharmacy Practice Act 2004* s 25(1)(2), available at <http://www.dms.dpc.vic.gov.au/Domino/Web_Notes/LDMS/PubLawToday.nsf/95c43dd4eac71a68ca256dde00056e7b/8f606050c926ffcbca256fd900174854/$FILE/04-80a002.pdf> at 1 September 2006; *Medsafe Guidelines for Those Wishing to Operate a Pharmacy* (2006) New Zealand Medicines and Medical Devies Safety Authority <http://www.medsafe.govt.nz/Profs/PharmLicence/guidelines.htm#Ownership> at August 2006.

[37] Physician Payment Review Commission, *Annual Report to Congress* (1995).

[38] Richard Merrill, 'The Importance and Challenges of "Mutual Recognition"' (1988) 29 *Seton Hall Law Review* 736.

[39] *Agreement Between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products* (2003) <http://www.tgamedsafe.org/about/treatytext.pdf>f at 1 September 2006.

concept, in order to achieve swifter, less costly, and more predictable approval for their new products.[40] They also want to engage in the most efficient compliance possible for hassle-free licensing and global marketing purposes, understanding full well that the compromises often necessary to achieving international agreement usually result in lessening the most rigorous regime's regulatory strictures.[41]

The positions of interested stake-holders on many of these questions may well differ from those of government policy makers, rendering seamless regulatory cooperation exceedingly difficult. Australia and New Zealand have proved no exception to that rule, and this article will explore a few of these controversies which have proved troublesome in coming to final legislative agreement to go forward with the agency.

Politicians and the media currently berate pharmaceutical regulatory agencies for ignoring legitimate safety concerns,[42] for turning a blind eye to conflicts of interest on scientific advisory committees,[43] and for failing to safeguard the welfare of human subjects of medical research adequately.[44] On the other hand, manufacturers and some patient interest groups have long chastised drug regulators for having unnecessarily bureaucratic and lengthy licensing processes, and for burdening them with unnecessary reporting requirements in the aftermath of approval.[45] Controversies over the appropriateness of advertising prescription drugs directly to patients, currently permitted only in New Zealand[46] and the US,[47] abound, and the issue has certainly loomed large in the ANZTPA negotiations.[48]

---

[40] Lee, above n 8, 177-9.

[41] Mary E Wiktorowicz, 'Emergent Patterns in the Regulation of Pharmaceuticals Institutions and Interests in the United States, Canada, Britain, and France' (2003) 28 *Journal of Health, Politics, Policy and Law* 615.

[42] *Grassley Continues Push for Transparency, Accountability and Independence at FDA* (2005) <http://grassley.senate.gov/index.cfm?FuseAction=PressReleases.Detail&PressRelease_id=4927> at 1 September 2006. Cf, Henry Waxman, 'The Lessons of Vioxx: Drug Safety and Sales' 352 *New England Journal of Medicine* 2576;

[43] Lurie, above n 3.

[44] D Beyleveld, D Townend and J Wrigt, *Research Ethics Committees, Data Protection and Medical Research in European Countries* (2005); *Ethical and Policy Issues in Research Involving Human Paricipants, Vol 2* (2001) National Bioethics Advisory Commission <http://www.georgetown.edu/research/nrcbl/nbac/clinical/Vol2.pdf> at 1 September 2006. Cf, Frances H Miller, 'Trusting Doctors: Tricky Business When It Comes to Clinical Research' (2001) 81 *BUL Review* 423.

[45] See, General Accounting Office, *FDA Drug Approval – A Lengthy Process That Delays the Availability of New Drugs* (1980). See also, 'FDA Reform and the European Medicines Evaluation Agency' (1995) 108 *Harvard Law Review* 2009; John Dillman, 'Prescription Drug Approval and Terminal Diseases: Desperate Times Require Desperate Measures' (1991) 44 *Vanderbilt Law Review* 925; Richard Dorsey, 'The Case for Deregulating Drug Efficacy' (1999) 242 *Journal of the American Medical Association* 1775. Cf, David Ridley et al, 'Spending on Postapproval Drug Safety' (2006) 25(2) *Health Affairs* 429 (In 2003 manufacturers spent 0.3% of sales on post-approval safety, in comparison with 15.6% on new product research and development).

[46] *Medicines Act 1981* §§ 56-62; *Medicines Regulations 1984* §§ 7-11.

[47] 21 CFR § 202.1 (2005). See generally, Wayne L Pines and John F Kamp, *DTC Advertising and Promotion: The Changing Environment* (2006).

[48] Les Toop, *For Health or Profit* (2003); see below Section IV A; Cf, Margaret Gilhooley, 'Heal the Damage: Prescription Drug Consumer Advertisements and Relative Choice' (2005) 38 *Journal of Health Law* 1; Caroline L Nadal, 'The Societal Value of Prescription Drug Advertisements in the New Millenium: Targeted Consumers Become The Learned' (2001) 9 *Journal of Law and Policy* 451; American Medical Association, 'Direct-to-Consumer Advertising of Prescription Drugs' (2000) 55 *Food and Drug Law Journal* 119; Tamar Terzian, 'Dirct-to-Consumer Prescription Drug Advertising' (1999) 25 American Journal of Law and Medicine 149; Lars Noah, 'Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues' (1997) 32 *Georgia Law Review* 141.

To complicate matters immensely, pharmaceutical agency licensing decisions inevitably affect drug access and pricing policies in all countries around the globe, even if not directly.[49] Manufacturers inevitably seek to stimulate demand for their newly-approved therapeutic products, often abetted by naïve and overly-enthusiastic media reports,[50] and patients often clamor for insurers to pay for the latest 'breakthroughs' touted by the media.[51] This tends in most countries to produce higher national spending on pharmaceuticals.[52] Even when patents on the pioneer products expire so that cheaper generic equivalents could capture large shares of the relevant market, if an 'innovative' (and usually equally or more expensive) replacement has gained regulatory approval in the interim, demand for that new product and resistance to the generic equivalent of the pioneer drug are likely to prove strong.[53] The resulting increased expenditures in turn usually lead to the higher total national health care costs that plague all countries.[54]

## THE TRANS TASMAN THERAPEUTIC PRODUCTS AUTHORITY

Against this backdrop of global turmoil and uncertainty about pharmaceuticals and their value comes the pending — but already several times postponed — consolidation of Australia's Therapeutic Goods Administration and New Zealand's Medsafe into the joint Trans Tasman Therapeutic Products Regulatory Authority. The new agency is still scheduled as of this writing to initiate operations in July of 2007,[55] but major hurdles to implementation remain. The governments of Australia and New Zealand signed a treaty at the end of 2003 agreeing in principle to establish this joint supra-agency,[56] but Parliamentary implementation in both countries has yielded to the realities of electoral politics. In the succinct words of New Zealand's Medsafe Manager, 'The regulatory process has to take account of the democratic process,'[57] and the full democratic process has yet to play out.

Both Australia and New Zealand delayed submitting legislation enabling the new agency for Parliamentary approval pending their respective national elections, but those elections are long past and facilitating legislation has yet to be enacted in either country. In

---

[49] Cf, Donald W Light and Tom Walley, 'A framework for containing costs fairly' in Elias Mossialos et al (eds), *Regulating Pharmaceuticals in Europe: striving for efficiency, equity and quality* (2004) 346 (setting forth process for achieving equitable distribution of licensed pharmaceuticals in Europe).

[50] Trudy Lieberman, 'Bitter Pill' (2005) *Columbia Journalism Review.* <http://www.cjr.org/issues/2005/4/lieberman.asp> at 1 September 2006.

[51] Ezekiel J Emanuel, 'Cancer in the Courts' (2006) 235(4772) *The New Republic* 9; R Moynihan et al, 'Selling Sickness: The Pharmaceutical Industry and Disease Mongering' (2002) 324 *BMJ* 886.

[52] Cf, Monique Mrazek et al, 'Regulating Pharmaceutical Prices in the European Union' in Mossialos et al (eds), *Regulating Pharmaceuticals in Europe: Striving for Efficiency, Equity and Quality* (2004) 114.

[53] It took until August of 2006 for Australia's PBS to list the first Indian-manufactured generic drugs eligible for government reimbursement. See, Mark Metherell, 'Cheaper Indian Drugs Put on PBS', *The Sydney Morning Herald*, 9 August 2006 <http://www.smh.com.au/news/national/cheaper-indian-drugs-put-on-pbs/2006/08/08/1154802890298.html> at 1 September 2006.

[54] Margaret Gilhooley, 'FDA and the Adaptation of Regulatory Models' (2004) 49 *St Louis University Law Journal* 131, 137-8. See also, Evan Doran et al, 'Moral hazard and prescription medicine use in Australia — the patient perspective' (2005) 60(7) *Social Science and Medicine* 1437.

[55] Australia New Zealand Therapeutic Products Authority <http://www.anztpa.org/> at 21 August 2006.

[56] *Agreement Between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products* (2003) <http://www.tgamedsafe.org/about/treatytext.pdf> at 1 September 2006.

[57] Personal communication with Clare van der Lem, May 16, 2005.

the meantime, their respective Health Ministers have been struggling with measurable success to work out the myriad details involved in implementing such a complex international regulatory agreement.[58] Significant progress has been reported, as witnessed by the 2005 agreement on a preliminary joint regulatory scheme for advertising therapeutic products,[59] developed by an Interim Advertising Council comprised of interested stakeholders from both countries convened for that specific purpose.[60] Draft labelling requirements for medicines were issued in May of 2006, and draft medicines, medical devices and administration rules, *inter alia*, have also been formulated.[61] The *sine qua non* for bringing all the hard work to fruition, however, remains passage of enabling statutes in both countries.

The organizational structure of the new joint entity, as envisioned by the 2003 Treaty, calls for a single trans-Tasman agency to regulate therapeutic products for both Australia and New Zealand jointly, the TPA. In brief, the agency is to regulate the 'quality, safety, and efficacy or performance of therapeutic products, and of their manufacture, supply, import, export and promotion'.[62] This includes authority over medicines (including over-the-counter medications), medical devices, and complementary healthcare products. In 2004 both countries agreed to add responsibility for blood, blood products, and blood components to the agency's remit as well.[63] Headquarters for the agency are to be established in Canberra, but 'full service' offices are envisioned for both countries as well.

The TPA will be accountable to a Ministerial Council composed of the Health Ministers from each country,[64] who will have appointment removal authority over the Board members and oversee its operations. Those Board members will actually govern the agency and make the rules, equivalent in status to governmental regulations, by which it functions.[65] The Board's rules must be tabled in both the Australian and New Zealand Parliaments after promulgation, and if disallowed in whole ('and not in part') by either country within a 'reasonable time' they are to have no further effect under the agreement or the enabling statutes.[66] Either country can thus veto any TPA regulation – a two-edged sword that could cut either to encourage better cooperation, or to facilitate division on national lines.

Both Australia and New Zealand have strong interests in keeping pharmaceuticals widely available for their citizens, including ensuring that orphan drugs (to treat diseases from which fewer than 200,000 people suffer world-wide) for treating rare diseases are readily accessible, and both would like to see a robust pharmaceutical industry presence within their borders. A joint agency should enable them to assure their individual health and safety objectives without imposing superfluous trade barriers. It should also allow them to

---

[58] See generally, <http://www.tgamedsafe.org/> at 1 September 2006.

[59] *Description of the Joint Regulatory Scheme for the Advertising of Therapeutic Products* (2006) Australia New Zealand Therapeutic Products Authority <http://www.tgamedsafe.org/advert/advmodel.htm> at 1 September 2006.

[60] The Interim Advertising Council was composed of 'consumers, practitioners, regulators and the therapeutic products media and advertising industries (i.e. those who advertise and those to whom advertising is directed and the regulators)'.

[61] See generally, reports and materials collected on the ANZTPA website <http://www.anztpa.org/> at 1 September 2006.

[62] Treaty, Article 2.1.

[63] 'International Treaty Examination of the Agreement between the Government of New Zealand and the Government of Australia for the Establishment of a Joint Scheme for the Rgulation of Therapeutic Products', p 3 in the Report of the Health Committee, *New Zealand House of Representatives* (2004).

[64] Treaty, Article 4.

[65] The Board is to be composed of a Chair, a Managing Director, one person with 'broad experience in relation to public health and regulatory matters' from each country, and 'a person with broad experience in commercial matters.' Treaty, Article 6.1.

[66] Treaty, Article 9.4.

coordinate their joint approach to conform as closely as possible with global best practices, thus facilitating wider international trade for both. The more coordinated and user-receptive their joint regulatory program, the more likely the pharmaceutical industry will be to keep, and with good strategic planning (and luck) to strengthen, the economic presence they already maintain Down Under.

The magnitude of the regulatory task is great, and both countries have relatively small populations[67] compared with the rest of the world. Thus both of them have much to gain by throwing their lot in together — especially New Zealand. With a population of only slightly more than four million people, it will find itself less and less able over time to command the range and depth of governmental scientific expertise required to cope with the increasing complexity of modern pharmaceuticals.[68] Maintaining the present system of drug regulation in New Zealand is in fact widely considered 'unsustainable.'[69] The devil always resides in the regulatory details, however, and powerful interest groups focusing on those details have been quite effective cogs in the wheels of progress toward final trans-Tasman consolidation thus far.[70]

## MAJOR ANZTPA CONSOLIDATION ISSUES

Australia and New Zealand regulate therapeutic products with rough similarity in many ways, notwithstanding New Zealand's two decades old legislation[71] and unavoidably thinner administrative resources devoted to the task. The user fees the countries charge manufacturers seeking new product approvals have until recently produced a significant difference in direct financial resources available to their respective agencies. Australia currently charges manufacturers A$178,000 to evaluate a new prescription drug,[72] while until August of 2006 New Zealand's application fee to Medsafe has been a nominal NZ$15,300.[73] That fee just jumped to NZ$122,625, however, in anticipation of the pending

---

[67] According to Australia's Board of Statistics, the projected population on August 22, 2006 (based on population estimates as of December 31, 2005), is 20,605,468 people: *Population Clock* (2006) Australian Bureau of Statistics <http://www.abs.gov.au/ausstats/abs@.nsf/94713ad445ff1425ca25682000192af2/1647509ef7e25faaca2568a900154b63?OpenDocument> at 21 August 2006.

[68] The provisional population number for New Zealand in March of 2006 (from the census night population count) was 4,116,900: *2006 Census Provisional Counts* (2006) Statistics New Zealand <http://www.stats.govt.nz/products-and-services/hot-off-the-press/2006-census/2006-census-provisional-counts-2006-hotp.htm> at 21 August 2006. See generally, *What Would a Joint Therapeutic Products Agency Mean for New Zealand?* (2002) Australia New Zealand Therapeutic Products Authority <http://www.anztpa.org/about/dietary.htm> at 25 August 2006.

[69] 'International Treaty Examination of the Agreement Between the Government of New Zealand and the Government of Australia for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products' p 24 in the Report of the Health Committee, *New Zealand House of Representatives* (2004), citing 2000 Regulatory Impact Assessment by the New Zealand Institute of Economic Research.

[70] Five minority reports were filed to the recommendations of the New Zealand Health Committee treaty examination report referenced at ibid 10-13, ranging from New Zealand First's 'don't ratify unless', to New Zealand National, Act New Zealand and United Future's 'don't ratify because', to the Green Party's 'total opposition'.

[71] *Medicines Act 1981* and *Medicines Regulations 1984*, as amended.

[72] *Summary of fees and charges at 11 August 2006* (2006) Therapeutic Goods Administration <http://www.tga.gov.au/fees/fees06.htm> at 21 August 2006).

[73] *Proposal to Increase Fees Payable under the Medicines Act 1981 and Misuse of Drugs Act 1975* (2005) New Zealand Medicines and Medical Devices Safety Authority <http://www.medsafe.govt.nz/Regulatory/Fees/FeesIncrease.htm> at 1 September 2006.

consolidation.[74] Presumably few manufacturers will choose to seek new product approval in New Zealand pending the initiation of the TPA, however, because the fee is now high and the market there is relatively small. When the TPA comes on line, however, it will issue licenses for new drugs to be marketed in both countries simultaneously, with no further necessity for the red tape associated with country-specific approval in all other countries of the world.

The ability to issue this simultaneous joint license constitutes the path-breaking difference between ANZTPA and virtually all previous harmonization efforts. Even EMEA approval of a new chemical entity for the European Community membership is only a 'recommendation' on safety and efficacy to the European Commission, as the EMEA's Legal Sector Head repeatedly stresses.[75] Technically the Commission must still formally adopt the EMEA's scientific opinion, and each member country must then accept it, before an 'approved' drug may be marketed legally within EU countries, although in reality they have little leeway for refusing to go along with an EMEA recommendation.[76]

Two primary areas of policy difference between the way Australian and New Zealand's regulatory agencies operate have to be resolved before the Trans-Tasman Pharmaceutical Products Regulatory Agency can commence its joint operations, and they are still instrumental in delaying current enactment of the enabling legislation. These divergences relate to direct-to-patient advertising of prescription drugs, which New Zealand has long permitted but Australia does not, and the regulation of complementary health products. Both differences reflect a more fundamental divergence going to the heart of each country's broader health philosophies – and some would argue to the country's ethical stance as well.[77]

**a. Advertising Prescription Drugs Directly-to-Consumers**

Australia, like the rest of the world except for the US and New Zealand, does not permit full-blown direct-to-consumer (DTC) advertising of prescription drugs,[78] although it does allow 'disease awareness' advertisements which can get much of the same marketing message across – at least by implication.[79] *Healthy Skepticism*,[80] an international

---

[74] *Schedule of Fees* (2006) New Zealand Medicines and Medical Devices Safety Authority <http://www.medsafe.govt.nz/Regulatory/Fees/ScheduleofFees.htm> at 21 August 2006; *Fees* (2006) New Zealand Medicines and Medical Devices Safety Authority <http://www.medsafe.govt.nz/Regulatory/fees.htm> at 18 August 2006 (contains documents relating to new fee schedule).

[75] Personal communication with Prof. Vincenzo Salvatore, Head of EMEA Legal Sector, 22 February 2006. Notes on file with the author.

[76] See generally, Silvio Garattini and Vittorio Bertele, 'The role of the EMEA in regulating pharmaceutical products,' in Elias Mossialos et al (eds), *Regulating Pharmaceuticals in Europe: Striving for Efficiency, Equity and Quality* (2004) 80, 'The FDA and the EMEA: Not a Mirror Image,' Drug Safety in the EU: *Understanding the Rules and Regulations*, (2005) 15 (FDA News, "[T]he EMEA, really does not have the final approval authority."

[77] Les Toop, 'Direct to Consumer Advertising of Consumer Drugs in New Zealand: For Pain or Profit?' *Report to the Minister of Health Supporting the Case for a Ban on DTCA* (University of Otago Dept of Health Sciences, Feb. 2003).

[78] Australia's advertising requirements are set forth in the *Therapeutic Goods Act 1989*, and accompanying regulations.

[79] See, eg, *Welcome Back, Tiger (Get your sex life back on track)* video and brochure, complete with winking tiger on a sofa holding a woman 'of a certain age' in his arms, produced (and made available to residents of Australia only) by Pfizer Australia. The message about the purported benefits of Viagra is clear from the detailed text, complete with illustrations, although the name of the drug is never mentioned.

[80] <http://www.healthyskepticism.org> at 1 September 2006.

organization of health professionals and others concerned about promoting truthful drug advertisements and countering misleading ones, is based in Australia, and has been active in the international debate about direct-to-consumer (DTC) advertising.[81] It conducts lively discussions over the internet,[82] in print,[83] and in other media which have helped to raise general public awareness[84] about the negative effects of advertising prescription drugs directly to patients.[85] Its members are actively engaged stakeholders in the pre-implementation ANTZPA consultations, and their views have been widely circulated and well-articulated.

New Zealand, on the other hand, permits direct-to-consumer advertising of prescription drugs on administrative fairness and informed patient choice grounds,[86] because the government sharply limits the range of pharmaceutical products it will underwrite through PHARMAC, its purchasing agency.[87] PHARMAC, which negotiates the price of the pharmaceuticals supplied to patients by New Zealand's health insurance system, engages in hard bargaining with pharmaceutical manufacturers and essentially puts many classes of drugs out for competitive tender. The lowest bidders gets the PHARMAC contracts, and any other manufacturers wishing to have their products in the same class underwritten by government insurance must meet the reference price – i.e. the low bid for the class. Reference pricing is used for drugs not engaged in competitive tendering as well.[88]

PHARMAC's Executive Director stated in 2005 that since the government generally contracts to underwrite only the lowest-priced drugs from each therapeutic class, he would consider it unfair — if not unethical — for New Zealand to disallow competing manufacturers (whose products are *not* available through the government's program because they are unwilling to match the reference price) from advertising to patients.[89] His view coincides with the classic freedom of commercial speech position; people who might wish to buy higher-priced drugs in that same therapeutic class from their own funds have the right to know what manufacturers (truthfully) represent those other products might offer to patients.[90]

Drug manufacturers currently submit their proposed advertisements to New Zealand's Therapeutic Products Pre-Vetting System (PAPS)[91] for approval prior to publication. As a

---

[81] <http://healthyskepticism.org/news.php> at 1 September 2006.

[82] Internet discussion takes place via the rough equivalent of a members-only list serve.

[83] http://healthyskepticism.org/library/byus.php lists more than 130 publications having to do with best practices, conflicts of interest, and misleading drug advertising and promotion by Healthy Skepticism members (including in highly respected medical journals like *The Lancet* and *BMJ*).

[84] Among other activities, the organization maintains an AdWatch site to 'illuminate' misleading drug advertising techniques: <http://www.healthyskepticism.org/adwatch.php> at 1 September 2006.

[85] Evidence (from the US and New Zealand) indicates that DTC advertising is probably more effective for increasing manufacturers' profits than for improving patients' health. J Hoffman and M Wilkes, 'Direct to consumer advertising of prescription drugs: an idea whose time should not come' (1999) 318 *BMJ* 1301.

[86] New Zealand advertising requirements are set forth in the *Medicines Act 1981*.

[87] Funding Application, Pharmaceutical Mangement Agency http://www.pharmac.govt.nz/funding_applications.asp at 14 September 2006.

[88] Peter Davis, '"Tough but fair"? The Active management of the New Zealand drug benefits scheme by an independent Crown agency' (2004) 28(2) *Australian Health Review* 171.

[89] Personal communication with Wayne McNee, 17 May 2005. Notes on file with the author.

[90] Ibid.

[91] TAPS was set up by the Association of New Zealand Advertisers (ANZA), and reviews therapeutic advertisements against benchmarked standards from its Code for Therapeutic Advertising, which in turn references Medsafe's labeling requirements. ANZA also administers the Advertising Standards Complaints Board, which adjudicates complaints that drug advertising fails to conform to approved indications for the product. See <http://www.anza.co.nz>.

result, their advertising copy has tended to be slightly more tasteful (if not always more informative) in comparison with prescription drug advertising for the same products in the US. When the Vioxx and other drug safety and efficacy controversies erupted in 2004,[92] and US products liability concerns highlighted the possibility of manufacturer legal responsibility for prescription drug over-promotion,[93] however, most US drug manufacturers shifted strategy and began re-casting their direct-to-consumer advertising in a more moderate tone.

The preliminary joint regulatory scheme for advertising therapeutic products issued in December of 2005 does not come to explicit terms with the divergence between the two countries' positions on prescription drug DTCA. In fact, it does not appear to separate out prescription drug promotion for any special treatment at all, articulating only general requirements for all therapeutic product advertisements.[94] It does, however, make the important point that the TPA Ministerial Council itself (i.e. each country's Health Minister), not the TPA Board which has responsibility for making other rules,[95] will determine the joint rules regulating therapeutic goods advertising which both countries must observe.[96] The draft advertising rule itself will be released in the fall of 2006 during the second round of public consultations on the TPA.[97]

Hands-on Ministerial attention to this subject signals a high level of sensitivity to the politics of the DTCA issue. The regulations they enact are to expand upon the scheme's Key Principles that advertising must be 'balanced, truthful, and not misleading,' that it 'observe a high standard of social responsibility' (and that it comply with the applicable statutes and rules). All well and good, but that begs the critical point of divergence.[98] Still up in the air is striking the appropriate balance between commercial speech protections on the one hand, and public safety on the other, to put the disagreement in its bluntest terms. Whether enabling legislation can manage to pass in both countries before they resolve that matter jointly is an interesting political question.

**b. Regulating Complementary & Traditional Medicines**

New Zealand is far more relaxed about the marketing and use of complementary medicine products than is Australia. This stems in part from New Zealand's greater reliance on and respect for the traditional medicine widely used by the Maori population,[99] and the values associated with traditional, herbal and homeopathic medicines are shared by a large fraction of the general populace as well. Australia, on the other hand, takes a more stringent approach toward any products touted to have medical value. In essence, complementary

---

[92] W John Thomas, 'The Vioxx Story: Would It Have Ended Differently in the European Union?' (2006) 32, *American Journal of Law and Medicine* 365.

[93] Cf, *Perez v Wyeth Laboratories Inc*, 734 A 2d 1245 (1999) (learned intermediary rule protecting drug manufacturer from liability for failing to warn patient of drug side effects negated by aggressive direct-to-patient advertising).

[94] Advertising Key Principles and Advertising Requirements, *Description of the Joint Regulatory Scheme for the Advertising of Therapeutic Products* (2005) 2-4.

[95] Above n 65 and accompanying text.

[96] Above n 94, 2.

[97] *Joint Release of the Therapeutic Products Interim Council, 29 August 2006* <http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2006-cp-pyn054.htm> at 1 September 2006.

[98] Ibid.

[99] Traditional Maori healers are specifically exempted from regulation by the *Australia New Zealand Therapeutic Products Regulatory Scheme (Medicines) Rule* 2006 <http://www.anztpa.org/consult/dr-medrule.pdf> at 1 September 2006.

health products are regulated as therapeutic goods in Australia,[100] while they are referred to as dietary supplements and more liberally treated as foods under New Zealand law.[101]

That disparity has proved a major stumbling block to ANZTPA progress, for the draft medicines policy now contemplates treating dietary supplements for which therapeutic claims are made as subject to pre-marketing quality and safety review. Once a transitional period has expired during which 'sponsors' of dietary supplements already on the New Zealand market must secure interim product licenses, all sponsors in either country making therapeutic claims will be required to apply for full licensure from the new joint agency.[102] The level of regulation will be 'risk based', in that since most complementary medicines have a relatively low risk of causing patient harm, they would be subject to less stringent requirements than would prescription medicines.[103] But the prospect of *any* new pre-market regulation raises a bright red flag to manufacturers and purveyors of goods which have heretofore enjoyed virtually unfettered access to the market, and it strikes alarm in the hearts of those consumers who believe in their claims.

This issue might have stayed relatively low-key had it not been for the large-scale Pan Pharmaceuticals (Pan) product withdrawals Down Under during the early ANTZPA discussions.[104] Pan, an Australian company, manufactured many over-the-counter products and was Australasia's largest manufacturer by far of herbal, vitamin and dietary supplements, which were often repackaged under local company names. In 2003 both Australia's TGA and New Zealand's Food Safety Authority recalled approximately 2,000 of Pan's complementary medicine products from their respective countries' markets following numerous patient reports of illness linked to some Pan-manufactured goods. A three-month quality audit of the company's manufacturing processes uncovered multiple reasonably serious quality and safety deficiencies.[105] Unfortunately, confusion existed about exactly which products were subject to the recall, under exactly what company labels, and information dissemination to and by all affected parties was often uncoordinated and inadequate.

Wide and at times sensational media coverage of that huge withdrawal drew the issue of regulating complementary medicines cross-border to broad public consciousness. Some raised the specter of government regulation gone amok, while others claimed officials had not done enough to assure public safety, and had failed to come down hard enough on deliberately shoddy manufacturing processes and dubious therapeutic claims. The economic impact of the recall on Pan was disastrous,[106] as most informed observers now maintain it should have been, but the economic ripple effect was felt throughout the complementary medicines sector. The smaller companies packaging Pan products for sale under their own

---

[100] *Therapeutic Goods Act 1989* s 52(F) (defining complementary medicines as therapeutic goods); *Therapeutic Goods Regulation* sch 14 (designated active ingredients); *The Regulation of Complementary Medicines in Australia, An Overview* (2006) Therapeutic Goods Administration <http://www.tga.gov.au/cm/cmreg-aust.htm> at 25 August 2006.

[101] *Food Act 1981* s 42; *Dietary Supplements Regulations 1985*.

[102] *Transition to the joint regulatory scheme for complementary products* (2005) Australia New Zealand Therapeutic Products Authority <http://www.anztpa.org/cm/cmtrans.htm> at 1 September 2006.

[103] *Australia New Zealand Therapeutic Products Regulatory Scheme (Medicines) Rule 2006*, 26 <http://www.anztpa.org/consult/dr-medrule.pdf> at 1 September 2006.

[104] See generally, Lynne Eagle et al, 'Regulatory Oversight or Lack of Foresight? Implications for Product Recall Policies and Procedures' (2005) 28 *Journal of Consumer Policy* 433.

[105] R Burton, 'Complementary medicines industry in crisis after recall' (2003) 326 *British Medical Journal* 1001.

[106] Pan Pharmaceuticals went into administration on 22 May 2003. Beth Quinlivan 'The un-health sector' (2003) 25(17) *Business Review Weekly* 16.

labels, and retail pharmacies, supermarket chains, and other sellers felt the financial loss.[107] Moreover, their customers were upset by the absence of products they may have been taking for years without incident from their shelves.

The Pan situation made it clear that serious quality problems permeated the complementary medicines industry, and that the existing powers of both governments to deal with those problems effectively were inadequate. It also convinced most of those participating in the ANTZPA negotiations that more effective and coordinated cross-border oversight of complementary medicines – rather than none – was the better route to take with the TPA. Australia is certainly not about to change course and abandon the degree to which it already regulates complementary medical products, but it remains to be seen whether the New Zealand Parliament can be convinced to enact legislation enabling the TPA to do it for both countries.

**c. Other Consolidation Issues**

Australia and New Zealand have relatively little disagreement over most other regulatory issues, such as adopting basic safety, efficacy and quality standards, thanks in part to the leadership of the ICH, the FDA and the EMEA in forging generally-accepted scientific and other technical parameters for evaluating new drugs.[108] The two countries also should have little trouble coming to basic agreement about appropriate standards for safely conducting clinical trials of experimental medications, including how clinical trials should be conducted, and who gets access to experimental medications while clinical trials are under way. Australia already has a 2-part process enabling patients to gain 'special access' to experimental medications,[109] and New Zealand seems to have fairly liberal 'compassionate use' [110] provisions[111] – perhaps in part because far fewer clinical trials are conducted within its borders, and therefore experimental drugs are less easily available to New Zealand patients. Presumably the rules of the new agency will follow the modern regulatory practice of affording wider access to drugs whose safety profiles are relatively acceptable but whose efficacy has not yet been fully established.[112]

Product labelling regulation has the potential to prove a hot button issue with both countries' complementary medicines constituencies, however.[113] Manufacturers of complementary medicines are often very small businesses, where compliance costs can amount to a financial substantial burden.[114] In addition, the information and technical

---

[107] Note 104, 441.

[108] See eg, *The Common Technical Document* of the International Committee on Harmonization, setting forth international consensus on regulatory standards for drug safety, quality and efficacy <http://www.ich.org/cache/compo/276-254-1.html> at 24 August 2006. See also *Guidelines for Transition to the Joint Regulatory Scheme for Class I Medicines and Medical Devices*, TGA Consultation Draft (May 2006).

[109] *Access to Unapproved Therapeutic Goods in Australia* (2001) <http://www.tga.gov.au/docs/pdf/unapproved/unapp.pdf> at 1 September 2006.

[110] See, Sheila R Shulman and Jeffrey S Brown, 'The Food and Drug Administration's Early Access and Fast-Track Approval Initiatives: How Have They Worked?' (1995) 50 *Food and Drug Law Journal* 503.

[111] <http://www.medsafe.govt.nz/profs/RIss/unapp.htm> at 1 September 2006.

[112] Sheila R Shulman and Jeffrey S Brown, 'The Food and Drug Administration's Early Access and Fast-Track Approval Initiatives: How Have They Worked?' (1995), 50 *Food & Drug L J* 503; Deborah G. Parver, Comment, 'Expediting the Drug Approval Process: Analysis of the FDA Modernization Act of 1997', (1999), 51 *Admin. L. Rev*. 1249.

[113] *See*, 'Major Issues Identified in Stakeholder Responses Relevant to Labelling' in *Draft Labelling Requirements for Medicines Under the Australia New Zealand Therapeutic Products Authority* (May 2006) 39– 45.

[114] Lisa Allen, 'Vitamin makers build TGA resistance', *Australian Financial Review*, 23 June 2005.

language dietary supplement manufacturers will be required to include on labeling constitute a significant change from their current practices.[115] Nonetheless, the draft labelling regulation reflects substantial progress toward achieving consensus on general medicines labelling.

Other areas of regulation will undoubtedly prove problematic in the final count-down to enactment, and questions have already been raised about legal issues such as potentially undue delegation of rule-making authority to the TPA's Board.[116] Whether appeals mechanisms from TPA decisions appropriately respect national sovereignty,[117] and what level of Parliamentary scrutiny should be accorded to the agency's rules, could also turn out to be nettlesome questions.[118] If and when the TPA finally initiates operations, these issues nonetheless should not be expected to threaten the continued existence of regulatory cooperation if they are handled with fairness, sensitivity, and legal sophistication.

## LESSONS LEARNED FROM OTHER HARMONIZATION EFFORTS

Existing cooperative efforts to achieve borderless pharmaceutical markets teach, among other things, that at least at the outset obtaining cross-border consensus on regulatory criteria is slow-going and difficult. Ideally, both individual nations and pharmaceutical companies would like seamless harmonization of the technical requirements for approving pharmaceutical products, so that drugs and devices meeting agreed standards for approval in any country could be marketed in all of them. In reality, however, striving for consensus often threatens local values and business interests, as can currently be seen regarding the TPA's proposed regulation of complementary medicine.[119] It can also raise touchy political, ethical, and cultural issues, such as those now swirling around research on embryonic stem cells and human cloning in the US and other countries.[120] Moreover, actually achieving consensus often entails weakening the more stringent regulatory options for drug and device approval, thereby rendering rigorous (and often expensive) post-marketing surveillance of regulated products, currently woefully poor, even more critical than might have been thought previously. [121]

Abundant evidence reveals that the pharmaceutical industry has wielded tremendous influence over pre-existing harmonization efforts, especially its interactions with the ICH, but also with the EMEA, and with the regulatory regimes of most individual countries.[122] Applying that important insight to ANZTPA, the user fees and charges intended to underwrite the costs of running the agency, after initial funding provided by the Australian and New Zealand governments, have more than just fiscal significance.[123] The message from other 'client-funded' regulatory regimes warns that primary reliance on industry

---

[115] *Draft Labelling Requirements for Medicines under a Joint Australia New Zealand Therapeutic Products Agency* (2005) Australia New Zealand Therapeutic Products Authority http://www.anztpa.org/label/medlabeldr.pdf at 18 September 2006.

[116] 'Treaty Examination', above n 69, Appendix B.

[117] Id.

[118] Id.

[119] See above n 100-8 and accompanying text.

[120] Angela Campbell, 'Ethos and Economics: Examining the Rationale Underlying Stem Cell and Cloning Research Policies in the United States, Germany, and Japan' (2005) 31 *American Journal of Law and Medicine* 47.

[121] Mary E Wiktorowicz, 'Emergent Patterns in the Regulation of Pharmaceuticals: Institutions and Interests in the United States, Canada, Britain, and France' (2003) 28 *Journal of Health Politics, Policy and Law* 615.

[122] Lee, above n 8, 177-78.

[123] Treaty, Article 15.

funding, rather than on tax revenues, to support an agency presages a more industry-friendly consultative administrative style for the fledgling regulator, such as is found throughout much, if not most, of the world.[124]

The US Food and Drug Administration utilized a more formally adversarial style in its regulatory activities until passage of 'user fee' statutes in 1992[125] and 2002[126] designed to provide more financial resources for, respectively, evaluating new drugs and devices. Since industry began supplying a larger percentage of the FDA budget, the agency has adopted a more conciliatory and consultative *modus operandi.* The agency is now paying for that deference, however, in a loss of public confidence following the Vioxx and other drug imbroglios, which have implicated less-than-rigorous FDA oversight.[127] When regulated industries foot the bill for their own policing, the public perceives — rightly or wrongly — that the regulators have at least subliminal incentives to tilt in the direction of regulatory capture.[128]

**a. The European Medicines Agency**

The European Union (EU) voted to establish a centralized agency for regulating pharmaceuticals in 1993,[129] and pursuant to its Directive the European Medicines Evaluation Agency (still known as the EMEA) came into existence just over a decade ago.[130] Member states in the EU already had their own nationaldrug regulatory bodies, but their licensing decisions were not technically required to be accepted by the other member states, and often were not.[131] The European Council designed the EMEA to function as a parallel, centralized, and more highly specialized and respected forum for making drug evaluation determinations that would be acceptable throughout the entire Common Market.[132]

Pharmaceutical manufacturers still have dual options for licensing many products; they can use either the centralized EMEA or the national regulatory schemes. In fact, since almost all national agencies depend to a large extent on user fees for their very existence, many compete for regulatory business by way of low fees and user-deference.[133] Member State decisions cannot be reliably assured of receiving mutual recognition in the rest of the

---

[124] Wiktorowicz, above n 121.

[125] *Prescription Drug User Fee Act of 1992,* Pub L No 102-571, 21 USC § 379(g)(h), 106 Stat 4491 (29 October 1992).

[126] *Medical Device User Fee and Modernization Act of 2002,* Pub L No 107-250, 21 USC §§ 379(i)(j), 289(g)(3), 116 Stat 1588 (26 October 2002).

[127] Cf, W John Thomas, 'The Vioxx Story: Would It Have Ended Differently in the European Union?' (2006) 32 American Journal of Law and Medicine 365.

[128] Cf, James L Zelaney Jr, 'The Prescription Drug User Fee Act: Is a Faster Food and Drug Administration Always a Better Food and Drug Administration?' (2005) 60 *Food and Drug Law Journal* 261, 262 (commenting on conflicts of interest raised when industry foots the bill for a substantial percentage of regulatory agency budget).

[129] Council Directive 93/39/EEC, 1993 OJ (L 214)22.

[130] See generally, Silvio Garattini and Vittorio Bertele, 'The role of the EMEA in regulating pharmaceutical products' in Elias Mossialos et al (eds) *Regulating Pharmaceuticals in Europe: Striving for Efficiency, Equity and Quality* (2004) 80.

[131] See generally, discussion in Lee, above n 8, 165-77.

[132] Richard F Kingham et al, 'The New European Medicines Agency' (1994) 49 *Food and Drug Law Journal* 301.

[133] Mary E Wiktorowicz, 'Emergent Patterns in the Regulation of Pharmaceuticals: Institutions and Interests in the United States, Canda, Britain and France, (2003) 28 *J.* of *Health Pol'y Pol & Law* 615, 639, citing Abraham and Lewis, 'Harmonizing and Competing for Medicines Regulation: How Healthy are the European Union's Systems of Drug Approval?' (1999) 48 *Social Science & Med.* 1655-67.

European Union, however, so manufacturers have reasons to be reluctant about choosing the single-nation/mutual recognition route to European markets.[134]

In 2004 the European Council, mindful of rapid scientific and technological advances and the imminent entry of fifteen new member-states, including several Central and Eastern European countries not all possessing sophisticated regulatory expertise,[135] amended the EMEA's jurisdiction to make the centralized procedure compulsory for high-technology and certain other medical products.[136] All medicinal products developed by recombinant biotech processes — DNA technology, for example — now must be approved by the EMEA. So also must all drugs containing any new active substance for treating AIDS, cancer, neurogenerative disorders and diabetes. After May of 2008, the category of mandatory submissions will expand to include new drugs for treating auto-immune diseases and other immune dysfunctions, plus viral diseases. Finally, all orphan medical products (for treating diseases from which fewer than 200,000 people suffer world-wide) must be submitted to the EMEA's centralized procedures as well.[137] The Council's legislative intent is obvious: member-state agency jurisdiction over drug licensure has no choice but to contract, and is expected eventually to (all but) wither away.

The lesson to take from the EMEA's expanded jurisdiction after a decade of operation could not be more clear; with the passage of time countries become more comfortable when they perceive a reasonably fair and efficient regulatory process. They thus become happier about ceding more power to a centralized joint authority. Presumably the higher the level of confidence both Australia and New Zealand come to have in the TPA, the easier it should become to achieve agreement on all manner of issues currently hindering the agency's birth, and on those inevitably arising in the future.

**b. The International Conference on Harmonization**

The International Conference on Harmonization is a forthright collaboration among US, EU and Japanese drug regulators and the pharmaceutical industry trade associations from each of them.[138] The ICH was established in 1990, 'aimed at ensuring that good quality, safe and effective medicines are developed and registered in the most efficient and cost-effective manner.'[139] In other words, all parties to the ICH strive to eliminate technical trade barriers for pharmaceutical products by agreeing on basic testing requirements, and industry concerns are extremely powerful factors in driving any resulting consensus.[140] Their objective was to avoid unnecessary and redundant licensing requirements, while still promoting reasonably safe and effective drugs.[141] Front and centre has been the goal of getting new drugs to global markets more quickly.

---

[134] See generally, Duncan Matthews and Caroline Wilson, 'Pharmaceutical Regulation in the Single European Market' (1998) 17 *Medicine and Law* 401.

[135] See generally, Monique Mzrazek, 'The pharmaceutical sector and regulation in the countries of Central and Eastern Europe' in Elias Mossialos et al (eds) *Regulating Pharmaceuticals in Europe: Striving for Efficiency, Equity and Quality* (2004) 323.

[136] Regulation (EC) No 726/2004 of 31 March 2004.

[137] Regulation (EC) No 141-2000.

[138] See generally, <http://www.ich.org/cache/compo/615-616-1.html> at 29 August 2006.

[139] 'Statement by the ICH Steering Committee Tokyo, October 1990' available as part of *History and Future of ICH* available at <http://www.ich.org/cache/compo/276-254-1.html> at 28 August 2006.

[140] In fact, the ICH Secretariat is supplied by the International Federation of Pharmaceutical Manufacturers & Associations. <http://www.ich.org/cache/compo/276-254-1.html> at 26 August 2006.

[141] David V Eakin, 'The International Conference on Harmonization of Pharmaceutical Regulations: Progress or Stagnation?' (1999) 6 *Tulsa Journal of Comparative and International Law* 221.

To harmonize technical requirements for approval as closely as possible, the ICH's working groups have wrestled with the three key subjects all pharmaceutical regulators focus on: safety, quality and efficacy. Common Technical Documents have now been issued on all three of those subjects, to which all six ICH parties now subscribe.[142] The next strategic move is for the organization to try to induce the World Trade Organization to adopt the ICH guidelines. That way they can be disseminated globally beyond just the parties to ICH, its official Observers (including the World Health Organization, Health Canada and the European Free Trade Association) and the ICH's Global Cooperation Group representatives from the Asian Pacific Economic Cooperation, the Association of Southeast Asian Nations and the Pan American Network for Drug Regulatory Harmonization.

The ICH has no formal regulatory authority itself, and thus differs substantially from the incipient Trans Tasman TPA. Any adherence to its nominally technical (at this stage) guidelines is completely voluntary, because it has no licensing or coercive power on its own right. The organization's recommendations have formidable persuasive weight, however, for the world's major regulatory players have not only signed onto them, but had a strong hand in their formulation. Moreover, very little objection has been voiced to their harmonization efforts by others.[143]

The ICH experience thus demonstrates the level of international agreement that *can* be achieved to harmonize pharmaceutical regulatory issues – albeit on relatively uncharged technical questions and having taken place over a period of fifteen years. If the ICH attempts to wade deeply into such controversial subjects as DTC prescription drug advertising or regulating complementary medicines, however, its success in achieving consensus would undoubtedly diminish substantially. At the present time, ICH activity appears to be relatively dormant, for the seventh International Conference on Harmonization scheduled for the coming year has been cancelled – the last one was held in 2003. The ICH Steering Committees and Expert Working Groups who do the bulk of the ICH's ongoing work to achieve harmonization are still scheduled to meet in May of 2007, however.[144]

## CONCLUSION

It ought to go without saying why the best overall interests of both Australia and New Zealand should be served by consolidating Medsafe and the TGA. Monitoring the safety, efficacy and quality of pharmaceuticals is an increasingly complex business, and for fiscal reasons alone it makes sense for the two countries to consolidate the personnel and other resources necessary for regulation to be effective. Moreover, the scientific expertise required to evaluate the safety and efficacy of cutting edge chemical entities, biologics, genetic therapies and devices is extremely sophisticated, not to mention expensive, and is not always easily obtainable by a government agency in a small country.[145] Pooling intellectual capital and sharing hard-won knowledge through a joint regulator are therefore especially valuable for both countries as they attempt oversight of increasingly powerful global pharmaceutical companies.

---

[142] See, *Synopsis of ICH Guidelines and Topics*, 12-13 (2004) <http://www.ich.org/cache/compo/276-254-1.html> at 28 August 2006.

[143] North America, the EU, and Japan together constitute more than 88% of the world pharmaceutical market, H P S Chawla, Nalin Diwan and Keertiman Joshi, Emerging Trends in World Pharmaceutical Market (2004) Business Briefing – Pharmatech http://www.touchbriefings.com/pdf/890/PT04_Chawla.pdf at 14 September 2006.

[144] *Schedule of ICH meetings*, http://www.ich.org/cache/compo/276-254-1.html, at 27 August 2006.

[145] Cf, Munir Pirohamed and Graham Lewis, 'The implications of pharmacogenetics and pharmacogenomics for drug development and health care', in Elias Mossialos et al (eds), *Regulating Pharmaceuticals in Europe: Striving for Efficiency, Equity and* Quality (2004) 279.

The ANZTPA Treaty's broad language recognizes that the existing pharmaceutical regulatory policies of Australia and New Zealand are bound to conflict, at least in some ways. The Treaty specifically provides room for regulatory divergence where 'exceptional public health, safety, third country trade, environmental or cultural factors' are involved.[146] Any good lawyer can see the potential for driving a truckload of issues, scientific, economic, political, and ethical, through that loophole. The success of the trans-Tasman joint venture, assuming it comes to pass, nonetheless hinges on the degree of regulatory convergence the two countries manage to achieve, while still maintaining the integrity of strongly-held national values. The policy and operational details now being hammered out between the two countries hold the key to the ultimate accomplishments or disappointments associated with this unique venture. The world is watching.

[146] ANZTPA Treaty, Articles 11 and 12.