This is **Exhibit "A"** referred to in the Affidavit of **Michael John Trebilcock** sworn before me this 24th day of July, 2007.

A Commissioner, etc.

APPENDIX I

EMPLOYMENT HISTORY:

National Vice-President, Consumers Association of Canada, 1974 – 1975

Chairman, Regulated Industries Program, Consumers Association of Canada, 1973 -1975

Research Director, Professional Organizations Committee, Government of Ontario, 1976 - 1980

BOOKS:

The Professions and Public Policy (University of Toronto Press, 1978) with Slayton (eds.)

Handbook on Consumer Rights in Canada (C.B.C., 1978; revised edition forthcoming)

Professional Regulation (Ontario Govt. Printer, 1979) with Tuohy and Wolfson

Lawyers and the Consumer Interest, Evans and Trebilcock (eds.) (Butterworths, 1982)

The Limits of Freedom of Contract (Harvard University Press, 1993)

Michael Trebilcock, Ralph Winter, Paul Collins, and Edward Iacobucci, The Law and Economics of Canadian Competition Policy (University of Toronto Press, 2002).

CHAPTERS IN BOOKS

"When is a Consumer Protection Bill not a Consumer Protection Bill?", (1971 Wainwright Lecture Collection)

"The Consumer in the Post-Industrial Market-Place", in Lindgreen and Mason (eds.), The Corporation and Australian Society, (Law Book Co. of Australia, 1974)

"The Consumer Interest and Regulatory Reform", in Doern (ed.), The Regulatory Process in Canada (Macmillan, 1978)

"The Consumer Interest and the Regulatory Process", (with Prichard and Waverman), in Duggan and Dorvall (eds.), Consumer Protection Law and Theory (Law Book Co., 1980)

"Regulating the Quality of Psychotherapeutic Services", (with Shaul) in Dewees (ed.), Quality Regulation, (1983); also in Journal of Law and Human Behaviour, (1983).

"Policy Options in Quality Regulation", (with Dewees), in Dewees (ed.), Quality Regulation, (1983)

"Rethinking Consumer Protection Policy," in Charles Rickett and Thomas Telfer (eds.), International Perspectives on Consumer Access to Justice (Cambridge 2003).

PUBLISHED ARTICLES

"Reform of the Law Relating to Consumer Credit" - (1970) Vol. 7, No. 4, *Melbourne University Law Review* 315

"Consumer Protection in the Affluent Society", (1970) 16 *McGill L.J.* 263

"Protecting Consumers Against the Purchase of Defective Merchandise", (1971) 4 Adelaide L.R. 12

"Private Law Remedies for Misleading Advertising" (1972) 22 *University of Toronto L.J.*

"Manufacturers' Guarantees," (1972) 18 *McGill L.J.* 2

"Market Considerations in the Formulation of Consumer Protection Policy" (1973) 23 *University of Toronto Law Journal* 396 (with Cayne)

"Winners and Losers in the Modern Regulatory System: Must the Consumer Always Lose?", (1975) 13 *Osgoode Hall L.J.* 417

"The Pathology of Credit Breakdown", (1976) 22 *McGill L.J.* 417

"Regulators and the Consumer Interest", (1977) 2 *Canadian Business L.J.* 101

"Class Actions and Private Law Enforcement", (with Prichard) (1978) 27 *U.N.B.L.J.* 5

"The Doctrine of Inequality of Bargaining Power", (1976) 26 *University of Toronto L.J.* 359

"An Economic Approach to the Doctrine of Unconscionability" in Reiter and Swan (eds.) *Essays in the Law of Contract* (Butterworths, 1979)

"A Consumer Perspective on the Anti-Dumping Act" (with Quinn) 1979 *Canada-U.S. Law Journal*

"Judicial Control of Standard Form Contracts: An Economic Analysis" (with Dewees), (in Veljanovski and Burrows, eds.)

"Lawyers Advertising" (with Hudec) *University of Western Ontario L.R.*, 1982)

"The Administration of the Federal Hazardous Products Act" (with Shaul) *Canadian Business Law Journal*, 1982

"Products Liability and the Allergic Consumer - A Study in the Problems of Framing an Efficient Liability Regime" (with Rogerson) (1986), *University of Toronto Law Journal*

"Rethinking Price-Fixing Law", (with Warner), (1992-93) 38 *McGill L.J.* 679.

"Protecting the Employment Bargain" (with Howse) (Summer 1993) 43 *U. of Toronto L.J.* 751-792.

"Taking Stock: Consumerism in the 1990s", (1991) 19 *Canadian Business L.J.* 412

"The Medical Malpractice Crisis: A Comparative Empirical Perspective", (with Dewees and Coyte) (1991) 65 *Law and Contemporary Problems* 217

"Rethinking Consumer Protection Policy" (with Hadfield and Howse) (1998) *Journal of Consumer Policy*

"Risk Regulation: Technocratic and Democratic Tools for Regulatory Reform", (with Fraiberg), (1998) 43 *McGill Law Journal* 835

POLICY PAPERS, ACADEMIC REPORTS AND SUBMISSIONS

Member, Adelaide Law School Committee, Report to the Standing Committee of Australian Commonwealth and State Attorneys-General on the law relating to Consumer Credit and Moneylending, (140 pp.) (South Australian Government Printer, July 1969)

Report (under contract) to the Canadian Minister of Consumer and Corporate Affairs on "The Problems of Product Quality in the Consumer Marketplace", (180 pp.) (1971)

Position Paper (under contract) for the National Council of Welfare, Prices and the Poor, (1973)

A Study on Consumer Misleading and Unfair Trade Practices, (Information Canada, 1976) with others (2 vols.)

The Choice of Governing Instrument (with Hartle, Prichard and Dewees), Economic Council of Canada, 1982

This is **Exhibit "B"** referred to in the Affidavit of **Michael John Trebilcock** sworn before me this 24th day of July, 2007.

A Commissioner, etc.

MICHAEL J. TREBILCOCK

PROFESSOR OF LAW AND ECONOMICS, UNIVERSITY OF TORONTO
LL.B. (University of Canterbury, New Zealand)
LL.M. (University of Adelaide, South Australia)

EMPLOYMENT HISTORY:

Appointed full-time Tutor, Law School, University of Adelaide, January, 1963

Appointed Lecturer in Law, Adelaide, January, 1964

Appointed Senior Lecturer, Adelaide, January, 1967

Barrister and Solicitor of the Supreme Court of New Zealand, 1964

Visiting Associate Professor of Law, McGill Law School, 1969 - 1970

Associate Professor of Law, McGill Law School, 1970 - 1972

Professor of Law, University of Toronto Law School, 1972 - present

Barrister and Solicitor of the High Court of Ontario, 1975

National Vice-President, Consumers Association of Canada, 1974 - 1975

Chairman, Regulated Industries Program, Consumers Association of Canada, 1973 - 1975

Member, Academic Advisory Panel, Department of Consumer and Corporate Affairs, 1973 - 1975

Chairman, Consumer Research Council, 1975 - 1976

Research Director, Professional Organizations Committee, Government of Ontario, 1976 - 1980

Participant, Summer Institute, Economics for Law Professors University of Rochester, 1974

Fellow in Law and Economics, University of Chicago Law School, 1976

Member of the Presidential Advisory Committee on Institutional Strategy (PACIS), University of Toronto 1982 - 1983

Acting Research Director; Institute of National Affairs, Papua New Guinea, 1982

Lay Member - Canadian Competition Tribunal, 1987 - 1989

EMPLOYMENT HISTORY (cont'd)

Faculty of Law, University of Toronto 84 Queens Park Toronto, Canada M5S 2C5
Tel (416) 978-5843 Fax (416) 978-1279 michael.trebilcock@utoronto.ca

University Law School Committees (at various times): Admissions Committee, Curriculum Committee, Graduate Committee, Hiring Committee, Course Assignments Committee

Director, Laidlaw Foundation, 1985-1991

Member, Research Board, University of Toronto, 1986 – 1988

Appointed University Professor, University of Toronto, 1990

Member of the Research Council of the Canadian Institute of Advanced Research, 1982 – 1986

Director, Law and Economics Programme, University of Toronto Law School, 1976 - present

Chairman, International Business and Trade Law Programme, University of Toronto Law School, 1988 - 1995

Director, Centre for the Study of State and Market, 1995 – 2000

Visiting Professor, University of Virginia Law School, Fall 1996

Global Law Professor, NYU Law School, Fall 1997 and 1999

Research Director, Ontario Legal Aid Reform Task Force, 1997 and 1999

Research Director, Ontario Electricity Market Design Committee, 1998

Research Director, Panel on the Future Role of Government in Ontario, 2002-2004

Visiting Professor, Yale Law School, 1985 and 2005

Visiting Professor, University of Pennsylvania Law School, February 2007

HONOURS AND AWARDS

Elected Fellow of Royal Society of Canada, 1987

Recipient, University of Toronto Teaching Award, 1986

Winner of the Walter Owen Prize for Best English Legal Text in Canada, 1986 - 1988 for The Common Law of Restraint of Trade

Recipient of the 1990 Joint Award of the Canadian Law Teachers Association and Law Reform Commission of Canada for outstanding contributions to legal research and law reform

Elected Honorary Foreign Fellow, American Academy of Arts and Sciences, 1999

Recipient of Canada Council Molson Award for contributions to the Social Sciences and Humanities, 1999

Recipient of an Honorary Doctorate in Laws from McGill University, 1999

Elected President American Law and Economics Association, 2002

Winner (with Ralph Winter, Paul Collins and Edward Iacobucci) of the Doug Purvis Memorial Prize for contributions to Canadian Economic Policy for their book, The Law and Economics of Canadian Competition Policy, 2003

Recipient of an Honorary Doctorate in Laws from the Law Society of Upper Canada, 2003

Recipient of the Ontario Attorney General's Mundell Medal for contributions to Law and Letters, 2007

GRADUATE SUPERVISION

80 LL.M.s since 1969

10 Ph.Ds

GRADUATE COURSES TAUGHT

Alternative Approaches to Legal Scholarship, 1985

The Public Policy-Making Process (Department of Economics), 1982 - 1985

Social Regulation (Osgoode Hall Part-time LL.M.), 1987

International Trade Regulation (Osgoode Hall Part-Time LL.M.), 1990

LL.B. COURSES TAUGHT AT VARIOUS TIMES

Commercial Law; Corporate Law: Contract Law; Competition Law; Government Regulation; Social Security Law; Economic Analysis of Law; International Trade Regulation; The Limits of Freedom of Contract; Debtor - Creditor Law; Consumer Protection Law; Public Goals Private Means; Law, Institutions & Development.

RESEARCH FUNDING

PROGRAMME GRANTS

Connaught Seed Grant to Law and Economics Programme, 1976 – 1980 ($140,000)

Donner Foundation Grant to Law and Economics Programme, ($150,000)

Connaught Grant to Legal Theory and Public Policy Programme, 1985 ($800,000)

Olin Grant to Law and Economics Programme, 1989 ($330,000)

PROJECT GRANTS (WITH OTHERS)

Crown Corporations in Canada (Ontario Economics Council), 1978 – $30,000

Federalism and the Canadian Economic Union (Ontario Economic Council and Canada - U.S. Law Institute), 1980 – $80,000

The Choice of Governing Instrument (Economic Council of Canada), 1980 – $80,000

The Political Economy of Business Bailouts (Ontario Economic Council), 1984 – $80,000

The Political Economy of Economic Adjustment (Macdonald Royal Commission, 1985 – $15,000

PROJECT GRANTS (WITH OTHERS) (cont'd)

Adjusting to Trade (Economic Council of Canada), 1988 – $ 15,000

Medical Malpractice (Federal-Provincial Health Care Task Force), 1988 – $55,000

American Law Institute, Tort Reform Project), 1990 – $80,000

PUBLICATIONS:

BOOKS:

A Casebook on Company Law, (Sweet and Maxwell, U.K. 1977) with H.R. Hahlo

The Professions and Public Policy (University of Toronto Press, 1978) with Slayton (eds.)

Handbook on Consumer Rights in Canada (C.B.C., 1978; revised edition forthcoming)

Professional Regulation (Ontario Govt. Printer, 1979) with Tuohy and Wolfson

Debtor and Creditor Casebook, (University of Toronto Press, 1982) with Reiter, Laskin, Springman and Gertner

Lawyers and the Consumer Interest, Evans and Trebilcock (eds.) (Butterworths, 1982)

Federalism and the Canadian Economic Union edited with Prichard, Whalley and Courchene, (University of Toronto Press, 1983)

The Political Economy of Business Bailouts with Chandler, Quinn, Halpern and Gunderson, (Ontario Economic Council, 1986)

The Political Economy of Economic Adjustment: The Case of Declining Sectors, (Macdonald Royal Commission, Research Monograph, 1986)

The Common Law of Restraint of Trade: A Legal and Economic Analysis (Carswell, Toronto, 1986) (winner of Walter Owen Prize)

Canadian Competition Policy: A Legal and Economic Analysis (with Dunlop and McQueen) (Canada Law Book Co., 1987)

Regulating Traffic Safety (with Friedland and Roach) (University of Toronto Press, 1990)

Trade and Transitions (with Chandler and Howse) (Routledge, 1990)

BOOKS (cont'd)

The Law and Economics of Competition Policy (Fraser Institute, 1990) (with Mathewson and Walker, eds.)

Fair Exchange: Reforming Trade Remedy Laws (C.D. Howe, 1990) (with York, eds.)

The Limits of Freedom of Contract (Harvard University Press, 1993)

Unfinished Business: Reforming Trade Remedy Laws in North America (With Boddez) (C.D. Howe, 1993)

Exploring the Domain of Accident Law: Taking the Facts Seriously (with Dewees and Duff) (Oxford University Press, 1996)

The Regulation of International Trade (with Howse) (Routledge, 1995)

Getting There: The Agreement on Internal Trade (edited with Schwannen) (C.D. Howe Institute, 1995)

Michael Trebilcock (with Ninette Kelley), The Making of the Mosaic: A History of Canadian Immigration Policy (University of Toronto Press, 1999).

Michael Trebilcock, Edward Iacobucci, and Huma Haider, Economic Shocks: Defining a Role for Government, published by the C.D. Howe Institute, 2001.

Michael Trebilcock, Ralph Winter, Paul Collins, and Edward Iacobucci, The Law and Economics of Canadian Competition Policy (University of Toronto Press, 2002).

Michael Trebilcock and John Kirton (eds.), Hard Choices, Soft Law: Voluntary Standards in Global Trade, Environment and Social Governance (Ashgate, 2004).

Michael Trebilcock (with Ron Daniels), Rethinking the Welfare State: The Prospects for Government by Voucher (London: Routledge, 2005).

Michael Trebilcock (with Robert Howse), The Regulation of International Trade (Routledge, 2005), 3rd edition.

Albert Breton and Michael Trebilcock (eds.), Bijuralism: An Economic Approach (Ashgate, 2006)

CHAPTERS IN BOOKS

"When is a Consumer Protection Bill not a Consumer Protection Bill?", (1971 Wainwright Lecture Collection)

"The Consumer in the Post-Industrial Market-Place", in Lindgreen and Mason (eds.), The Corporation and Australian Society, (Law Book Co. of Australia, 1974)

"The Consumer Interest and Regulatory Reform", in Doern (ed.), The Regulatory Process in Canada (Macmillan, 1978)

"Problems of Economic Integration in a Decentralized Federation", (with Shiroky), in The Canadian Confederation at the Cross-roads (Fraser Institute, 1978)

"Economic Analysis of Commercial Law", (with Prichard) (Annual Commercial Law Workshop Volume, 1978)

"Markets for Regulation", (with Waverman, Prichard), in Government Regulation (Ontario Economic Council, 1978)

"Interprovincial Restrictions on the Mobility of Resources", (with others) (Ontario Economic Council, 1977)

"The Consumer Interest and the Regulatory Process", (with Prichard and Waverman), in Duggan and Dorvall (eds.), Consumer Protection Law and Theory (Law Book Co., 1980)

"Crown Corporations: The Calculus of Instrument Choice", (with Prichard) in Prichard (ed.), Public Enterprise in Canada, (Butterworth, 1983)

"An Approach to Framing Regulatory Policies for the Professions", (with Tuohy and Wolfson) in Rottenberg (ed.), Occupation Licensure, (American Enterprise Institute, 1980)

"Regulating the Quality of Psychotherapeutic Services", (with Shaul) in Dewees (ed.), *Quality Regulation*, (1983); also in *Journal of Law and Human Behaviour*, (1983).

"Policy Options in Quality Regulation", (with Dewees), in Dewees (ed.), *Quality Regulation*, (1983)

"Comparative Advertising", in Evans and Trebilcock (eds.), *Lawyers and the Consumer Interest*, (Butterworths, 1982)

"Licensure in Law", (with Reiter) in Evans and Trebilcock (eds.), *Lawyers and the Consumer Interest*, (Butterworths, 1982)

CHAPTERS IN BOOKS (cont'd)

"Crown Corporations in Canada", (with Prichard) in Chandler and Atkinson (eds.), *Public Policy Making in Canada*, (University of Toronto Press, 1982)

"Customary Land Law Reform in Papua New Guinea", *Adelaide Law School Centenary Essays*, (1983)

"Federalism and the Canadian Economic Union", in Bakvis and Chandler (eds.) *Federalism and the Role of the State* (University of Toronto Press, 1987)

"Can We Become Better Losers? The Political Economy of Economic Adjustment", in Maslove and Winer (eds.), *Knocking on the Back Door* (I.R.P.P. 1987)

"Economic Analysis of Law" in Devlin (ed.), *Studies in Canadian Legal Theory* (Carswell, 1990)

"The Evolution of Competition Policy: A Comparative Perspective" in Mathewson, Trebilcock and Walker (eds.), *The Law and Economics of Competition Policy* (Fraser Institute, 1980)

"Throwing Deep: Trade Remedy Laws in a First-Best World" in Trebilcock & York (eds.), *Fair Exchange: Reforming Trade Remedy Laws* (C.D. Howe, 1990)

"The Future of Ontario Hydro: A Review of Structural and Regulatory Options" (with Daniels) in Daniels (ed), *Ontario Hydro at the Millenum: Has Monopoly's Moment Passed?* (McGill-Queen's Press, 1996)

"Choice of Policy Instrument in the Provision of Public Infrastructure" (with Daniels) in Mintz (ed.) *Infrastructure and Competitiveness* (John Deutsch Institute, 1994)

"What Makes Poor Countries Poor? The Role of Institutional Capital in Economic Development" in Buscaglia and Cooter (eds.), *The Law and Economics of Development* (JAI Press, 1997)

"Competition Policy and Intellectual Property Rights" (with Gallini) in Anderson & Gallini: eds. *Competition Policy and Intellectual Property Rights* (Industry Canada, 1998).

"The Value and Limits of Law and Economics", in Hadfield and Richardson (eds) *The Second Wave of Law and Economics* (Federation Press, 1999)

"Immigration Policy" in *Palgrave Dictionary of Economics and the Law* (1998)

"Mostly Smoke and Mirrors: NGOs and the WTO", paper presented to an International Conference at New York University in March 2000, commemorating the 200th anniversary of the Library of Congress. This paper was published in a volume of conference papers.

CHAPTERS IN BOOKS (cont'd)

"Regulatory Diversity and Trade and Investment Liberalization"; paper presented at OECD Conference, Paris, December 2000, published in a volume by the OECD, 2001.

"International Trade Policy and Domestic Food Safety Regulation," (with Julie Soloway), in David Kennedy and James Southwick (eds.), *The Political Economy of International Trade* (Cambridge University Press, 2002).

"International Trade & International Labour Standards," in Stefan Griller (ed.), *International Economic Governance and Non-Economic Concerns* (Springer-Wien, 2003).

"Rethinking Consumer Protection Policy," in Charles Rickett and Thomas Telfer (eds.), *International Perspectives on Consumer Access to Justice* (Cambridge 2003).

"Trade Policy and Labour Standards," in J. Kirton and M. Trebilcock (eds.), *Hard Choices, Soft Law* (Ashgate, 2004).

"The National Treatment Principle in International Trade Law," (with Shiva Giri), in Choi and Hartigan (eds.), *Handbook of International Trade*, Volume II (Oxford: Blackwell, 2005).

"The Choice of Governing Instrument: A Retrospective," in Eliades, Hill and Howlett (eds.), *Designing Government* (McGill-Queens Press, 2005).

"Towards a New Compact in University Education in Ontario," (with Ron Daniels) in F. Iacobucci and C. Tuohy (eds.), *Taking Public Universities Seriously* (University of Toronto Press, 2005).

"Journeys Across the Divides," in Parisi and Rowley (eds.), *The Origins of Law and Economics: Essays by the Founding Fathers* (Edward Elgar, 2005).

"Electricity Restructuring in Canada," (with Roy Hrab) in Sioshansi and Pfanffeyer (eds.), *Electricity Market Reform: An International Perspective* (Elsevier, 2006).

CHAPTERS IN BOOKS (cont'd)

"Competition Class Actions: An Evaluation of Deterrence and Corrective Justice Rationales," (with Margaret Sanderson), in Stephen Pitel (ed.), *Litigating Conspiracy: An Analysis of Competition Class Actions* (Irwin, 2006)

"Rationales and Instruments for Government Intervention in Natural Disasters," (with Ron Daniels), in Daniels, Kettl and Kunreuther (eds.), *On Risk and Disaster* (U. of Pennsylvania Press, 2006)

"The Political Economy of Deregulation in Canada," (with E. Iacobucci and R. Winter), in Martin Levin (ed.), *Creating Competitive Markets: The Politics of Regulatory Reform* (Brookings Institute, 2007).

"The Demand for Bijurally Trained Canadian Lawyers," (with Kevin Davis), in Breton and Trebilcock (eds.), *Bijuralism: An Economic Approach* (Ashgate, 2006)

"The Lessons and Limits of Law and Economics," in Pierre Noreau (ed.), *In the Eye of the Beholder* (Montreal: Université de Montréal, Centre de recherche en droit public, 2007)

"International Trade: Barriers to Trade," (with Michael Fishbein), in Guzman and Sykes (eds.), *Research Handbook in International Economic Law* (Edward Elgar, 2007)

PUBLISHED ARTICLES

"Finders Keep - How True Today?" [1962] *N.Z.L.J.* 276

"Scope of the Defence of Provocation in New Zealand Law" [1963] N.Z.L.J. 619

"Section 260: A Critical Examination" (Income Tax) (1964) 38 *Australian Law Journal* 237 (discussed and applied by the New Zealand Supreme Court in *Lewis v. Commissioner of Inland Revenue*, [1965] N.Z.L.R. 634)

"Taxation of Assigned Income" (1963) 4 *The Australian Lawyer* 121 and 145

"Company Contracts" (1966) Vol. 2, No. 3 *Adelaide Law Review* 310

"Rights on a Bill of Exchange" (1966) Vol. 2, No. 3 *University of Tasmania Law Review* 270

PUBLISHED ARTICLES (cont'd)

"Effects of Alterations to Articles of Association" (1967) Vol. 31, No. 2 *The Conveyancer* (U.K.) 95

"Re-opening Hire-purchase Transactions" (1968) 41 *Australian Law Journal* 424

"The Liability of Company Directors for Negligence" (1969) U.K. *Modern L.R.*, September issue

"Company Law Problems in Family Tax Companies" 1969 *Australian Law Journal*, January, February, March issues

"When does a Settlement 'Take Effect'?" (Succession Duty) (1969) 42 *Australian Law Journal* 308

"Reform of the Law Relating to Consumer Credit" - (1970) Vol. 7, No. 4, *Melbourne University Law Review* 315

"Consumer Protection in the Affluent Society", (1970) 16 *McGill L.J.* 263

"Protecting Consumers Against the Purchase of Defective Merchandise", (1971) 4 Adelaide L.R. 12

"Private Law Remedies for Misleading Advertising" (1972) 22 *University of Toronto L.J.*

"Manufacturers' Guarantees", (1972) 18 *McGill L.J.* 2

"Market Considerations in the Formulation of Consumer Protection Policy" (1973) 23 *University of Toronto Law Journal* 396 (with Cayne)

"Winners and Losers in the Modern Regulatory System: Must the Consumer Always Lose?", (1975) 13 *Osgoode Hall L.J.* 417

"The Pathology of Credit Breakdown", (1976) 22 *McGill L.J.* 417

"Regulators and the Consumer Interest", (1977) 2 *Canadian Business L.J.* 101

"Class Actions and Private Law Enforcement", (with Prichard) (1978) 27 *U.N.B.L.J.* 5

"The Doctrine of Inequality of Bargaining Power", (1976) 26 *University of Toronto L.J.* 359

"An Economic Approach to the Doctrine of Unconscionability" in Reiter and Swan (eds.) *Essays in the Law of Contract* (Butterworths, 1979)

PUBLISHED ARTICLES (cont'd)

"A Consumer Perspective on the Anti-Dumping Act" (with Quinn) 1979 *Canada-U.S. Law Journal*

"Judicial Control of Standard Form Contracts: An Economic Analysis" (with Dewees), (in Veljanovski and Burrows, eds.)

"A Tax Credit for Public Interest Groups" (with Engelhart), *Canadian Taxation* 1982

"An Economic Analysis of Cost and Fee Rules and Class Actions" (with Dewees and Prichard) (1981) 10 *Journal of Legal Studies*, University of Chicago, 155)

"An Economic Analysis of Limited Liability in Corporation Law" (with Halpern and Turnbull), (1980) 30 *University Toronto L.J.* 117

"The Deregulation Debate", (1979) 10 *Canadian Marketer* 9

"Compensation, Transition Costs and Regulatory Change" (with Quinn) 1982 *University of Toronto L.J.*

"The Choice of Governing Instrument" (with Hartle) *The International Review of Law and Economics*, U.K., 1982

"Lawyers Advertising" (with Hudec) *University of Western Ontario L.R.*, 1982)

"The Administration of the Federal Hazardous Products Act" (with Shaul) *Canadian Business Law Journal*, 1982

"The Prospects of Law and Economics: A Canadian-Perspective" (1983) 33 *J. Leg. Ed.* 288

"Regulatory Reform and the Political Process", (with Hartle) (1982) 20 *Osgoode Hall L.J.* 643

"Products Liability and the Allergic Consumer - A study in the Problems of Framing an Efficient Liability Regime" (with Rogerson) (1986), *University of Toronto Law Journal*

"Communal Property Rights: The Papua New Guinean Experience", (1984) 34 *University of Toronto L.J.* 377

"The Law and Economics of Contract Modifications" (with Aivazian and Penny), (1984) 22 *Osgoode Hall L.J.* 173

PUBLISHED ARTICLES (cont'd)

"Restrictive Covenants in the Sale of a Business", (1984) *International Review of Law and Economics*

"Economic Mobility and Constitutional Reform", (1987) *University of Toronto L.J.* 268 (with Lee)

"The Social Insurance-Deterrence Dilemma of Modern North American Tort Law", (1987) 24 *San Diego L.R.* 929

"The Role of Insurance Considerations in the Choice of Efficient Civil Liability Rules", (1988) *Yale J. L. Ec. and Org.*

"Incentive Issues in the Design of No-Fault Compensation Schemes", (1988) *University of Toronto Law Journal*

"The Case for Free Trade", (1988) 14 *Can. Bus. L. J.* 387

"The Future of Tort Law: Mapping the Contours of the Debate", (1989) 15 *Can. Bus. L.J.*

"Punitive Damages: Divergence in Search of a Rationale", (with Chapman) (1989) 40 *Alabama L. Rev.* 741

"An Empirical Analysis of the Application of Canadian Antidumping Laws: A Search for Normative Rationales", (with Hutton), (1990) 24 *J. World Trade* 123

"Trade Restrictive Policies and Democratic Politics: A Proposal for Reform" (with Chandler and Howse) (1990), 1 *Public Law* 234

"Smaller or Smarter Government?" (with Howse and Prichard) (1990) 40 *Univ. Toronto L.J.* 498

"Making Hard Social Choices: Lessons From the Auto Accident Compensation Debate", (with Chapman) (1992) 44 *Rutgers L. Rev.* 78

"The Efficacy of the Tort System and its Alternatives: A Review of the Empirical Evidence", (with Dewees) (1992) 30 *Osgoode Hall L.J.* 57

"The Role of Private Ordering in Family Law: A Law and Economics Perspective", (with Keshvani) (1991) 41 *U. of Toronto L.J.* 5

"Rethinking Anti-Competitive Conspiracy Law", (with Warner), *McGill L.J.* (forthcoming)

"Protecting the Employment Bargain" (with Howse) *U. of Toronto L.J.* (forthcoming).

PUBLISHED ARTICLES (cont'd)

"Taking Stock: Consumerism in the 1990s", (1991) 19 *Canadian Business L.J.* 412

"The Medical Malpractice Crisis: A Comparative Empirical Perspective", (with Dewees and Coyte) (1991) 65 *Law and Contemporary Problems* 217

"Reforming Trade Remedy Law in North America" (with Boddez) (1994) *Minnesota J. of Global Trade*

"Testing the Limits of Freedom of Contract: Commercialization of Reproductive Technologies and Materials" (with Martin, Lawson and Lewis) (1994) 32 *Osgoode Hall L.J.* 613

"The Canadian Internal Trade Agreement" (with Behboodi) in Schwanen and Trebilcock, *Getting There* (C.D. Howe, 1995)

"Voice and Exit in New Zealand Health Care Reforms" (*University of Auckland Research Journal*)

"Can Governments Be Reinvented?" in Boston (ed.) *The State in an Age of Contracting Out* (1995)

"The Prospects for Reinventing Government" (C.D. Howe Institute, Toronto, 1994)

"Do Institutions Matter: A Comparative Pathology of the HIV-Infected Blood Tragedy" (with Howse & Daniels), (1996) 82 *Virginia L. Rev.* 1407

"The Fair Trade - Free Trade Debate: Trade, Labour and the Environment", (with Howse), (1996) *International Review of Law and Economics*

"The Economics of Nuclear Accident Law", (with Winter), (1997) 17 *International Review of Law and Economics* 215

"Private Provision of Public Infrastructure: An Organizational Analysis of the Next Privatization Frontier", (with Daniels) (1996) 46 *U. of Toronto L. J.* 375

"Public Accountability in an Age of Contracting Out", (with Atwood), (1996) 27 *Canadian Business L. J.* 1

"Competition Policy and Trade Policy: Mediating the Interface", (1996), 30 *J. of World Competition* 71

"An Introduction to Law and Economics", (1997) 23 *Monash University Law Review* 124

PUBLISHED ARTICLES (cont'd)

"Rethinking the Role of the Competition Tribunal" (with Campbell and Janisch) (1997) 76 *Canadian Bar Review* 297

"Private Enforcement of Competition Laws" (with Roach) (1996) 34 *Osgoode Hall Law Journal* 462

"The Limits of the Full Court Press: Of Blood and Mergers", (with Austin) (1998) 48 *University of Toronto Law Journal* 1

"Trade Liberalization and Regulatory Diversity: Reconciling Competitive Markets with Competitive Politics", (with Howse) (1998) 6 *European Journal of Law and Economics* 5

"Rethinking Consumer Protection Policy" (with Hadfield and Howse) (1998) *Journal of Consumer Policy*

"Risk Regulation: Technocratic and Democratic Tools for Regulatory Reform", (with Fraiberg), (1998) 43 *McGill Law Journal* 835

"Market Power Issues in Electricity Industry Restructurings", (with Gal) (1999) 22 *Journal of World Competition*, 119

"Lurching Around Chicago: The Positive Challenge of Explaining the Recent Regulatory Reform Agenda", published in Bird, Trebilcock and Wilson (eds.), *Rationality and the Policy Process* (Canadian Tax Foundation), 1999

"Government by Voucher" (with Ron Daniels) (February 2000) 80 *Boston University Law Review* 205

"Electricity Restructuring: The Ontario Experience", (with Ron Daniels) (April 2000) 33, *Canadian Business Law Journal* 161

"The State of Efficiencies in Canadian Merger Policy" (with Ralph Winter) (Winter 2000) 19 *Canadian Competition Record* 106

"The Supreme Court and Strengthening the Conditions for Effective Competition in the Canadian Economy" (2001) 80 *Canadian Bar Review* 542.

Michael Trebilcock and Steven Elliott, "The Scope and Limits of Legal Paternalism: Altruism and Coercion in Family Financial Arrangements", in Peter Benson Ed. *The Theory of Contract Law*, Cambridge University Press, 2001.

Michael Trebilcock, "Regulating Legal Competence" (2001) 34 *Canadian Business Law Journal* 444.

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PERSONAL

DATE OF BIRTH: September 15, 1941

CITIZENSHIP: Canadian

MARITAL STATUS: Married: Five children

This is **Exhibit "C"** referred to in the Affidavit of **Michael John Trebilcock** sworn before me this 24th day of July, 2007.

A Commissioner, etc.

BACKGROUND PAPER No. 3 – DEFINING THE MEDICARE BASKET

SUMMER/FALL 2004

Criteria for Listing on Provincial Drug Formularies

By Natalie de Paulsen and Lisa Minuk, Research Assistants,

and Professor Colleen M. Flood,

Faculty of Law, University of Toronto.

Prepared for Principal Investigators: Professors C.M. Flood, C. Tuohy, and M. Stabile.

This Research is funded by the Canadian Health Services Research Foundation (RC2-0861-06) and the Ontario Ministry of Health and Long Term Care.

NB: This research is on-going and should not be considered definitive. It is provided for information/discussion purposes only and should not be cited or quoted.

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Question: What methods can be used to control drug costs across Canada?

Summary:

Drug costs in Canada are largely constrained by not listing new drugs on formularies or by listing drugs for limited use, where clinical criteria must be met for reimbursement. The practice of not listing newer, more expensive drugs has the potential to negatively affect people whose diseases that have limited treatment options. Drug costs are also reduced through mandatory substitution legislation (brand-name for generic, more expensive generic for less expensive generic).

Throughout this report various incentives that are used by (U.S.) Pharmaceutical Benefit Management Companies are cited. Physician directed financial incentives are often used in the U.S., but have not been employed by provincial drug programs. In contrast, the provincial drug programs have employed pharmacist directed financial incentives.

Paper Framework:

1. Provincial drug plans in Canada

All the provinces employ a variety of methods to control prescription drug costs.

(a) Who they serve

There is no national drug coverage plan in Canada, and so each province chooses which segment of the population to insure. Quebec offers universal coverage while residentsin Alberta, British Columbia, Manitoba and Saskatchewan may opt-in to the provincial drug program.[1] In Ontario, the Trillium Benefit Plan covers residents not covered by the Ontario Drug Plan, who meet income requirements and whose drug costs exceed certain thresholds.[2] Criteria commonly used in determining beneficiaries include: age, income and type or severity of illness (See Table 1).[3]

Table 1. Comparison of the beneficiaries of the provincial drug plans.

	BC[4]	AB[5]	Sask[6]	Man[7]	ON[8]	Que b[9]	NB[10]	NS[11]	PEI[12]	Nfld.[13]
Catastrophic Care for residents not covered by other programs[14]	X		X	X	X[15]					
Purchased care for residents not otherwise covered[16]		X[17]				X[18]				
Resident over 65 years	X	x	X	x	x	X	x	x	x	x
Social services clients	X	x	X	x	x	X	x	x	x	x
Nursing home / long Care facility residents	X		X	x	x	X	x	x	x	x
Cystic fibrosis persons	X		X	x	x	X	x	x	x	x
Diabetic persons		x	X	x	x	X		x	x	
Cancer patients	X		X		x	X		x		
Organ transplant recipients	X		X		x	X	X	x	x	
AIDS patients	X		X		x	X	X		x	
Palliative care patients		x	X		x					
Other disease programs	X		X		X		X		x	

i. Opt-in programs

Four provinces offer optional prescription drug coverage to their citizens.

The BC, Manitoba and Saskatchewan plans are geared to residents whose drug costs are high in relation to their incomes. Residents registered for Pharmacare are assigned an income-contingent deductible, after which the province will take over a portion of drug costs.

In 2002-2003, approximately 67% of eligible Saskatchewanians opted into the provincial drug plan.[19]

In Manitoba, approximately 88, 0000 family units apply for Pharmacare.[20] All Manitobans who are not privately covered are eligible for Pharmacare.

(b) Summary of Benefit Plans

Every province except British Columbia employs a formulary listing to constrain drug costs.[21] British Columbia uses a reference pricing system.[22] To lower costs, provincial drug plans limit drugs listed on the formulary, provide incentives for patients, physicians, and pharmacists and enforce cost-sharing.

See Appendix 1 for a table comparing the provincial drug plans.

2. Federal Drug Plans

(a) Overview

The federal government will provide "income tax relief to households with large drug and other medical expenses."[23]

The federal government directly subsidizes aboriginals and veterans.

The non-insured health benefits (NIHB) program insures approximately 735, 000 First Nations and Inuit for a range health related goods and services, including drugs.[24] The NIHB is supplementary insurance, meaning that it will only reimburse for things that are not available to claimant under a provincial, territorial or 3rd party health plan.[25] In 2002-2003, the prescription drug component of the NIHB cost the government $290.1 million.[26] The average expenditure per claimant was $544 nationally, but that varied widely across provinces: in Quebec the per-claimant average was $752 and in Saskatchewan it was $470.

(b) Generic Substitution

The federal government has its own drug formulary, and it reimburses claimants for any prescribed, listed drugs. All things being equal, the NIHB will only reimburse the "lowest cost alternative" in a family of drugs with the same active ingredient. There are exceptions where (a) the patient's physician fills out an Adverse Drug Reaction Form and writes "no substitution" on the prescription and (b) the dispensing pharmacist requests and obtains prior approval from the Health Canada NIHB Drug Exception Centre.

(c) Accountability Mechanisms

The NIHB has an array of accountability measures. These include:

1. conducting "next-day" review of on-line claims and automatically flags files where pharmacists have made claims over a specific dollar amount.
2. sending a quarterly mail-out to a random selection of clients, to confirm that they have received the drugs claimed on their behalf.
3. going on-site and checking a sample of the pharmacies records.[27]

"Providers must reverse...all claims paid in error" and, if that is not possible, the pharmacy must send a cheque reimbursing First Canadian Health for the error. Those who fail to comply, risk "the reversal of all applicable claims and...the termination of the...Provider Agreement."[28] In 2002-2003 the audits netted a $2,308,055 savings in drug costs.[29]

3. Stakeholder interests

Methods used to constrain prescription drug costs invoke various stakeholder interests.

Table 2. Stakeholders' interests in the development of formularies and other methods to control costs.

Group	Interest	
	Positive Effects	**Negative Effects**
Insurance Providers	Reduce cost of providing drug benefits to members	Negative patient and physician responses
	Reduce unnecessary costs (i.e., switching generic drugs for brand-name drugs)	(i) when complicated procedures are necessary to receive coverage for a drug
	Allow savings by securing rebates from manufacturers' by placing products on a preferred drug list[30]	(ii) where coverage of a necessary drug is denied

Health Care Professionals	By use of a formulary physicians may be meeting their ethical obligation to the community at large to provide medical care[31]	May not be able to treat patients with an effective resource[32]
Patients	May ensure that effective medicines for a particular indication are used	Incentives increase patients' costs Necessary pharmaceuticals may be omitted from listings Drugs which do not provide more benefits than their counterparts on average may be optimal for a small percentage of patients who will no longer be able to get them Patient autonomy may be lessened
Pharmaceutical Companies	Allow negotiation for high volume of a particular drug product when listed on the formulary	

4. Cost control mechanisms

Formularies, preferred drug lists, therapeutic interchange programs, drug utilization review, prior authorization, treatment guidelines, mail service dispensing, consumer information and consumer compliance programs can be used to influence drug costs.[33] The cumulative effect of these measures can result in significant savings.

A 2002 report by one Pharmacy Benefit Management company (PBM)[34] estimated the individual and cumulative benefits of different cost savings mechanisms (Table 3).[35]

Table 3. Mechanisms for Managing Prescription Drug Costs[36]

	Range of savings in drug expenditures
Formulary management (includes drug list content, formulary administration and enrolee and physician education)	Up to 11%
Drug Utilization Review (concurrent and retrospective)	Up to 6%
Coverage management (includes prior authorization, step therapy, clinical protocols, dispensing, dose and quantity protocols)	Up to 4%

Generic substitution	Up to 4%
Total real savings	**Up to 26%**
Mail service dispensing (for maintenance drugs)	Up to 10% of retail cost
Retail Pharmacy networks	Up to 4% of retail cost
Total retail savings	**Up to 14% of retail Costs**

PricewaterhouseCoopers (PwC) published its own cost effectiveness analysis in 2004.[37] The results were fairly consistent with the industry's reports, particularly when one considers that the industry only stated the maximum savings. PwC estimated that PBMs save a total of 25% through their cost savings strategies.[38]

The PwC study was responding to a legislative proposal to constrain PBMs, and that proposal shaped the scope of the study by dictating which strategies received close scrutiny. The results (table 4) are therefore not exhaustive, but they are a nice complement to the industry list because they are more independent and because they represent the most up-to-date assessment available of the savings generated by particular strategies – including some not included in the other analysis.

PwC estimates the amount that drug costs would increase for individuals in PBMs in 2005 if the specified savings strategies were prohibited by the legislature. For the purpose of this memo, I have paraphrased this as "estimate of cost savings" in the table below.

Table 4. Estimated cost savings for individuals in PBM managed plans in 2005

	Yearly savings across all PBMs
Therapeutic Interchange programs	4.4%
Prior authorization and drug utilization reviews	4%
Mail Service Dispensing	2.6%
Network discounts and manufacturer rebates generated through ability to keep contract terms and pricing data secret from competing insurers	5.2%

(a) Formularies defined

Formularies are lists of approved pharmaceuticals.[39] Formularies are categorized depending on the policy for reimbursing unlisted drugs. All provinces using formularies have restricted formularies, reimbursing only listed drugs. In some situations, a patient prescribed an unlisted drug will be reimbursed for the amount of a comparable listed drug.

Table 4. The different type of formularies.

Type	Description
Open formularies	List recommended drugs and relative cost information.[40] Physicians and patients are educated on the costs of alternate medicines.[41] Prescription outside the plan is acceptable.
Preferred formularies	Impose lower co-payments for drugs on the formulary.[42]
Closed (Restricted) Formularies	Insurers provide reimbursements only for drugs on the formulary.[43] May include mechanisms to allow patients access to unlisted drugs.

(b) Therapeutic interchange and generic substitution

Therapeutic interchange programs exchange less expensive but equally effective (i.e., therapeutically equivalent) drugs for their more costly counterparts.[44] In programs that use generic substitution a brand name drug is replaced with its generic (i.e., chemically identical) form.[45] No provincial plans require that a patient be consulted about generic substitution.[46]

(c) Reference Based Pricing

Reference based pricing [RBP] limits reimbursement to a "reference standard" within a group of drugs with similar therapeutic applications and effectiveness but different active ingredients.[47] This reference standard is typically either the lowest priced drug or the average price of the drugs in a category.[48]

In British Columbia, the Pharmacare program reimburses patients for the lowest cost drug in each therapeutic class.[49] Patients prescribed higher priced drugs can pay the difference between the cost and the reference price or request a cheaper drug.[50] There are exceptions for patients who can show that the higher priced drug is medically necessary.[51] Reference pricing only works to reduce prices in situations where therapeutically equivalent drugs exist. It would therefore have no effect on first-in-class drugs or single drug markets.

The literature on the efficacy of RPB relative to other incentive structures is extremely limited; further research is clearly needed. As recently as July 2004, Schneeweiss *et al.*

commented that, "evidence on the effects of reference pricing outside of BC is sketchy." In BC, however, Schneeweiss *et al.* attribute a significant (6%) net health care savings between 1996 and 1997 to the application of RPB to anti-hypertensive drugs. Ionnides-Demos *et al.*, in the course of their review on the effect of RPB in the countries that have implemented it (Table 5), say that "where the reference price is based on the lowest priced drug(s) in the group, RPB appears to be one of the few strategies likely to be effective at encouraging doctors to use the least expensive agents as first-line therapy".

Table 5: Summary of reference based pricing[52]

Table II. Summary of reference-based pricing (RBP)

Country	RBP phase	Year introduced	Determinant of reference price	Total drug expenditure
Germany	I	1989	Statistically derived average price of drugs in a category	Decreased rate of increase 1989, 1993-1995; smaller decrease in 1992
	II	1992		
	III	1993		
Australia	I	1990	Lowest priced drug	Decreased expenditure growth rate 1997/1998, 1998/1999; increased expenditure 1998/1999, 1999/2000[a]
	II	1999		
The Netherlands	III	1991	Average price of drugs in a category	Decreased expenditure growth rate 1991; increased expenditure 1992, 1993
New Zealand[b]	II	1992	Lowest priced drug	Decreased expenditure 1998-1999; decreased expenditure growth rate 1993-1998
Sweden	I	1993	Lowest priced drug plus 10%	Increase total pharmacy sales 1993, 1994; cost savings 1993, 1994
Denmark	I	1993	Average dosage unit price for two lowest cost products in a group	Decreased expenditure growth rate in first year
Norway	I	1993	NA	NA
Canada[c] (British Columbia)	II	1995	Lowest priced drug	Decreased expenditure and expenditure growth rate in 1998

a Data from the Pharmaceutical Benefits Scheme.[21] Data were also directly obtained from the Drug Utilisation Sub-Committee, Pharmaceutical Benefits Advisory Committee, Canberra, ACT, Australia.

b Tendering for sole subsidizing of generic drugs to be the preferred brand on the Pharmaceutical Schedule since 1997.

c Ontario has a system for generic categories which is equivalent to phase I RBP.

NA = no readily available information.

Reference based pricing raises the concern that patients may switch to less effective medications or stop treatment, rather than incurring additional cost.[53] Two studies have shown that this has not occurred for at least two classes of drugs that have reference standards in British Columbia. Schneeweiss *et al.* reported that introducing reference pricing for ACE inhibitors "was not associated with changes in the rates of visits to physicians, hospitalizations, admissions to long-term care facilities or mortality."[54] There was, therefore, little evidence that reference pricing induced patients to stop treatment, leading to increased health care utilization and costs.[55] Secondly, Grootendorst *et al.* reported that although expenditures on nitrates prescribed to senior citizens declined $14.9 million in the 3.5 years after reference based pricing was introduced, there was no deterioration in patient health.[56]

(d) Disease Management

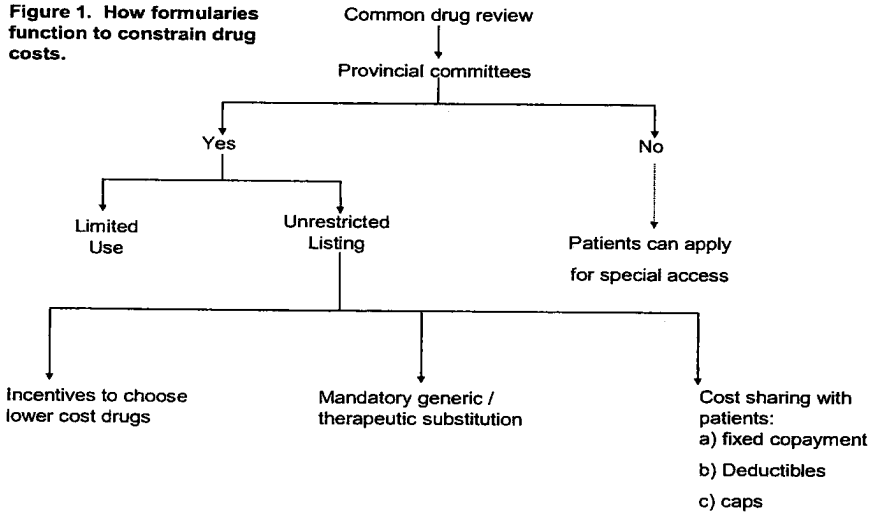
Disease management describes a coordinated healthcare intervention for populations with conditions that require significant self-care efforts, such as diabetes and asthma.[57]

Prescription costs and other medical costs are reduced by more effectively treating the chronic condition, which includes following guidelines for drugs used in treatment. Disease management strategies are directed at out of control cases of chronic conditions that have the greatest emergency room use, hospitalization, and other resource intensive interventions. Positive effects on quality of care, cost of care, and patient and physician satisfaction have been reported for patients in well-structured, repetitive programs.[58]

4. Controlling costs in the formulary system

Please see figure 1 and 2 for a summary of how drug costs are constrained in the provincial formulary systems.

Figure 1. How formularies function to constrain drug costs.



(a) The listing of new drugs

One of the main factors inflating drug costs is the introduction of new, more costly drugs.[59] This section reviews how the decision to list, not list (or de-list), or list with conditions for use influence expenditures.

i. Common drug review

A common drug review (CDR) process is used to assess pharmaceuticals for listing on publicly funded drug plan formularies in Canada.[60] The objectives of the CDR undertaken by the CCOHTA are to:

- Provide a consistent and and rigorous approach to drug reviews and an evidence-based listing recommendation;
- Reduce duplication of efforts by drug plans;
- Maximize the use of limited resources and expertise and;
- Provide equal access to the same high level of evidence and expert advice by all participating plans.[61]

ii. Provincial Committees

The refusal to list new drugs is often used to constrain drug costs. Each public drug plan formulary can make its own decision as to whether any drug will be funded.[62] This has resulted in a lack of agreement between provincial drug formularies. In a study of new drug molecules introduced between 1991-1998, listings ranged from less than 50% (four provinces) to more than 70% (four provinces).[63]

iii. Coverage for New Drugs in Canada

Just because a drug is approved by Health Canada is no indication that it will also be placed on a provincial formulary. For example, the Ontario Drug Benefit formulary has only listed 25% of new products launched in the last two years.[64] This has the potential to severely disadvantage some patients.[65]

(b) Limited use drugs and step protocols

Limited use products are drugs that are only reimbursed when specific clinical conditions are met.[66] The Ontario Drug Benefit indicates that limited drug use program is used for drugs which may:

- have the potential for widespread use outside the indications for which benefit has been demonstrated;
- be useful but are associated with predictable severe adverse effects and a less toxic alternative is available as a benefit;
- be very costly and a lower-cost alternative is available as a general benefit.[67]

One of the clinical conditions that may be required is attempted therapy with other less expensive or less toxic drugs.[68] In requiring this limited use drugs are tracking the use of "step protocols" in the United States.

In step protocols, treatment guidelines indicate that cheaper drugs are the first line therapies. Step protocols may be voluntary and educational or mandatory, and tend to follow "the recommendations of national commissions, government agencies and leading medical associations."[69] Jones *et al.* found that a stepped protocol requiring at least a trial with an inexpensive non-steroidal anti-inflammatory drug (NSAID) before progressing to an expensive NSAID lead to a reduction of expensive NSAID use (34% to 21%) and decreased costs by 30%.[70]

(c) Access to Drugs Not Listed on the Formulary

Almost all of the provinces have information on their web-sites for the process to be used by physicians/patients for access to drugs not listed on the provincial formulary.[71] This authorization is often required for coverage of expensive and new drugs.[72] Critiques of prior authorization procedures point out they have the potential to increase administrative costs[73] and may unduly discourage optimal therapy.[74]

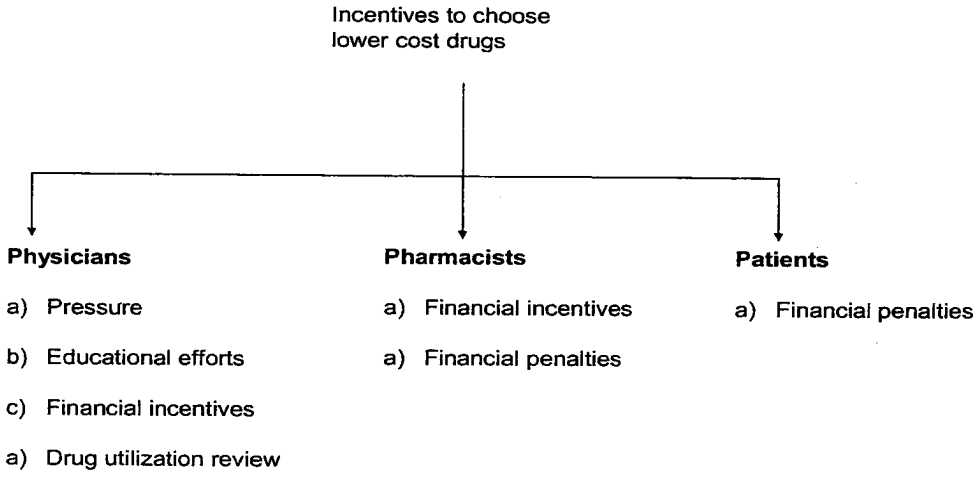
(d) Ontario's Section 8 Mechanism

This section examines the use of Ontario's prior authorization system for unlisted drugs.

Patients who are eligible for the Ontario Drug Benefit[75] and who require a drug not listed on the formulary or special drugs program can apply under s.8 of the Ontario Drugs Benefit Act for special coverage of a non-listed drug product.[76] This program can also be used for drugs that have been approved by Health Canada but are not yet listed on the formulary.[77] To receive funding the patient's physician must submit a standardized request form that includes medical information about why the patient cannot use products that are on the provincial formulary. Medical experts then screen requests.[78] Although over 80% of requests are granted, this process can be inefficient and time consuming as assessments must be done before routine events, like filling a prescription.[79] Furthermore, while 88% of successful requests are filled within three days the remaining 12% of requests are substantially delayed.[80]

The Committee responsible for the ODB is slowly overhauling s.8; attempting to make it a more efficient and more transparent mechanism. To facilitate **efficiency**, the Committee is working to develop standardized request forms and criteria for expedited internal reviews and external reviews. The ODB also intends to implement a document management system, to improve workflow processes. For **transparency**, the Committee hopes to use the Internet to make those forms and information about reimbursement criteria available to the public.[81]

Figure 2. Patient, physician and pharmacist incentives in the formulary system.



5. Patients' Incentives and Cost Sharing

All the provincial drug programs use financial incentives and cost-sharing mechanisms to constrain drug costs.[82] Financial incentives are used to encourage patients to choose less expensive drugs. Cost sharing policies reduce the overall cost of the programs and may influence some prescription habits, but are not necessarily designed to increase the use of lower cost medicines.[83]

(a) Financial Penalties

A drug program may refuse to reimburse a patient for drugs not listed on the formulary. There are also incentives and financial penalties to encourage patients to use lower cost medicine. For example, when only the low cost alternative or reference based price is covered the patient bears a cost if substitution does not occur and a more expensive drug is chosen.[84]

In the United States, drug utilization reviews are used to prospectively or retrospectively deny reimbursement of drugs that are not medically necessary or drugs that are considered experimental.[85]

(b) Tiered formularies

Tiered formularies are commonly used in the United States to encourage generic and less expensive drug use by introducing or raising co-payments for select drugs.[86] A three-tier formulary, for instance, might have co-pays of $10 for generics, $25 for formulary brands and 50% non-formulary brands.[87]

Switching to tiered co-payments reduces spending by the insurance provider on drugs. Joyce *et al.* analyzed a 420 786 member database for prescriptions received by patients with employer provided drug benefits.[88] Doubling co-payments in a 2-tier plan from $5 generics and $10 brands to $10 generics and $20 brands reduced costs by 33%.[89] Adding a third tier for non-formulary drugs further reduced spending by 4%.[90]

A longitudinal study by Fairman *et al.* buttresses Joyce et al.'s results, finding a significant reduction in "the growth of the insurer's net costs" after shifting from a 2-tier to a 3-tier structure – even not including the effect of rebates "which enhance savings associated with the 3 tier structure."

In a similar study, Haiden *et al.* studied spending on drugs in two employer sponsored health plans – one that had, like Fairman's subjects, switched from a 2-tier to a 3-tier group. The second group switched from a 1-tier group to a 2-tier group.

(c) Health Outcomes and Medical Service Utilization

One result of adopting a tiered model is that the number of people using medicines placed in the higher tiers will decrease. This prompts concerns that patients who legitimately need the more expensive drugs will stop taking them and (i) get sick or (ii) overuse other medical services, such as office visits, ER visits and inpatient hospitalizations to compensate.

Health Outcomes

Huskamp et al., in the study described *supra* at 23, found that "some enrollees (in the group that switched from the 1-tier system to the the 3-tier system) stopped taking medications in these classes (cholesterol reducing drugs) altogether."[91] In contrast, enrollees in the plan that had shifted more gradually – making the switch to a 3-tier system from the 2-tier system – experienced "little effect on the probability of the use of a drug...or the likelihood of the discontinuation of the use of a medication."[92] Presuming that people who stop taking cholesterol reducing drugs may suffer poorer health outcomes than those who continue taking them, this discontinuation compromises health. The study indicates that incremental changes to insurance plans may have fewer long-term negative consequences to the people insured.

No Effect on Medical Service Utilization

Fairman *et al.* acknowledged the second concern and conducted a study that helps greatly in alleviating it. The 30-month study compared drug costs and medical utilization in a group of employee's whose employer had shifted them into from a 2-tier plan ($7 copayment for generics, $12 brands) to a 3 tier prescription benefit ($8 generics, $15 formulary brands, $25 nonformulary brands). Fairman and colleagues found "no evidence that implementation of the 3-tier plan affected utilization of medical services, including numbers of office visits, emergency department visits and hospitalizations. In 4 (chronic medication) drug classes...continuation rates did not differ sign"[93]

Caveat

It seems that all the studies have been done through employee insurance plans. This is significant because it implies that the people covered have a job with benefits and, therefore, are more likely to have the disposable income likely to make the higher co-payments where necessary. The outcome on medical utilization and health might be different if the insurer was public and many of the insured could not afford to get the higher priced drug, no matter how necessary it might be.

(d) Fixed Co-Payments

All the provinces, except Manitoba, require co-payments when prescriptions are dispensed.[94] Co-payments are considered ineffective in encouraging consumers to request less expensive or generic drugs, since the consumer bill remains the same.[95] They may, however, be used to encourage patients to change prescription drug purchasing habits. For example, Saskatchewan requires a 35% co-payment to discourage quantity loading at the end of the deductible period.[96]

(e) Deductibles

Deductibles are used by British Columbia, Saskatchewan, Manitoba, Quebec and Ontario (Trillium Drug Program). See Appendix 1 for more information.

(f) Caps

Insurance providers also constrain placing an annual dollar limit or "cap" on drug benefits.[97] Caps allow "some benefits to be provided to many people at a predictable level of total expenditures" in the face of rapidly rising drug costs.[98] Tseng *et al.* studied the effects of implementing caps that ranged from $750 - $2000 in Medicare plans. Caps were determined solely by where a patient lived, and a beneficiary could not choose higher or lower caps by paying different premiums. The researchers reported that at lower caps, 1 in 5 patients exceeded their annual monetary allotment.[99] Other studies have shown that higher cost sharing generally leads to decreased medication use.[100]

Caps are uncommon in the provincial drug plans. The Alberta Blue Cross plan covers 70% of the cost of prescription drugs, the consumer pays the remaining 30% (to a maximum of $25.00 / prescription).[101] There is an annual/lifetime maximum of $25 000 per year, which may be increased after review.[102] I was unable to find evidence of other caps.

Some argue that caps can potentially alter nature of health insurance, from the defined benefits model to a defined contribution model. Where the benefits model provided all beneficiaries with the same package of health benefits, defined contribution plans, simply fix a maximum sum of money (the cap) to which each beneficiary is entitled. Victor Fuchs argues that this shift is problematic, because [103]the defined contribution model will compromise the traditional risk-sharing function of insurance, shifting the costs to those who are the most in need of drug coverage. This is particularly troubling when the discussion is about public insurance, because *need* is -- at least ostensibly – the reason the public is subsidizing health or drug insurance in the first place. Cost sharing measures, like imposing user fees and drug caps, do reduce costs – but usually by cutting use of services among the lowest income groups.

6. Incentives for Physicians

(a) Financial Incentives

My literature search did not reveal any financial incentives for physicians given by the provincial programs. Other countries, however, do try to constrain drug costs through physician incentives. Their experiences may be instructive for us.

i. Year-End Bonus for Low Prescribers

Financial incentives are used in the United States to persuade doctors to use more cost effective prescriptions. One common financial incentive is a year-end bonus if prescription drug costs are minimized or requests to switch patients to lower drug costs are met.[104]

ii. Budget Caps

Germany has had overall expenditure caps for pharmaceutical prescribing since 1993 to 1997.[105] This, unlike the fund-holder model, put costs into 'silos' so savings on drugs could not be used to subsidize other aspects of the medical practice. Initially, liability was collective. German physicians had to reimburse the government for the first 280 million DM – or the first 125% -- they spent above the cap.

The cap was effective.[106] The Germans report that physicians "reduced the number of prescriptions by 11.2% and increased their prescriptions for generics."[107] As well, between 1992-2002 there was a 64% decrease in the number of prescription drugs of disputed effectiveness.[108] Expenditure on products of disputed effectiveness decreased by 62% and expenditures on non-disputed products increased by 69%.[109]

Some literature suggests, however, that some of the savings may be theoretical, and rooted in cost shifting. Soumeri *et al.* say that "an increase in costs of specialists and hospital care (who were exempt from the capping regulations) that approximately equals the savings in drug expenditures."[110]

In 1995, costs exceeded the budget in 9 out of 24 German regions. Germany discontinued the budget caps in 2001 because of legal difficulties collecting.[111]

Physicians now have target volumes, based on their patient demographics, for which they are individually liable. Each year, they were given a target based on data (which they also had access to) on regional prescription volume for their specialist group. Those who exceed the target by 25% must explain and provide reasons for over-prescribing (e.g., drugs for severe disease). I could not find any literature specifically discussing the effects of the individual caps, perhaps because the change was too recent to allow time for academic study.

iii. Fund-holding and capitation based budgets

In Great Britain, between 1991 and 1999, prescribing budgets were included within GP fund-holding[112] budgets. Practices that exceeded 5000 patients could choose to manage the budge for elective surgery, outpatient care, diagnostic testing, community nursing *and* prescribing costs. The budget would be based on (a) spending in the previous year and (b) on the specific needs of the patient population. Insofar as the budget attended to the composition of the patient population, it was capitation based.

The fund-holding model was intended to give participating doctors an incentive to be more careful in their prescribing practices. Initially, the prescribing costs of fund-holding practices increased at slower rate than their non-fund-holding counterparts did.[113] The slower increase

rate was not because physicians stopped prescribing, but because they became more likely to prescribe the more economical generic drugs.[114] However, Harris & Scrivener conducted a longitudinal 6 year studied that revealed that most of the savings occurred in the first year of implementation. "Successive waves of fund-holders showed a similar pattern of change: maximum relative reduction in the first year (of implementing a fund-holding model), and a declining relative reduction in the second and third years. After this, (fund-holders') increases in costs were largely similar to those of non-fund-holders.)"[115] Some authors suggest that this prescribing problem occurred because premising the budget formula primarily on the previous years prescribing rewarded inefficient prescribing and vice versa.[116]

The capitation aspect of the formula literature was also subject to much academic criticism. Specifically, the criteria used to calculate the budgets were still likely too crude – and poor substitutes for more detailed reflection and association. The formulas did not reflect all variations in costs and differences in clinical practice and could not substitute for reflection and negotiation – this indicates that capitation *could* be workable with a more nuanced formula.[117] There is also the normal capitation problem of creating incentives for practitioners to reject patients most in need of medical services.[118]

James Robinson suggests a more fundamental reason for the failure of capitation models to meet expectations:

> [P]hysicians...no longer aspire to the dual role of agent for society and for the individual patient, for managing costs as well as quality. Physicians want to be on the side of their patients, advocating for more resources and better quality, rather than taking on the social responsibility for comparing costs and benefits in a complex and volatile environment.[119]

Though made in the context of capitation, if we take Robinson's critique seriously than it gives cause to question *all* the efficacy and desirability physician side incentive models. This is the kind of critique that forces a value assessment: is it desirable effect the kind of paradigm shift that would make physicians willing to sacrifice individual health outcomes for a larger social good?

(b) Pressure from other stakeholders

A phone call from pharmacists or plan administrator persuading physicians to switch products can be an effective tactic.[120] As well, some evidence suggests that physicians respond to pressure to prescribe drugs that will be reimbursed for patients.

In 1997, the Nova Scotia Seniors Pharmacare Program (NSSPP) became concerned about the cost and risk of antibiotic resistance associated with fluorquinolones, a class of anti-microbial drug that NS physicians were prescribing heavily to seniors.[121]

The NSSPP implemented a policy limiting reimbursement of fluoroquinolones to specific criteria, and prescription claims for fluoroquinolones decreased by 80.2%, and the overall the total number of anti-microbial claims decreased by 2.2%. The total NSSPP expenditure on anti-microbials also dropped, from $35.24 to $27.51 per user.[122]

Part of the decrease in price was because physicians were switching from fluorquinolones to listed, but cheaper, antimicrobials.[123] Some of the substitutes, notably the substances known as trimethoprim/sulfamethoxazole carry "a significant risk for adverse drug reactions in the elderly."[124] This is an important reminder that incentives to save the government money can have other, health outcome level costs.

Other, more recent studies involving the NSSPP produced similar results. This time, the NSSPP stopped reimbursing its elderly beneficiaries for all but 2 **combination** topical corticosteroid products (TCPs). Campbell et al. found that following this change, prescriptions for **combination** TCPs decreased by 4% and prescriptions for (reimbursable) **potent** TCPs increased by 3 percent.[125] Again, it is unclear in this scenario whether the savings to the system come at the expense of patient outcomes.

However, yet another Nova Scotia study concluded that the "de-insuring of chlorpropamide and the educational strategies that accompanied it resulted in the selection of more appropriate anti-hyperglycemics for Nova Scotia Seniors." [126]

This all goes to say that prescription incentives are a double-edged sword. If they are used only to cut costs without attending to patient outcomes, the net result will likely be harm. If, however, they are used to create prescribing incentives that accord with clinical practice guidelines, then the net result will likely be better health outcomes.

(c) Educational Efforts

Education efforts range from publication of price lists and disseminating cost–effectiveness studies to individualized feedback to a physician on his or her prescribing habits. The price of drugs listed in the formulary is available to physicians and the public.[127] Two Canadian studies on the effectiveness of confidential feedback comparing a physician's prescribing habits with best practices came to opposite conclusions. Confidential feedback was effective in improving prescribing habits for antibiotic use.[128] However, it did not have an effect on reducing prescriptions for benzodiazepine use in elderly patients.[129]

(d) Drug Utilization Review

Drug utilization reviews can occur at the level of the health care professional or patients.[130] These reviews ensure that prescriptions are based on medical necessity and are for drugs which are not considered experimental. In the United States, physicians that fall outside prescribing targets are subject to "alert letters" and possible financial penalties.[131]

7. Incentives for Pharmacists

(a) Financial Incentives

Some provinces provide incentives to physicians for dispensing generic drugs: Pharmacists are fully reimbursed for dispensing generics, but only partially reimbursed for dispensing brand name drugs. [132] Ontario accomplishes this by only reimbursing pharmacists for the lowest priced interchangeable drug available.[133] BC pays a flat $8 dispensing fee no matter

what, which I suppose has a similar effect if one assumes that it will cost the pharmacist more to dispense a name brand drug. Manitoba?

In Nova Scotia, the government previously used financial incentives to promote generics. Pharmacists received a higher drug fee from the drug plan as well as $0.40 for each prescription substituted for a generic. Following this change the market share of generics increased from 25.9% (April-June 1987) to 32.4% in July 1987 [despite remaining stable previous to other incentives being reduced].[134]

(b) Mandatory Substitution

The majority of provinces also have legislation in place mandating substitution by the pharmacist from a brand name or more expensive generic drug to a cheaper generic drug.[135]

(c) Financial Penalties

The Inspection Unit of the Drug Programs Branch "routinely conducts on-site audits" of pharmacies to (i) verify that the prescription form is validly filled out and (ii) enforce recoveries where pharmacists do not provide evidence that limited use criteria is met. There is also a Limited Use Committee that is working on a "monitoring and accountability framework" for Limited Use drugs. The framework will likely require that prescribers provide supporting documentation on request.[136] This declaration was made in 2003 and I could not find information on whether the new framework had proceeded beyond the discussion phase.

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[1] Ron Corvari (PMPRB), Derek King, & Michalis Sanidas (LSE Health), "Canada: Pharmaceutical Pricing and Reimbursement" Online: < http://pharmacos.eudra.org/F3/g10/docs/tse/Canada.pdf>. (Country profile prepared for the London School of Economics) at 8.

[2] Ron Corvari (PMPRB), Derek King, & Michalis Sanidas (LSE Health), "Canada: Pharmaceutical Pricing and Reimbursement" Online: < http://pharmacos.eudra.org/F3/g10/docs/tse/Canada.pdf>. (Country profile prepared for the London School of Economics) at 8.

[3] Ron Corvari (PMPRB), Derek King, & Michalis Sanidas (LSE Health), "Canada: Pharmaceutical Pricing and Reimbursement" Online: < http://pharmacos.eudra.org/F3/g10/docs/tse/Canada.pdf>. (Country profile prepared for the London School of Economics) at 8.

[4] Ministry of Health and Services, "Fair Pharmacare?" Online: Government of British Columbia <http://www.healthservices.gov.bc.ca/pharme/plani/planiinfo.html#F >.

[5] Health and Wellness, "Health Care Insurance Plan and Services Prescription Drug Coverage for Seniors" Online: Alberta Government <http://www.health.gov.ab.ca/ahcip/prescription/seniors.html>.

[6] Saskatchewan Health – Drug Plan, "Drug Plan & Extended Benefits Branch" Online: Saskatchewan <http://www.health.gov.sk.ca/ph_br_drug_plan_ext_ben.html>.

[7] Manitoba Health, "Manitoba Drug Benefits & Interchangeability Formulary" Online: Manitoba <http://www.gov.mb.ca/health/mdbif/>.

[8] Ontario Ministry of Health and Long-Term Care, "Ontario Drug Benefit" Online: Ontario <http://www.health.gov.on.ca/english/public/pub/drugs/odb.html>.

[9] Drug Coverage: A Guide to Reimbursement, "Régie de l'assurance maladie du Québec (RAMQ)" Online: Drug Coverage.ca <http://www.drugcoverage.ca/content/benefit/quebec.asp#3>.

[10] New Brunswick Canada, "Health and Wellness Prescription Drug Program" Online: New Brunswick Canada <http://www.gnb.ca/0212/intro-e.asp>.

[11] Nova Scotia Pharmacare, "Questions and Answers about Pharmacare Benefits" Online: Nova Scotia Canada <http://www.gov.ns.ca/health/pharmacare/benefits_faq.htm#exception%20status%20drugs>.

[12] Prince Edward Island Canada, "Health Minister Advises New Funding Will Strengthen Front Line Services and Make Strategic Investments in Health" Online: Prince Edward Island Canada Official Website http://www.gov.pe.ca/news/getrelease.php3?number=1065>.

[13] Government of Newfoundland and Labrador Health and Community Services, "Newfoundland and Labrador Prescription Drug Program" Online: Government of Newfoundland and Labrador <http://www.gov.nf.ca/health/nlpdp/plan_n.htm>.

[14] The provinces that have catastrophic care reimburse drug costs in excess of an income contingent deductible. Thomas Crossley, Paul Grootendorst and Michael Veall. "National catastrophic drug insurance revisited: who would benefit from Senator Kirby's recommendations." July 2003. Online: http://individual.utoronto.ca/grootendorst/pdf/Kipby.pdf.

[15] Other residents may be eligible for the Trillium Drug Plan with further eligibility based on drug expenses and family income.

[16] Premiums are income contingent, but deductibles are lower than in the other provinces. Crossley *supra* note 14.

[17] Coverage may be purchased by residents under 65.

[18] Quebeckers must purchase a minimum level of drug coverage, but they can choose whether to buy that insurance publicly or privately. Crossley *supra* note 14 at footnote 1.

[19] Out of 928,075 individuals (524,522 family units), 620,666 (433,044 family units) purchased eligible prescriptions. Saskatchewan Health: Drug Plan and Extended Benefit Branch. "Annual Statistical Report 2002-2003" at 24. Online at http://formulary.drugplan.health.gov.sk.ca/publications/2002-2003_Annual_Report.pdf.

[20] Email from Jack Rosentreter, executive director of provincial drug programs for Manitoba Health.

[21] Ron Corvari (PMPRB), Derek King, & Michalis Sanidas (LSE Health), "Canada: Pharmaceutical Pricing and Reimbursement" Online: < http://pharmacos.eudra.org/F3/g10/docs/tse/Canada.pdf>. (Country profile prepared for the London School of Economics) at 9.

[22] Ron Corvari (PMPRB), Derek King, & Michalis Sanidas (LSE Health), "Canada: Pharmaceutical Pricing and Reimbursement" Online: < http://pharmacos.eudra.org/F3/g10/docs/tse/Canada.pdf>. (Country profile prepared for the London School of Economics) at 9.

[23] Crossley *supra* note 14 at 2.

[24] Including medical transport, dental care, medical supplies, vision care and crisis intervention counselling.

[25] NIHB Pharmacy/MS&E Provider Information Kit.

Online: www.hc-sc.gc.ca/fnihb/nihb/pharmacy/provider_kit.pdf

[26] NIHB Annual Report 2002-2003. Online: www.hc-sc.gc.ca/fnihb/nihb/annualreport/annualreport2002_2003.pdf.

[27] *Ibid.* at 94.

[28] Information Kit *supra* note 25 at 29.

[29] Annual Report, *supra* note 26 at 95.

[30] Henry Grabowski and C. Daniel Mullins, "Pharmacy Benefit Management, Cost Effectiveness Analysis and Drug Formulary Decisions" (1997) 45 Med. Care 535 at 535.

[31] Glen A. Franklin, "The driving force in hospital formularies: economics versus efficacy" (2003) 186 Am. J. of Surgery 55S at 58S.

[32] Glen A. Franklin, "The driving force in hospital formularies: economics versus efficacy" (2003) 186 Am. J. of Surgery 55S at 57S "physicians are ethically required to advocate for additions to the formulary when they think patients would benefit and for exceptions to the formulary on a case by case basis when justified by the health care needs of a particular patient." (American Medical Association, "Managed Care Cost Containment Involving Prescription Drugs" (1998) Food & Drug L.J. 25 at 30.)

[33] Henry Grabowski and C. Daniel Mullins, "Pharmacy Benefit Management, Cost Effectiveness Analysis and Drug Formulary Decisions" (1997) 45 Med. Care 535 at 535; PricewaterhouseCoopers at 3.

[34] PBMs are private companies that work to reduce drug costs for health insurance payors, usually employers who offer drug benefits to their employees.

[35] I could find no truly independent data on the cost saving potential of these measures. Even data that appeared in peer reviewed journals (see, for instance, Grabowski and Mullins (1997) *infra*) is ultimately derived from PBM literature and interviews with industry officials.

[36] Health Policy Alternatives Inc., Prepared for Pharmaceutical Care Management Association. "Pharmacy Benefit Managers (PBMs): Tools for Managing Drug Benefit Costs, Quality, and Safety" August 2003. Online: www.pcmanet.org/2004_pdf_downloads/HPA_Study_Final.pdf.

[37] PricewaterhouseCoopers [Prepared for the Pharmaceutical Care Management Association] "The Value of Pharmacy Benefit Management and the National Cost Impact of Proposed PBM Legislation" July 2004. Online:
www.pcmanet.org/keyfindings_pdfs/PricewaterhouseCoopers_Report_Value%20of%20PBMs_Impact_Proposed_LegislationJuly_2004.pdf.

[38] *Ibid.*

[39] American Medical Association, "Managed Care Cost Containment Involving Prescription Drugs" (1998) Food & Drug L.J. 25.

[40] Henry Grabowski and C. Daniel Mullins, "Pharmacy Benefit Management, Cost Effectiveness Analysis and Drug Formulary Decisions" (1997) 45 Med. Care 535 at 537.

[41] Henry Grabowski and C. Daniel Mullins, "Pharmacy Benefit Management, Cost Effectiveness Analysis and Drug Formulary Decisions" (1997) 45 Med. Care 535 at 537.

[42] Henry Grabowski and C. Daniel Mullins, "Pharmacy Benefit Management, Cost Effectiveness Analysis and Drug Formulary Decisions" (1997) 45 Med. Care 535 at 537.

[43] Henry Grabowski and C. Daniel Mullins, "Pharmacy Benefit Management, Cost Effectiveness Analysis and Drug Formulary Decisions" (1997) 45 Med. Care 535 at 538.

[44] American Medical Association, "Managed Care Cost Containment Involving Prescription Drugs" (1998) Food & Drug L.J. 25 at 28.

[45] American Medical Association, "Managed Care Cost Containment Involving Prescription Drugs" (1998) Food & Drug L.J. 25 at 28.

[46] Ron Corvari (PMPRB), Derek King, & Michalis Sanidas (LSE Health), "Canada: Pharmaceutical Pricing and Reimbursement" Online: < http://pharmacos.eudra.org/F3/g10/docs/tse/Canada.pdf>. (Country profile prepared for the London School of Economics) at 17.

[47] Paul V. Grootendorst *et al*, "Impact of reference-based pricing of nitrates on the use and costs of anti-anginal drugs" (2001) 165 CMAJ 1011 and Corvari *supra* note 1 at 9.

[48] Ionnides-Demos *et al.* "Reference Based Pricing Schemes: Effect on Pharmaceutical Expenditure, Resource Utilization and Health Outcomes" Pharmacoeconomics 2002 20(9) at 577.

[49] Ron Corvari (PMPRB), Derek King, & Michalis Sanidas (LSE Health), "Canada: Pharmaceutical Pricing and Reimbursement" Online: < http://pharmacos.eudra.org/F3/g10/docs/tse/Canada.pdf>. (Country profile prepared for the Lond on School of Economics) at 9.

[50] Ron Corvari (PMPRB), Derek King, & Michalis Sanidas (LSE Health), "Canada: Pharmaceutical Pricing and Reimbursement" Online: < http://pharmacos.eudra.org/F3/g10/docs/tse/Canada.pdf>. (Country profile prepared for the London School of Economics) at 9.

[51] Sebastian Schneewiss *et al.*, "Net Health Plan Savings From Reference Pricing for Angiotensin-Converting Enzyme Inhibitors in Elderly British Columbia Residents" (2004) Medical Care 42:7 at 653.

[52] Ioannides-Demos *et al.* "Reference-based pricing schemes: effect on pharmaceutical expenditures, resource utilisation and health outcomes." Pharmacoeconomics (2002) 20:9 577.

[53] Sebastian Schneeweiss *et al.*, "Outcomes of Reference Pricing for Angiotensin Converting Enzyme Inhibitors" (2002) 346 NEJM 822.

[54] Sebastian Schneeweiss *et al.*, "Outcomes of Reference Pricing for Angiotensin Converting Enzyme Inhibitors" (2002) 346 NEJM 822.

[55] Sebastian Schneeweiss *et al.*, "Outcomes of Reference Pricing for Angiotensin Converting Enzyme Inhibitors" (2002) 346 NEJM 822.

[56] Paul V. Grootendorst *et al*, "Impact of reference-based pricing of nitrates on the use and costs of anti-anginal drugs" (2001) 165 CMAJ 1011. This study used sublingual nitroglycerin as a marker for deteriorating health for angina patients.

[57] Victor Villagra, "Strategies to Control Costs and Quality – A Focus on Outcomes Research for Disease Management" (2004) 42 Med. Care III-24 at 24. Disease management is based on the premise that medical costs in many diseases are concentrated in a small portion of the population (Henry Grabowski and C. Daniel Mullins, "Pharmacy Benefit Management, Cost Effectiveness Analysis and Drug Formulary Decisions" (1997) 45 Med. Care 535 at 542).

[58] Victor Villagra, "Strategies to Control Costs and Quality – A Focus on Outcomes Research for Disease Management" (2004) 42 Med. Care III-24 at 25.

[59] Patented Medicines Prices Review Board, "Provincial Drug Plans Overview Report: Pharmaceutical Trends 1995/1996 – 1999/00" (2001) Online: <http://www.pmprb-cepmb.gc.ca/CMFiles/overview-e14IRL-492003-6326.pdf> at 14.

[60] http://www.hc-sc.gc.ca/english/media/releases/2002/2002_58bk2.htm

[61] http://www.ccohta.ca/entry_e.html

[62] http://www.hc-sc.gc.ca/english/media/releases/2002/2002_58bk2.htm

[63] JP Gregoire *et al.*, "Inter-provincial variation in government drug formularies" (2001) 92 Can. J. Public Health 307.

[64] Best Medicines Coalition, "Submission to the Ontario Drug Benefit (ODB) Drug Strategy Review" (May 14, 2003) Online: Best Medicines Coalition http://www.bestmedicines.ca/downloads/ODB_strategic_review_may03.pdf.>.

65 An example of this was recently seen after the approval of the drug Fabrazyme to treat Fabry's disease, which without treatment leads to death in middle age. Fifty-eight Canadians (about half of the total population of sufferers) received the Fabrazyme for free during the clinical trial, between 2001 – 2004. However, now that the clinical trial is over and the drug is approved, the provinces have each begun their own review processes. No province has committed to pay for the high priced ($270 000 per year, per sufferer) drug. (Andre Picard, "Fabry disease sufferers face a Catch-22" The Globe and Mail, Tuesday February 10, 2004 A6.) Only Alberta agreed to pay for the drug on an interim basis while it underwent review. Anne Kelly. "Decision urged on Fabry drug; Witmer wants Ontario Liberals to cover cost of enzyme therapy on interim basis" 11 September 2004 Kitchener-Waterloo Record B4). The review may still be ongoing; as of October 1, 2004 neither Fabrazyme nor the equivalent drug Replagal was on the Alberta Drug Benefit List). Internet: www.ab.bluecross.ca/db/pdfs/ahwdbl_full_list.pdf.

[66] http://www.health.gov.on.ca/english/public/pub/drugs/limited.html. A physician must complete a limited use prescription form when prescribing limited use products (*Ibid.*).

[67] http://www.health.gov.on.ca/english/providers/program/drugs/limited_use_mn.html

[68] For example see http://www.health.gov.on.ca/english/providers/program/drugs/formulary/limited_use_062304.pdf.

[69] Henry Grabowski and C. Daniel Mullins, "Pharmacy Benefit Management, Cost Effectiveness Analysis and Drug Formulary Decisions" (1997) 45 Med. Care 535 at 540.

[70] D. L. Jones *et al.*, "Cost savings using a stepped-care prescribing protocol for non-steroidal anti-inflammatory drugs" (1996) 275 JAMA 926.

[71] BC, Sask, Manitoba, Ontario, Quebec, Nova Scotia, New Brunswick.

[72] Henry Grabowski and C. Daniel Mullins, "Pharmacy Benefit Management, Cost Effectiveness Analysis and Drug Formulary Decisions" (1997) 45 Med. Care 535 at 540 and AMA at 29.

[73] American Medical Association, "Managed Care Cost Containment Involving Prescription Drugs" (1998) Food & Drug L.J. 25 at 30.

[74] American Medical Association, "Managed Care Cost Containment Involving Prescription Drugs" (1998) Food & Drug L.J. 25 at 30.

[75] Ontario Ministry of Health and Long-Term Care, "Ontario Drug Benefit: Section 8 Mechanism" Online: Ontario <http://www.health.gov.on.ca/english/public/pub/drugs/section8.html>.

[76] Ontario Ministry of Health and Long-Term Care, "Ontario Drug Benefit: Section 8 Mechanism" Online: Ontario <http://www.health.gov.on.ca/english/public/pub/drugs/section8.html>.

[77] Ontario Ministry of Health and Long-Term Care, "Ontario Drug Benefit: Section 8 Mechanism" Online: Ontario <http://www.health.gov.on.ca/english/public/pub/drugs/section8.html>.

[78] Ontario Ministry of Health and Long-Term Care, "Ontario Drug Benefit: Section 8 Mechanism" Online: Ontario <http://www.health.gov.on.ca/english/public/pub/drugs/section8.html>.

[79] Best Medicines Coalition, "Submission to the Ontario Drug Benefit (ODB) Drug Strategy Review" (May 14, 2003) online: Best Medicines Coalition <http://www.bestmedicines.ca/downloads/ODB_strategic_review_may03.pdf.>

[80] Best Medicines Coalition, "Submission to the Ontario Drug Benefit (ODB) Drug Strategy Review" (May 14, 2003) online: Best Medicines Coalition <http://www.bestmedicines.ca/downloads/ODB_strategic_review_may03.pdf.>

[81] Email. October 24th. Eric Nauenberg, Ph.D.

[82] Ron Corvari (PMPRB), Derek King, & Michalis Sanidas (LSE Health), "Canada: Pharmaceutical Pricing and Reimbursement" Online: < http://pharmacos.eudra.org/F3/g10/docs/tse/Canada.pdf>. (Country profile prepared for the London School of Economics) at 10.

[83] Ron Corvari (PMPRB), Derek King, & Michalis Sanidas (LSE Health), "Canada: Pharmaceutical Pricing and Reimbursement" Online: < http://pharmacos.eudra.org/F3/g10/docs/tse/Canada.pdf>. (Country profile prepared for the London School of Economics) at 10.

[84] Ron Corvari (PMPRB), Derek King, & Michalis Sanidas (LSE Health), "Canada: Pharmaceutical Pricing and Reimbursement" Online: < http://pharmacos.eudra.org/F3/g10/docs/tse/Canada.pdf>. (Country profile prepared for the London School of Economics) at 16.

[85] Victor Villagra, "Strategies to Control Costs and Quality – A Focus on Outcomes Research for Disease Management" (2004) 42 Med. Care III-24 at 25.

[86] Haiden A. Huskamp, PhD "The Effect of Incentive-Based Formularies on Prescription Drug Utilization and Spending" (2003) 349 NEJM 2224 at 2225.

[87] D. S. Fullerton, PhD, and Deborah Scott Ahterly, MPH, RPh, "Formularies, Therapeutics, and Outcomes - New Opportunities" (2004) 42 Med. Care III-39 at 43.

[88] Geoffrey F. Joyce *et al.* "Employer Drug Benefit Plans and Spending on Prescription Drugs" (2002) 288 JAMA 1733.

[89] Costs were reduced from $678 to $455 (P <0.001)

[90] P <0.001

[91] Huskamp *supra* note 86 at 2231.

[92] *Ibid.*

[93] KA Fairman, BR Motheral, & RR Henderson, "Retrospective, long-term follow-up study of the effect of a three-tier prescription drug co-payment system on pharmaceutical and other medical utilization and costs" (2003) 25 Clin. Ther. 3147 at 3157.

[94] Ron Corvari (PMPRB), Derek King, & Michalis Sanidas (LSE Health), "Canada: Pharmaceutical Pricing and Reimbursement" Online: < http://pharmacos.eudra.org/F3/g10/docs/tse/Canada.pdf>. (Country profile prepared for the London School of Economics) at 11. See Appendix 1.

[95] Ron Corvari (PMPRB), Derek King, & Michalis Sanidas (LSE Health), "Canada: Pharmaceutical Pricing and Reimbursement" Online: < http://pharmacos.eudra.org/F3/g10/docs/tse/Canada.pdf>. (Country profile prepared for the London School of Economics) at 10.

[96] Ron Corvari (PMPRB), Derek King, & Michalis Sanidas (LSE Health), "Canada: Pharmaceutical Pricing and Reimbursement" Online: < http://pharmacos.eudra.org/F3/g10/docs/tse/Canada.pdf>. (Country profile prepared for the London School of Economics) at 11.

[97] Chein-Wen Tseng *et al.* "Impact of an Annual Dollar Limit or "Cap" on Prescription Drug Benefits for Medicare Patients" (2003) 290 JAMA 222.

[98] Chein-Wen Tseng *et al.* "Impact of an Annual Dollar Limit or "Cap" on Prescription Drug Benefits for Medicare Patients" (2003) 290 JAMA 222.

[99] Chein-Wen Tseng *et al.* "Impact of an Annual Dollar Limit or "Cap" on Prescription Drug Benefits for Medicare Patients" (2003) 290 JAMA 222 at 224.

[100] Chein-Wen Tseng *et al.* "Impact of an Annual Dollar Limit or "Cap" on Prescription Drug Benefits for Medicare Patients" (2003) 290 JAMA 222 at 226. In a related study 1 in 6 patients with a cap reported stopping

a medication because of a cap. Cox E.R. *et al.* Medicare beneficiaries' management of capped prescription benefits. Med Care. 2001; 39:296-301.

[101] Ron Corvari (PMPRB), Derek King, & Michalis Sanidas (LSE Health), "Canada: Pharmaceutical Pricing and Reimbursement" Online: < http://pharmacos.eudra.org/F3/g10/docs/tse/Canada.pdf>. (Country profile prepared for the London School of Economics) at 10.

[102] Ron Corvari (PMPRB), Derek King, & Michalis Sanidas (LSE Health), "Canada: Pharmaceutical Pricing and Reimbursement" Online: < http://pharmacos.eudra.org/F3/g10/docs/tse/Canada.pdf>. (Country profile prepared for the London School of Economics) at 10 and Patented Medicines Prices Review Board, "Provincial Drug Plans Overview Report: Pharmaceutical Trends 1995/1996 – 1999/00" (2001) Online: <http://www.pmprb-cepmb.gc.ca/CMFiles/overview-e14IRL-492003-6326.pdf> at 28.

[103] What's Ahead for Health Insurance in the United States? NEJM 346:23 at 1822.

[104] American Medical Association, "Managed Care Cost Containment Involving Prescription Drugs" (1998) Food & Drug L.J. 25 at 31.

[105] World Health Organization, Regional Office for Europe. Country Profile: Germany. Online: www.euro.who.int/pharmaceuticals/Topics/Overview/20020435_2.

[106] There were, however, confounding variables such as education campaigns.

[107] WHO *supra* note 109.

[108] Jonas Shreyogg and Reinhard Busse "Physician Drug Budgets in Germany: Effects on Prescription Behaviour" presented at 2004 European Conference on Health Economics. Online: www.lse.ac.uk/collections/LSEHealthAndSocialCare/europeanConferenceOn HealthEconomics2004/EHPGPAPERS/EHPG7Schreyogg%20Busse.doc.

[109] *Ibid.*

[110] Stephen Soumerai *et al.*, "Prescribing budgets: economic, clinical and ethical perspectives." Australian Prescriber (1997) 20:28.

[111] Physicians associations refused to reimburse the government – because of unclear rules about how the debt would be distributed among doctors in the region (if the overprescribers paid, they would go bankrupt but if all doctors in the region shared the debt then it was perceived as unfair to those who exercised physician restraint). This was never resolved – the debts were ultimately waived.

[112] Diana Delnoij & Gerhard Brenner. "Importing budget systems from other countries: what can we learn from the German drug budget and the British GP fundholding." (2000) Health Policy 52:3 157-169.

[113] Toby Godsen & David Torgerson. "The effect of fundholding on prescribing and referral costs: a review of the evidence. (1997) Health Policy. 40:2 103.

[114] Delnoij & Brenner *supra* note 116.

[115] Harris & Scrivener. "Fundholders' prescribing costs: the first five years" BMJ 1996 313(7071).

[116] Delnoij & Brenner *supra* note 118. See also J. Le Grand et al. Learning from the NHS Internal Market. A review of the Evidence. London: King's Fund, 1998. Fundholding itself, however, was doomed in the UK for reasons beyond its inability to curb prescription drug costs – including high administrative costs and its tendency to create a *de facto* 2-tiered scheme because practices that opted in tended to be larger ones serving a more affluent population. As well, as Delnoij and Brenner point out, GP fundholding generally only works where GPs have fixed patient lists are the gatekeeper to specialist care.

[117] Azeem Majeed & Stephen Head. "Capitation based prescribing budgets will not work." (1998) BMJ 316.

[118] Darrin Baines and David Parry. "Analysis of the ability of the new needs adjustment formula to improve the setting of weighted capitation prescribing budgets in general English practice." (200) BMJ 320 288-290.

[119] James Robinson. "The End of Managed Care" (2001) JAMA 285(20) 2622-2628.

[120] Henry Grabowski and C. Daniel Mullins, "Pharmacy Benefit Management, Cost Effectiveness Analysis and Drug Formulary Decisions" (1997) 45 Med. Care 535 at 538.

[121] Using formularies to combat over-prescription of antibiotics is an instructive example of the way in which well-structured drug formularies can be used to further ends beyond mere cost saving, such as adherence with clinical practice guidelines.

[122] *Ibid.* The authors also cite numerous study limitations that could have influenced the results. For instance, the authors only track reimbursement claims - "seniors who opted to pay out-of-pocket for a fluroquinolone prescription are not included." The total decrease in claims may therefore be illusory; the costs may have

simply been offloaded to the public. As well, a national public education campaign on antibiotic resistance was launched weeks after the policy and could have accounted for part of the decrease.

[123] Prescriptions increased for sulfonamides and trimethoprim (34.9%), cephalosporins 17.0% and macrolides and lincosamides by 16.5%. ME MacCara *et al.*, "Impact of a limited fluoroquinolone reimbursement policy on antimicrobial prescription claims" (2001) 35 Annals of Pharmocotherapy 852.

[124] *Ibid.* at 855.

[125] Chloe A. Campbell *et al.* Topical Corticosteroid Prescribing Patterns Following Changes in Drug Benefit Status. Annals of Pharmacotherapy: 37:6 787-93.

[126] Sketris et al. The effect of deinsuring chlopropamide on the prescribing of oral antihyperglycemics for Nova Scotia Seniors' Pharmacare beneficiaries. Pharmacotherapy 2004 Jun 24(6).

[127] For example see
http://www.health.gov.on.ca/english/providers/program/drugs/formulary/ed38_0_bk.pdf

[128] Janet E. Hux, Michele P. Melady, & Donald DeBoer, "Confidential prescriber feedback and education to improve antibiotic use in primary control: a controlled trial" (1999) 161 CMAJ 388.

[129] Nicholas J. G. Pimlot *et al.*, "Educating physicians to reduce benzodiazepine use by elderly patients: a randomized controlled trial" (2003) 168 CMAJ 835.

[130] The discussion is drawn from the United States, except for the audits of limited drug use in Ontario, discussed under Pharmacists incentives, I did not find examples of drug utilization review plus penalties in the literature.

[131] Henry Grabowski and C. Daniel Mullins, "Pharmacy Benefit Management, Cost Effectiveness Analysis and Drug Formulary Decisions" (1997) 45 Med. Care 535 at 539

[132] See Corvari *supra* note 1 at 18.

[133] Drug Interchangeability and Dispensing Fee Act RSO 1990 c.P.23 s.7(2).

[134] Ron Corvari (PMPRB), Derek King, & Michalis Sanidas (LSE Health), "Canada: Pharmaceutical Pricing and Reimbursement" Online: < http://pharmacos.eudra.org/F3/g10/docs/tse/Canada.pdf>. (Country profile prepared for the London School of Economics) at 18. (*Ibid.* at 16)

[135] Ron Corvari (PMPRB), Derek King, & Michalis Sanidas (LSE Health), "Canada: Pharmaceutical Pricing and Reimbursement" Online: < http://pharmacos.eudra.org/F3/g10/docs/tse/Canada.pdf>. (Country profile prepared for the London School of Economics) at 17.

[136] Ontario Drug Benefit Formulary/Comparative Index. Effective January 30, 2003. Online at www.health.gov.on.ca/english/providers/program/drugs/formulary/ed38_0_bk.pdf at I.10-I.11.