What States Can Do to Reform Health Care:

A FREE-MARKET PRIMER

By James R. Copland, Roy Cordato, John R. Graham, Nina Owcharenko, Brett J. Skinner, Shirley V. Svorny, and J.P. Wieske

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With a foreword by South Carolina Governor Mark Sanford

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The American Legislative Exchange Council (ALEC) has given us the opportunity to launch this book at its annual conference in San Francisco, for which I am most appreciative.

John R. Graham
Director, Health Care Studies
Pacific Research Institute
San Francisco, CA
July 2006

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Pacific Research Institute
755 Sansome Street
Suite 450
San Francisco, CA 94111
T: 415/989-0833
F: 415/989-2411
Website: www.pacificresearch.org

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Foreword

Health care reform is one of the biggest challenges facing our country. The increasing costs of government-run health-care programs have strained federal and state budgets, while the number of uninsured has not appreciably changed.

Free-market advocates recognize that the core weakness of American health care lies in government's intrusion: it significantly weakens the incentives necessary to ensure that health providers put the needs of patients first. Americans experience health systems that are burdened by more rules and regulations every year. Consequently, patients, providers, and public officials struggle to understand the nature of American health care, and find it difficult to bring policies to fruition that will promote healthy competition.

Most books that promote consumer-directed health care in the United States are focused at the federal level. These efforts have resulted in valuable reforms, including Health Savings Accounts. However, states also have an important role to play in reforming health care. Now, we have a primer on how states can achieve that reform.

In South Carolina, I have invested considerable energy in developing reforms to our state's Medicaid program by proposing to give the beneficiaries the resources they need to take control of their health. This autonomy will improve outcomes and save taxpayers money. I am pleased that our proposal figures well in Nina Owcharenko's chapter on Medicaid

reform in this book, and am glad that other states now have an opportunity to learn about the promise and challenge of this reform.

Every state is different, and priorities for health reform understandably differ among the states. The authors of this book are the leaders in consumer-directed health care. They cover Medicaid reform, medical-malpractice reform, and prescription drug purchasing, as well as the regulation of hospitals, health professionals, and private insurance.

I trust that this book will find a place on the shelf of every state policymaker for reference when addressing much needed, state-based health reforms.

Governor Mark Sanford
South Carolina
July 2006

Introduction

This book is unique. Much has been written about the need to reform American health care. For many years, scholars and public policy analysts who appreciate the benefits that individual choice and free enterprise bring to human welfare have examined the consequences of ever-increasing government interference with our health system. We have proposed changes that will bring about what is now called "consumer-directed health care."

At the federal level, innovative reforms such as Health Savings Accounts are necessary, but certainly not sufficient, to allow Americans to receive higher quality health care at lower cost. However, we also have to reform the health care system in California, New York, Florida, and across America.

States have significant authority to make positive changes independent of what the federal government does. Recent and pending federal legislation, such as the Deficit Reduction Act, which President George W. Bush signed last year, or the Health Care Choice Act (H.R. 2355), introduced by Representative John Shadegg of Arizona, pose challenges and opportunities for state policymakers who want to introduce free-market health reforms that will help their citizens.

This is the first book that specifically addresses *what states can do to reform health care.* The Pacific Research Institute has invited seven leading scholars to examine the most important areas of health care that states have the responsibility to legislate, regulate, and finance.

This book has two goals. First, it helps concerned citizens and policymakers ask the right questions about health reform. For example:

- Are new hospitals free to compete in my state? Or can incumbents use certificate-of-need regulations to protect their advantage and stifle patients' and physicians' choices?

- Is my state taking advantage of the opportunities that the federal government is giving states to manage Medicaid, and creating tools to give Medicaid beneficiaries and providers better incentives? Or is it still just trying to contain costs by layering on more bureaucracy?

- Are health professionals free to implement new ways to collaborate to improve patient care? Or do burdensome licensing regulations protect certain professions' turf and inhibit innovation in practice?

- Does my state government understand how to motivate drug makers to voluntarily reduce prices for low-income patients? Or do the politicians simply grandstand by promoting futile and harmful measures like international piracy from Canada or other countries?

Second, this book proposes answers to the complex challenges facing states as they address these questions. Although every state faces a different situation, the steps outlined in this book will guide each one to reforms that will benefit patients.

I trust that every concerned citizen and state policymaker will find a place on his or her bookshelf for this primer on state-based health reform.

John R. Graham
Director, Health Care Studies
Pacific Research Institute
San Francisco, CA
July 2006

1. Options and Opportunities for State Medicaid Reform

NINA OWCHARENKO

Key Points

- Medicaid, the federal-state health program for the poor, faces draining state budgets and declining quality for those who depend on it. State policymakers must lay the groundwork for meaningful and lasting change that will serve both Medicaid enrollees and taxpayers.

- The challenge is to develop policies consistent with increasing personal freedom that promote free-market competition – two features lacking in the current government-run, one-size-fits-all Medicaid model.

- State policymakers should use successful welfare reform, which started at the state level, as a model for Medicaid reform.

The Basics

Medicaid was created in 1965 along with Medicare as part of President Lyndon B. Johnson's Great Society agenda. Its aim was to provide health care to poor Americans, but the program has expanded far beyond its original intent and has arguably crowded out private coverage options for this population.

Medicaid is financed jointly by the federal government and the states, but is administered predominantly at the state level. In other words, there is no

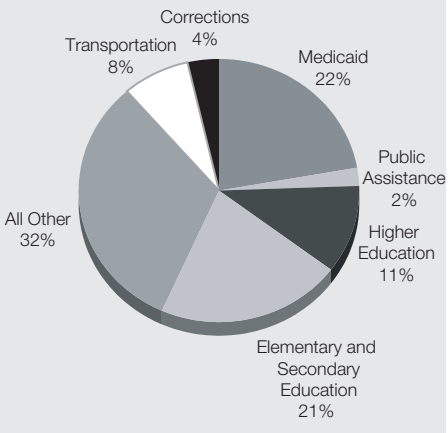
single Medicaid program; rather, there are 50 different state programs. The federal government matches each state's Medicaid spending based on a formula, the Federal Medical Assistance Percentage (FMAP), and contributes approximately 57 percent of all Medicaid spending. No state may receive a federal contribution of less than 50 percent, and poorer states can receive as much as 76 percent.[i] Because of this open-ended matching structure, there is great incentive for states to leverage and maximize the federal contribution.

Growing Spending

Like other entitlement programs, Medicaid consumes an ever-growing share of taxpayer dollars. Its cost has more than doubled over the past 10 years. In 2004, Medicaid spending grew by 7.9 percent, and total (federal and state) spending reached $292 billion – $173 billion in federal spending and close to $120 billion in state and local spending.[ii] Even with the economic recovery, these dramatically rising costs are of greater concern to the states.

Unlike the federal government, which routinely runs big deficits, nearly all states are required to balance their budgets. According to the National Association of State Budget Officers, 22 states faced Medicaid shortfalls in 2004, and 26 expected to face shortfalls in 2005.[iii]

Chart 1. Total State Expenditures, 2004

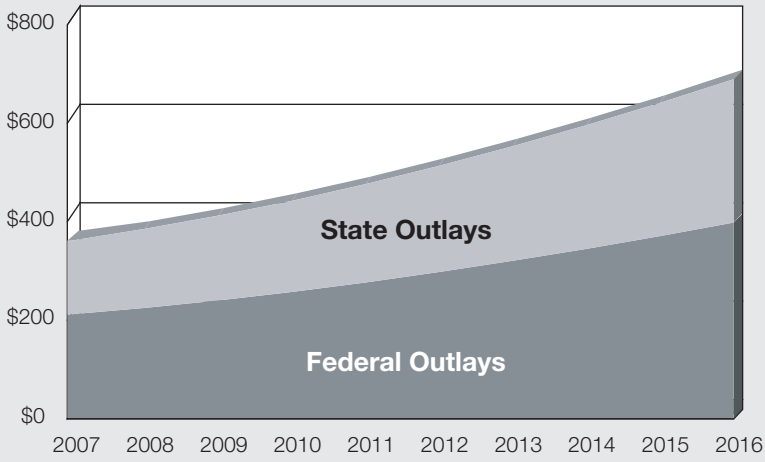


Source: National Association of State Budget Officers, State Expenditure Report 2004, p.4.

For the second year in a row, Medicaid surpassed education – which traditionally accounts for the largest portion of state budgets – by consuming 22.3 percent of total state expenditures in 2004.[iv] (See Chart 1.) It also is taking an even greater share of state general revenue funds. In 2004, Medicaid captured 16.9 percent of state general fund expenditures – a steep 12 percent more than the previous year.[v] The future is not much brighter for the states.

While the rate of spending growth has slowed in recent years, it is expected to accelerate back up to 8.5 percent by 2007 and to average 8.6 percent each year until 2015.[vi] Medicaid spending, federal and state combined, is expected to reach $320 billion in 2006 and $670 billion by 2015 (figures in nominal dollars).[vii] Undoubtedly, states will continue to face difficult decisions as fiscal limitations and growing Medicaid demands squeeze out other important state priorities, such as education, transportation, and law enforcement.

Chart 2. Federal State Medicaid Spending: Projection 2007 to 2016



Source: Centers for Medicare and Medicaid Services, Budget in Brief FY 2007, p 63.

Shifting Demographics

Today Medicaid provides health care to more than 50 million people: 11.5 million children, 25.1 million adults, 5.2 million elderly, and 8.8 million disabled.[viii] While the federal government requires state Medicaid programs to cover certain "mandatory" populations and services, states can go beyond the mandatory requirements and extend Medicaid to federally designated "optional" populations and services. The Kaiser Family Foundation, a prominent think tank specializing in Medicaid policy, has estimated that approximately 60 percent of all Medicaid spending is "optional," either by extending eligibility to "optional" populations or by providing "optional" services to "mandatory" and "optional" populations.[ix]

Though the elderly and disabled are small in number, they account for the largest share of Medicaid spending. The Centers for Medicare and Medicaid Services (CMS), a part of the U.S. Department of Health and Human Services, estimates that the aged, blind, and disabled receive 67.4 percent of all Medicaid spending.[x] Even with passage of the Medicare Modernization Act, which transferred many Medicare-Medicaid dual-eligible individuals into the Medicare prescription drug benefit, the imminent retirement of the baby-boom generation will certainly place additional pressures on state Medicaid capacity and financing, especially for long-term care services.

Declining Quality

Medicaid's fiscal challenges and broadening scope have consequences. The growing constituencies based on optional beneficiaries and services make it politically difficult to retract any optional expansions in order to regain fiscal control of the program, and changes in mandatory populations are even further entrenched. Even though current enrollment trends have slowed and the economy continues to thrive, it offers states only short-term relief. Thus, most states turn to short-term cost containment strategies to keep pace with the program. While most states employ cost-containment strategies that do not directly cut beneficiaries or eliminate services, as noted, they will continue to face difficult decisions as fiscal limits and growing Medicaid demands squeeze out other important priorities. These decisions will have a direct impact on access and quality of care.

Most prominent among the state cost-containment strategies are cutting or freezing provider reimbursements and imposing cost controls on prescription drugs. Survey analysis published by the Kaiser Family Foundation found that while some improvements were being made, "virtually every state is still freezing or cutting some provider rates."[xi] Forty-two states and the District of Columbia adopted and implemented controls on prescription drugs in 2005.[xii] Such indirect cuts are more hidden to enrollees, but they clearly have an adverse affect on enrollees' access to quality care.

In fact, Medicaid's reimbursement rates are consistently lower than Medicare's rates, and its bureaucracy has become so burdensome that many providers, especially physicians, have been forced to stop accepting Medicaid patients. A 2002 Medicare Payment Advisory Commission (MedPac) survey found "more than 30 percent of all physicians are now

refusing to accept any new Medicaid patients."[xiii] Another study, which looked at Medicaid physician reimbursements over five years, concluded that "Despite some improvement … physicians continue to be paid less for Medicaid beneficiaries than for other groups of insured patients, and they are much less likely to accept new Medicaid patients than other insured patients."[xiv] Medicaid beneficiaries also face limitations on access to prescription drugs.

As noted, 43 states adopted and employed prescription drug cost controls in 2005. These restrictions take the form of prior authorization, where an enrollee's physician must receive permission from the state to write a prescription, and imposing or expanding the formulary lists, where enrollees are limited to a select group of prescription drugs.[xv] Both types of controls can have serious health implications for Medicaid enrollees.[xvi] With the continuing growth of Medicaid, problems with the quality of care are likely to increase.

For example, a recent study on the treatment and prevention of diabetes, a rapidly growing chronic disease, found that dual-eligible diabetics enrolled in both Medicaid and Medicare had higher rates of adverse outcomes and used fewer preventive services than did Medicare diabetics who were not enrolled in Medicaid.[xvii]

In other words, without adequate access to physicians and services, such as prescription drugs, many Medicaid beneficiaries do not receive important care and treatment, possibly adding more cost to the health-care system. It is evident that Medicaid is spread too thin and can sustain its current form only by further rationing care, thereby adversely affecting those who truly need it. While these techniques provide some short-term relief, they can jeopardize enrollees' access to care, and its quality, and do not provide fundamental solutions for the program.

Federal Actions That Affect State Medicaid Programs

Since Medicaid is a joint state and federal program, it is important for state policymakers to be aware of the role of the federal government.

- **Waivers.** Federal waiver authority, under CMS, gives states the ability to adjust the standard structure of their Medicaid programs. Waivers allow states to test and implement new approaches to

delivering health-care benefits to enrollees. There are a variety of waivers available to the states. Some offer broad flexibility, such as the 1115 Research and Demonstration Project waivers, and others are more tailored demonstrations, such as the Independence Plus initiative. Regardless of the waiver, states must adhere to some basic federal requirements, but they also have the opportunity to experiment with new and innovative ways to improve Medicaid.

- **Deficit Reduction Act**. Congress enacted several Medicaid changes as part of the Deficit Reduction Act (DRA) of 2005.[xviii] The primary objective of the legislation was to find cost savings in Medicaid. Congress also gave states more flexibility in establishing cost-sharing requirements and in designing benefit packages as well as new and expanded demonstration initiatives. These changes, while seemingly small, illustrate an understanding that the program cannot continue in its current form and that greater flexibility and innovation should be encouraged at the state level.

- **SCHIP Reauthorization**. In 1997, Congress enacted the State Children's Health Insurance Program (SCHIP) to provide health-care coverage to uninsured children. There is greater latitude in designating a coverage package in SCHIP than in Medicaid.[xix] States receive an enhanced federal match (ranging from 68 percent to 85 percent), but unlike Medicaid, federal spending is capped and states are allocated a share from this federal fund.[xx] The program is up for reauthorization in 2007. With its strong ties to Medicaid, federal changes in SCHIP can affect state Medicaid programs both directly and indirectly.

Opportunity for Reform

Medicaid's unique structure provides states with great latitude in their Medicaid programs. The federal waiver process and existing state administrative flexibility enable states to pursue a variety of approaches.

What States Should Avoid

Change for the sake of change does not constitute reform. There are a few common, but misdirected, policy initiatives that states should avoid, including:

- **Expanding Medicaid/SCHIP eligibility.** As states rebound from the economic cycle, it is tempting for state policymakers to consider extending eligibility and coverage to new populations. However well-intentioned, this approach is shortsighted. It is far more difficult to retract coverage than it is to expand it, as illustrated recently in Tennessee, Missouri, and other states. Such efforts may also crowd out existing private coverage options. Many individuals, even those with lower incomes, either have access to private coverage through their place of work or purchase coverage on their own. Policies to expand coverage create a negative incentive for these individuals to drop existing coverage. More than 17 million Americans under 200 percent of the federal poverty level (FPL) have purchased private health insurance on their own.[xxi]

- **Depending on the existing government-run model.** Another common mistake made by states is to believe that the government can function like an insurer and replace the market. States use micromanagement techniques that control supply and demand in order to squeeze greater efficiencies out of the program. However, states should *not* try to replicate the market in their Medicaid programs. Rather, they should turn to and trust the market to produce efficiencies. Efforts to consolidate the program under the heavy hand of government go in the wrong direction, away from personal freedom and market competition.

What States Should Pursue

State policymakers should pursue meaningful change in their Medicaid programs. The key principles behind these efforts should be to maximize private coverage, integrate consumer-directed models, and incorporate proven alternative strategies. The following approaches, especially some key changes provided for under the DRA, can help states transform their bureaucratic-centered Medicaid programs to patient-centered programs characterized by individual choice, competition, and greater fiscal stability.

- **Premium Assistance.** Premium assistance gives Medicaid enrollees the ability to obtain private health-care coverage, most likely through the place of work. As states have expanded Medicaid and SCHIP eligibility, more of these enrollees are part

of a working family. Premium assistance enables enrollees with access to private coverage to receive financial assistance from Medicaid to help pay their premiums and other health-related costs. For example, parents offered dependent coverage through their employer could choose to have their Medicaid-enrolled children join the employer plan and have Medicaid help pay for the worker's share of the dependent coverage. The Health Insurance Flexibility and Accountability (HIFA) demonstration waiver stresses the importance of integrating private coverage. According to the CMS, "The Administration puts a particular emphasis on broad statewide approaches that maximize private health insurance options."[xxii] Premium assistance is one way states meet that condition. While it is traditionally used in conjunction with employer coverage, states should also allow premium assistance recipients to purchase private coverage offered in the individual market if they so choose.[xxiii]

- **Managed Care/Defined Contribution.** States have long had the ability to enroll Medicaid beneficiaries into managed-care plans. Typically, states contract with a participating Medicaid managed-care plan to provide care to Medicaid enrollees. In 2004, more than 61 percent of the Medicaid population was in an arrangement for managed care.[xxiv] States utilize these arrangements to help coordinate enrollee care, improve access, and better manage costs. A recent study concluded that expanding the Medicaid managed-care model, especially for the disabled population, can result in meaningful savings for the states.[xxv]

  States should use Medicaid managed care as a platform to change their Medicaid programs from a defined-benefit system, where the state pays for services used based on a defined set of benefits, to a defined-contribution system, where Medicaid enrollees would be assigned a risk-adjusted amount to purchase private coverage. Instead of the retrospective, pay-as-you-go payment structure, a defined-contribution model would allow states to maintain a more predictable and consistent budget, encourage greater competition and participation among private insurers, and give individuals a choice from a menu of competing insurers and plans.[xxvi] Combined with new benefit and cost-sharing flexibility (discussed later), Medicaid insurers could design more

tailored plans, and enrollees could choose a plan that best suits their personal needs. This approach could also be the first step in removing the stigma of Medicaid by fully mainstreaming Medicaid enrollees into private coverage.

- **Flexible Benefit Packages and Cost Sharing.** The Medicaid program is a one-size-fits-all model of health care. It generally provides one benefit package to all enrollees regardless of differing needs or ability to pay. As previously discussed, Medicaid eligibility has expanded beyond the traditional categories of children and pregnant mothers, and benefits have broadened to meet the needs of this growing and very diverse population. There is no reason why states should not be able to distinguish between individuals with a family income at 300 percent of the FPL and individuals with a family income below 100 percent of the FPL.

  As part of the DRA, states can now develop more flexible benefit packages and cost-sharing arrangements.[xxvii] The new flexibility allows states to design benefit packages for certain enrollees based on the benchmark options established under SCHIP and to adopt new cost-sharing arrangements, such as premiums, deductibles, and higher co-pays, for certain enrollees based on the varying income levels and ability to pay.[xxviii] While limited to certain groups, states should utilize this new tool where at all possible and continue to pursue efforts through the normal waiver process to allow such a distinction for other Medicaid populations.

- **Home and Community-Based Services.** Traditionally, states wanting to provide certain long-term care services to Medicaid enrollees, who would otherwise receive such services in an institutional setting such as a nursing home, could do so by applying for a Home and Community-Based Service (HCBS) federal waiver.[xxix] The HCBS waiver provides states with broad authority in determining the type of services, such as adult day health care, respite care, or personal care, needed to maintain the enrollee in a non-institutional setting. Over the years, this approach has become more and more popular in the states. Today, all states provide such services either through the HCBS waiver or through the broader Section 1115 federal waivers.

The DRA removes the waiver requirement and allows states to provide certain home and community-based services as an optional benefit under their Medicaid plans.[xxx] This new change enables states to give eligible enrollees greater choice of the setting in which they receive care, keeping them from leaving their homes and entering institutional facilities. It is an important tool to improve care for those who are truly needy and must depend on Medicaid. However, these efforts should *not* simply encourage individuals to qualify for Medicaid or be seen as a substitute for individuals' responsibility to prepare for and save for their own long-term care needs.

- **Self-Direction/Cash and Counseling.** The self-direction concept builds on the philosophy of giving Medicaid enrollees – specifically, disabled populations – a greater voice in the care and services they receive. Unlike traditional Medicaid, under which the bureaucracy dictates the delivery of services, the self-direction model empowers disabled enrollees and their families to select the services that meet their individual needs.

  Under the "cash and counseling" demonstration, for example, certain disabled Medicaid enrollees, with assistance from family members and a Medicaid case manager, are given an individual budget to manage and direct payment for their personal care services. This model enables enrollees to determine which supportive services they want and from whom they wish to have these services delivered. For example, an enrollee could choose to pay a spouse or family member for providing personal care and service assistance.

  Evaluations have concluded that the "cash and counseling" approach improves satisfaction among its participants and has potential long-term care cost savings.[xxxi] Because of its success, the CMS offered a simplified waiver for this approach as part of its Independence Plus waiver, and the DRA included provisions to allow states to offer the "cash and counseling" and other self-directed models as options without a waiver.[xxxii] States should use this approach as an alternative to top-down government rationing care and allow enrollees with a fixed budget to decide which services they value most, based on their own preferences.

- **Health Opportunity Accounts.** In addition to the new flexible benefit and cost-sharing design features, the DRA established a demonstration program for "Health Opportunity Accounts."[xxxiii] This 10-state demonstration would give interested states the ability to offer a health savings account (HSA) insurance model for some of their Medicaid enrollees as a way to give them greater access and control in choosing their health-care providers and services.

  Under this demonstration, states would establish a contribution to an enrollee's individual health account. The enrollee, in return, would choose a health plan that had a deductible at least as high as the state contribution. Other individuals and entities could also contribute to the account, provided that those contributions did not exceed the maximum set by the state. These accounts would be monitored for proper use and facilitated through a debit card–type system. Any remaining balances at the end of the year could be carried over, and once an enrollee no longer qualifies for Medicaid, remaining balances would be split between the state and the enrollee, who could continue to use those funds for qualified medical services and for purchasing private coverage.

  In the private sector, HSAs are a growing segment of the marketplace. Recent data show that individuals at all income levels are purchasing HSAs and that a growing portion has an income of less than $35,000 a year.[xxxiv] This demonstration gives states a new opportunity to integrate the successful private-sector HSA model into Medicaid. While somewhat prescriptive, states should seize this opportunity to introduce an HSA model into their Medicaid programs. States can also continue to request further authority through the traditional waiver process for broader or alternative application of this concept in the program.[xxxv]

- **Long-Term Partnerships.** Another new option aimed at assisting states with long-term care costs is restoration of the Long Term Care Partnership program. This program allows individuals who purchase a private long-term care insurance policy to apply for Medicaid and have their assets, up to the amount paid into a long-term care insurance plan, exempt from determining their eligibility. This program was halted and restricted only to those

states with an approved plan before the 1993 freeze. California, Connecticut, Indiana, and New York were the only four states with approved and operational Partnership programs.

Evaluations of these existing Partnership programs have shown that they can increase the number of private long-term care policies purchased and reduce dependence on Medicaid.[xxxvi] The DRA removed the restriction on Long Term Care Partnerships and established a set of requirements for states to meet in order to qualify.[xxxvii] This program creates incentives for individuals to purchase a long-term care policy instead of manipulating the system to qualify for long-term care services under Medicaid. It also protects the state and taxpayers from spending money on services that otherwise could have been planned for by an individual. Ideally, individuals should take personal responsibility to prepare for and save for their own long-term care needs, as they do for retirement and other expenditures such as college tuition. The Long Term Care Partnership program provides an alternative and a bridge to delay or eliminate an individual's need to depend on Medicaid for these services.

- **Asset Transfer Enforcement.** Due to loopholes in the Medicaid law, many middle-class seniors manipulate the system in order to qualify for Medicaid long-term care services. The DRA made significant changes in the asset laws applied to determining Medicaid eligibility for long-term care.[xxxviii] Most significant are those starting the look-back penalty period on asset transfers from the point of Medicaid application rather than from the point of the transfer; disqualification of an individual with a home equity of $500,000 or more; and other technical rule changes that are exploited to qualify for Medicaid. States should utilize these stricter rules and pursue other aggressive strategies, such as asset recovery, to protect taxpayers and preserve Medicaid for those who need it most.[xxxix]

The Path to Reform

State policymakers are on the front lines of Medicaid reform. They should follow the success of welfare reform by developing innovative approaches at the state level that can spur national reform.

Whether by using existing waiver authority or by taking advantage of new tools, states should seize the opportunity to bring much-needed change to Medicaid. By building on the principles of maximizing private coverage, integrating consumer-directed models, and incorporating proven alternative strategies, states can establish predictable and manageable budgets, improve the quality of care for the poor and disabled, and transform Medicaid from a bureaucratic-centered program to a patient-centered program that trusts in personal freedom and market competition.

Endnotes

[i] U.S. Department of Health and Human Services, *Budget in Brief, Fiscal Year 2007,* p. 61. www.hhs.gov/budget/docbudget.htm

[ii] This total includes Medicaid and State Children's Health Insurance Program (SCHIP) spending. See Christine Borger, Sheila Smith, Christopher Truffer, Sean Keehan, Andrea Sisko, John Poisal, and M. Kent Clemens, "Health Spending Projections Through 2015: Changes on the Horizon," *Health Affairs Web Exclusive,* February 22, 2006, p. w-67. http://content.healthaffairs.org/cgi/reprint/25/2/w61

[iii] National Governors Association and National Association of State Budget Officers, *The Fiscal Survey of States,* December 2005, p.3. www.nasbo.org/Publications/fiscalsurvey/fsfall2005.pdf

[iv] Elementary and secondary education accounted for 21.4 percent of total state spending in 2004. See National Governors Association and National Association of State Budget Officers, *State Expenditure Report,* January 2006, p. 4. www.nasbo.org/Publications/PDFs/2004ExpendReport.pdf

[v] Ibid., p. 4.

[vi] Borger et al., "Health Spending Projections Through 2015," p. w-67.

[vii] Ibid.

[viii] Based on CMS enrollment estimates for 2006. See Department of Health and Human Services, *Budget in Brief,* p. 61.

[ix] "Medicaid: An Overview of Spending on 'Mandatory' vs. 'Optional' Populations and Services," Kaiser Family Foundation *Issue Paper,* June 2005, p. 5, at www.kff.org/medicaid/upload/Medicaid-An-Overview-of-Spending-on.pdf

[x] Department of Health and Human Services, *Budget in Brief,* p. 62.

[xi] Vernon Smith et al., "Medicaid Budgets, Spending and Policy Initiatives in State Fiscal Years 2005 and 2006," Kaiser Family Foundation, October 2005, p. 24. www.kff.org/medicaid/upload/Medicaid-Budgets-Spending-and-Policy-Initiatives-in-State-Fiscal-Years-2005-and-2006-report.pdf

[xii] Ibid., p. 25.

[xiii] Medicare Payment Advisory Commission, "2002 Survey of Physicians About the Medicare Program," p. 2. www.medpac.gov/publications/contractor_reports/Mar03_02PhysSurv_summary2pdf.

[xiv] Stephen Zuckerman, Joshua McFeeters, Peter Cunningham, and Len Nichols, "Changes in Medicaid Physician Fees, 1998–2003: Implications for Physicians' Participation," *Health Affairs Web Exclusive,* June 23, 2004, p. w-382. http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.374v1.pdf

[xv] Smith et al., "Medicaid Budgets, Spending and Policy Initiatives," p. 25.

[xvi] Peter J. Cunningham, "Medicaid Cost Containment and Access to Prescription Drugs," *Health Affairs,* Vol. 24, Issue 3 (May/June 2005), at http://content.healthaffairs.org/cgi/reprint/24/3/780.

[xvii] Maryland Health Care Commission, "Trends in Diabetes Prevalence and Care among Medicare Beneficiaries in Maryland—2002," December 2004, p. 3.

[xviii] Public Law 109-171 (S. 1932).

[xix] If a state chooses to design a separate SCHIP plan, that benefits package can be based on one of three benchmark plans: (1) the standard Blue Cross/Blue Shield preferred provider option under the Federal Employees Health Benefits Program (FEHBP); (2) a plan that is available to state employees; or (3) the health-care plan that is offered by the health maintenance organization (HMO) with the largest commercial enrollment in the state. For more information, see Elicia J. Herz, Bernadette Fernandez, and Chris L. Peterson, "State Children's Health Insurance Program (SCHIP): A Brief Overview," Library of Congress, Congressional Research Service *CRS Report for Congress,* August 4, 2005. See also Carrie Gavora, "KidCare Implementation: A Helpful Guide for the States," Heritage Foundation *FYI* No. 168, December 31, 1997. www.heritage.org/Research/Healthcare/upload/fyi_168.pdf

[xx] Upon enactment, Congress appropriated $40 billion over 10 years for SCHIP. See Department of Health and Human Services, *Budget in Brief,* p. 66.

[xxi] Paul Fronstin, "Sources of Health Insurance and Characteristics of the Uninsured: Analysis of the March 2005 Current Population Survey," Employee Benefit Research Institute *Issue Brief* No. 287, November 2005, p. 14. www.ebri.org/pdf/briefspdf/EBRI_IB_11-20051.pdf4

[xxii] Centers for Medicare and Medicaid Services, "Health Insurance Flexibility and Accountability (HIFA) Demonstration Initiative," at www.cms.hhs.gov/HIFA/

[xxiii] For example, the Idaho Card waiver allows enrollees to receive premium assistance for employer-sponsored *or* private coverage purchase on their own. See Centers for Medicare and Medicaid Services, "Medicaid Waivers and Demonstrations List." www.cms.hhs.gov/MedicaidStWaivProgDemoPGI/MWDL/list.asp#TopOfPage

[xxiv] "Medicaid Managed Care Enrollees at Percent of State Medicaid Enrollees," Kaiser Family Foundation *State Health Facts.* www.statehealthfacts.org

[xxv] The Lewin Group, "Medicaid Capitation Expansion's Potential Cost Savings," April 2006, p. 23. www.lewin.com/NR/rdonlyres/eh4mdox7zvlbfqrnsgtkcaakobxfal26jrptdazhtgnk4auk2moyuces6w655jjvamdpxapxrovykd/33791.pdf

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2. Health-Insurance Reform in the States: Two Steps Backward in Some States, One Step Forward in Others

J.P. WIESKE

Key Points

- Many health-insurance reforms of the 1990s simply transferred costs from one group to another – often with harmful effects.
- Insurance regulation that harms patients often rewards politicians, making positive reforms very challenging.
- Entire insurance markets have been destroyed in states such as New York, Massachusetts, and New Jersey, and are being destroyed in Maine.
- Proven options are available to states that want to reduce the cost of health insurance through increasing freedom of choice.

Introduction

Over the last several years, news stories have abounded about the United States' health-care crisis. Businesses and individuals have seen double-digit cost increases, and fewer businesses are offering health insurance to their employees. Not coincidentally, the number of uninsured Americans has continued to grow. Fortunately, the news is not all bad.

In the past year health-insurance costs have begun to moderate. Milliman Inc.'s survey of HMO and PPO insurance carriers shows increases of 8 percent – still too high, but a marked improvement over the past few years. Better still, the survey found that premiums for high-deductible PPO plans increased by only one percent. Even so, health-insurance premiums continue to be unaffordable for many Americans.

State policymakers have responded with a variety of new reforms, some good, some bad.

- Last year the Vermont Legislature passed a single-payer system (i.e., the government is the primary payer for health care) that was later vetoed by the governor.

- Maine has created Dirigo Health, a new government-run program that provides subsidized health-insurance coverage.

- New York has "Healthy New York," a government-subsidized insurance program offered in the private market that targets the uninsured.

- Montana has created financial incentives for its smallest employers to offer coverage.

- Some states have enabled carriers to offer benefit plans at reduced cost.

The difficulty for policymakers is that health insurance is a complicated subject. Even more problematic is that regulations seem to function much like a balloon – squeeze one end of the balloon and the other end becomes bigger. For example, laws that ensure that health insurance is more affordable for one group of people can lead to unaffordable rates for others.

The market for health insurance, however, functions much like other markets, and imposing a one-size-fits-all solution is counterproductive. The best approach creates the right economic incentives to encourage people to take personal responsibility while targeting limited solutions to those populations that need help most.

Two Steps Backward

State legislatures across the country have a long and sordid history of passing a variety of "reforms" that ultimately raise the cost of health insurance and drive up the number of uninsured. Many of these reforms were well-intentioned policies implemented during the debate over the Clinton health-care plan. Generally speaking, they were aimed at one or more of the following goals:

- Making insurance more affordable for the sick.
- Providing insurance benefits to small business owners, individuals, and farmers.
- Adding additional benefits that are not typically covered by insurance policies.

However, as will be discussed more fully later, many of these policies merely transfer costs from one group to another – for example, forcing younger and healthier people to pay higher premiums so that older and sicker people can pay lower premiums. Such laws encourage the young and healthy to cancel their coverage and become uninsured. Several states have seemingly learned nothing from a decade of declining health-insurance markets.

Massachusetts, Maine, and New York, for example, have recently passed reforms that move away from the market and toward government-centered solutions. They are trying to address the high cost of health insurance, but they could have solved their affordability problems by repealing a number of ill-conceived reforms passed in the 1990s. Unlike the latest efforts, repealing earlier reforms would not cost a dime in state money.

Unfortunately, many states continue to ignore market principles, opting for the changes listed below, despite their disastrous consequences.[i]

Community Rating

In an effort to create premium equity, some states require health insurers to charge the same price to everyone in a "community" or "pool," regardless

of individual risk differences. In a strict community rating, state, age, lifestyle, health, and gender factors may not be used to determine rates. However, most states have adopted "modified community rating" laws that allow the premium rates to vary based on age, gender, and geography. Proponents argue that this rating arrangement provides better equity for those with pre-existing health conditions.

Community rating's real impact on the health-insurance market differs significantly from the rhetoric. In a traditional health-insurance market, insurers base their rates on a variety of demographic and underwriting factors that estimate the amount of risk each individual brings to the pool. Rates may vary based on age, gender, geographic location, health status, and other factors. Including these factors leads to less expensive policies for the young and healthy since they spend relatively little on health care. Their contributions help to subsidize those in the pool who develop a medical condition. Premium-rate variations attract both the largest number of people and a pool that is representative of the general population, which are the optimum conditions for a health-insurance pool that is affordable and sustainable.

The handful of community-rated states restrict the ability of an insurer to price health insurance based on the risk an applicant brings to the pool. These states undermine the development of a sustainable pool. Younger and healthier people pay far more while presenting little risk. As a result, many of them will choose to forgo insurance. As the health-insurance pool gains a disproportionate number of unhealthy people, insurance rates will climb. Eventually, the premiums will be so high that the only individuals left are those too sick to obtain more affordable coverage. This is what is known in the industry as a "death spiral."

The New York market is a poster child for the problems created by this type of "reform." In 1992, New York passed legislation applying both community rating and guaranteed issue to health-insurance policies issued statewide. Before the law was passed, a 55-year-old healthy male paid about twice as much for a policy as a 25-year-old healthy male. After the law was implemented, the rates for the 25-year-old man jumped more than 60 percent. Faced with this kind of rate increase, younger people dropped out of the market. The "death spiral" started, and within a few years everyone was paying far more than before the law was passed.

Guaranteed Issue

Guaranteed issue requires insurers to accept every application for insurance regardless of the risk, allowing people to forgo insurance when they are healthy and purchase it when they are sick. This type of legislation creates what is known as "adverse selection," a situation in which a disproportionate number of sick people are included in a health-insurance pool.

Guaranteed-issue legislation has led to very predictable outcomes. Indeed, insurers and health-policy experts have routinely warned states that have passed such legislation of the problems it would create. Legislation passed in the early 1990s in several states has destroyed their individual markets. The passage of guaranteed issue was made worse in a number of states because it was implemented in conjunction with community rating. The coupling of these two concepts in several states has driven numerous insurance carriers out of the market, and increased premiums beyond the reach of all but the wealthy.

A 1998 Urban Institute study, *Variations in the Uninsured: State and County Level Analyses,* stated the problem succinctly:

Nevertheless, our results strongly suggest that guaranteed issue plus non-group premium rating restrictions in tandem work to decrease overall and private health insurance coverage. Thus, while they surely helped some individuals who are likely to be high risk, state non-group reforms appear to have decreased coverage.[ii]

When New Jersey's guaranteed-issue legislation became effective in 1994, a family policy (known as "Plan D") with a $500 deductible and a 20-percent co-payment (i.e., the insurer pays 80 percent) cost as little as $463 a month and as much as $1,076, depending on which of the 14 participating insurers the family chose.

By April 2006, that same policy purchased from one of the 10 remaining companies cost between $4,262 (Oxford Health Insurance Company) and $21,992 (Celtic) *per month* – or $51,144 to $263,904 per year.

In Kentucky, guaranteed-issue and community-rating rules adopted in 1994 required insurers to offer a limited number of state-designed,

standardized health plans. As a result, 45 insurers abandoned the state, leaving only Anthem Blue Cross, Humana (in a limited capacity), and Kentucky Kare, the state-run plan (now Kentucky Access, a high-risk pool). Legislation passed in 2000 and 2005 to revise the reforms has encouraged a number of insurers to return, but premiums still run above average and Kentuckians still have relatively few choices.

Supporters of guaranteed issue have continued to argue that it is necessary to make coverage accessible to those who need it most, despite the significant cost increases. This is not true. State-sponsored high-risk pools are the best way to make coverage accessible to the medically uninsurable.

Mandated Benefits

Increasingly, states have passed mandated benefit laws that require health insurers to cover specific providers, procedures, or benefits. The Council for Affordable Health Insurance has compiled an annual report enumerating these mandates.[iii] The report highlights the growth of mandated benefits from a handful in the 1960s to the more than 1,800 mandates in place today – and more are on their way.

For legislators, mandated benefits are a no-lose proposition. A new mandated benefit allows an elected representative to provide a benefit to an important and politically motivated interest group. Since voters rarely connect the cost of mandated benefits with the cost of health insurance, legislators can propose and vote for mandates with few political consequences. Indeed, there is a political upside, since legislators can claim they are making health insurance more comprehensive. However, mandates also make health insurance more expensive.

In certain states, mandated benefits have increased the cost of individual health insurance by as much as 45 percent. When costs increase, more people drop or decline coverage. According to a 1999 study conducted by the Health Insurance Association of America (now America's Health Insurance Plans), as many as one in four individuals without coverage are uninsured because of the cost of state mandates for health benefits. At a time when consumers are counting every dollar, it is important to recognize that there is a cost to the consumer who is required to purchase a benefit he or she may never want or use. That cost may be

the determining factor in whether or not the consumer can afford health insurance. Because legislators have saddled health insurance plans with so many mandates – states have about 35 on average and Minnesota leads the pack with 62 – the choice for many people is Cadillac coverage, loaded with benefits, or no coverage at all.

States are increasingly offering ways to bypass the mandate problems by allowing mandate-lite insurance plans and creating mandate commissions. Mandate commissions generally require a study of the cost of newly proposed mandates, as well as requiring a legislature to take extra time for further consideration.

State Regulations

A number of states have made it very difficult for health-insurance companies to do business. They deploy significant bureaucracies that make it expensive for companies to operate, limit plan design options, and both delay and decrease proposed insurance company rates. These regulations are described as "consumer protections," but in the end they merely lead to higher costs and fewer choices.

While not as glamorous as other issues, state regulation of insurance is important. A number of companies have offered low-cost benefit plans (for example, see tonikhealth.com) targeted at the young "invincibles" – those ages 18 to 30, one of the groups with the highest percentage of uninsured but the lowest health-care costs. These plans have proved popular in attracting the uninsured back to the marketplace. But some states, through complicated rules, ban companies from selling the plans. Other states have delayed rate increases which force companies to abandon an unprofitable market, and unfortunately leave those who had insurance without coverage.

Government-Run Insurance Pools

A number of states have destroyed their markets for health insurance with guaranteed issue and community rating or other reforms. While the solution would seem obvious – repeal guaranteed issue and community rating – instead state legislators sometimes craft alternative solutions that expand the government's role in health care. The proposals run the gamut

from helpful and targeted market reforms to new systems that sink state residents deeper into a health-insurance crisis. New York and Maine exemplify the two extreme ends of this spectrum.

In 2000, New York created the Healthy New York program, which allows private companies to provide a subsidized low-cost insurance plan to the uninsured. The mandate-lite policy has defined benefits, and insurance carriers are subsidized by a reinsurance mechanism that covers 90 percent of claims between $5,000 and $75,000. The plan is by no means perfect, and if New York had repealed guaranteed issue and community rating laws, it may not have needed Healthy New York. Nevertheless, the plan was a limited and targeted response to a growing problem in the state.

The Dirigo Health program in Maine is another matter entirely. Dirigo is a complicated, government-subsidized health insurance plan targeting the uninsured, especially those in small businesses. By most objective accounts, the plan has been a disaster. It is difficult for both individuals and businesses to understand and administer. Despite burning through millions of dollars, the plan has only been able to attract 2,300 people who were previously uninsured. It has had much better success enrolling those who had coverage at one time, but dropped it in order to get into the state-subsidized program. In order to keep the plan going, Maine will be taxing private policyholders through a claims tax, while proclaiming the plan has saved the health-care and health-insurance industry more than $100 million (the latest count at this writing).[iv]

Business Group of One

The Health Insurance Portability and Accountability Act of 1996 expanded guaranteed issue rights to all small groups with two to 50 employees. In an effort to expand coverage to some individuals, states have broadened the definition of small group to include so-called "groups of one" – individuals who are considered a group in order to purchase coverage in the small group market. On its face, the proposal makes little sense.

Webster's Dictionary defines "group" as "two or more figures forming a complete unit in a composition." Thus by definition a group of one is impossible. Group policies function differently from those in the individual market, and currently fall under different laws and incur different administrative costs.

The net result of mandating a group of one is that applicants can game the system, leading to increased administrative and claims costs for the small-group market. Individuals who do not meet health-insurer standards in the individual market will choose to purchase guaranteed-issue coverage as a group of one. This approach leads to an adverse selection, because only those with a pre-existing medical condition choose it. Were the individual healthy, he or she would have simply bought coverage in the individual market. Over time, the option will make the small group market unaffordable for legitimate small groups.

One Step Forward

The one common mistake among policymakers is the attempt to solve every problem with one grandiose solution. Single-payer plans ignore the reality that the majority of the U.S. population is already insured. Consumer-driven plans solve affordability problems but may not work for the uninsurable. Policymakers' focus on big solutions ignores the myriad problems faced by individual health-insurance buyers.

For example, the uninsured population is diverse. According to U.S. Census data, one-third of the uninsured have incomes less than $25,000, but one-sixth have incomes of more than $75,000. While 21 percent of the uninsured are unemployed, 79 percent have full or part-time jobs. Even the ages of the uninsured are diverse, with 41 percent between 18 and 34, and 21 percent from 45 to 64.

The solutions to these unique problems are also diverse. Low-cost, subsidized benefit plans may be attractive to those with incomes under $25,000, but those with incomes over $75,000 may be interested in other plans. High-risk pools – created to provide coverage to the medically uninsurable – are seldom used by the young and healthy, but low-income middle-aged people may not be able to afford their higher premiums.

The goal of reform has been to produce low-cost benefit plans, provide health insurance to the uninsured, and to make sure the uninsurable – uninsured individuals with serious medical conditions (some of the technically uninsurable have coverage through an employer plan) – are able to obtain affordable health insurance. Targeted, pro-market solutions provide the biggest bang for the buck. They ensure the existing

marketplace can continue to operate and that specific populations will be able to obtain affordable health insurance.

Below, we highlight some of those targeted solutions.[v]

High-Risk Pools

High-risk pools have been around for more than 25 years, and in 2005 they covered more than 180,000 people in 34 states. They are the social safety net for the uninsurable, providing access to health coverage for some of the society's most vulnerable. High-risk pool members typically have serious medical conditions and do not have access to guaranteed-issue insurance coverage, which is required in the small group or large group markets.

High-risk pools are a win-win proposition. Since providing coverage is costly, most successful high-risk pools are funded through a partnership with high-risk pool members, state government, health insurers, and health care providers. Health insurers are able to predict more accurately their costs, because high-risk pools typically budget and assess carriers on a prospective basis according to the number of lives or market share. In addition, state governments typically supply some funding from state revenues. Finally, health-care providers discount the care received by high-risk pool members.

More important, individuals with health conditions are able to obtain high-quality and often lower-cost health insurance. Typically, the high-risk pool members pay between 125 percent and 200 percent of the standard insurance rates – far less than what insuring their conditions would actually cost. Even so, premiums do not cover claims. So insurers are assessed for the pool's losses – usually based on their share of the insurance.

Health Savings Accounts

Health Savings Accounts (HSAs) allow employers or employees to contribute pre-tax dollars into personal savings accounts from which to pay medical expenses. HSA funds will not be taxed as long as they are spent on qualified medical expenses. HSAs must be linked to a high-deductible medical plan. The minimum deductible is $1,050 for individuals or $2,100 for a family in 2006, but this amount will be adjusted by inflation annually.

The move to high-deductible health plans in conjunction with some type of spending account has begun the consumer revolution in health care, providing people with more options and giving them a reason to be value-conscious shoppers in the health-care marketplace.

These changes don't mean the battle is over. States have proposed numerous new laws that would limit the ability of consumers to purchase HSAs. Some states have proposed new first-dollar mandates, others have proposed deductible limits, and California proposed a public hearing requisite for any plan that required a deductible. If this consumer revolution is to remain intact, it must be vigilantly guarded and such needless restrictions opposed.

List Billing

List billing is the process that allows an insurance company to send employers a single bill for several employees' individual policies, if the employer and employee agree to payroll-deduct employee premiums.

The process usually begins with an agent identifying a company that does not offer health insurance to its employees. After obtaining an agreement from the employer, the agent offers any interested employees the opportunity to apply for the health insurance plan of their choice.

Once accepted by the insurer, the employees agree to have the premiums deducted from their paychecks. The insurer, in turn, sends a single bill, listing each employee's premium – hence "list bill" – to the employer.

The large majority of the uninsured, about 83 percent, come from a household where someone is employed. These individuals may work part time, seasonally or for one of the many firms (especially small firms) that do not offer health insurance. Many of these employees could benefit from list billing.

- With no minimum participation requirements (as in the small group market), any employee who wants coverage can apply.

- The insurance policy is owned by the employee, not the employer, so the coverage will remain intact as long as the premiums are paid – even if the worker switches employers (though a new employer is not and should not be required to honor a list-billing arrangement).

- The policy could cover only the worker, or it could include other family members.

- Insurers in the individual market sometimes charge a billing fee on each bill; list billing eliminates the billing fee.

- If their employer takes advantage of a Section 125 plan, individuals may be able to have their premiums deducted on a pre-tax basis, which will increase their net take-home pay and decrease the effective cost of their benefits.

In addition, by not having to seek out their own insurance agent, sort through numerous plan designs and companies, and keep track of their own premium payments, employees eliminate many of the transaction costs associated with buying health insurance. However, list billing does have some restrictions common to the individual market.

It is important to note that these plans are individually underwritten. That means that an older employee or one with a medical condition might have to pay higher premiums than younger and healthier employees. And in some instances, employees may be denied coverage because of a pre-existing medical condition. In those cases, the uninsured employees have the option of entering the state's high-risk pool – similar to other applicants in the individual market.

Tax Credits

Federal and state tax codes have been used to encourage employer-sponsored health insurance. The result has been an extremely high rate of employers offering health insurance as a benefit to their employees. The tax code provides a break for the employee portion of health insurance if employers offer a Section 125 plan.

However, individuals working for employers who do not provide health coverage (i.e., they are not self-employed) do not receive a tax break for purchasing health insurance. This situation creates an equity issue and the more practical question of whether or not tax credits can be used to help the uninsured.

In 2001, Mark V. Pauly and Bradley Herring published an article in *Health Affairs* that concluded that a "fixed-dollar" tax credit (one that pays a flat

amount regardless of a person's age, income, or cost of a chosen policy) "targeted toward a more comprehensive plan could cut the proportion of uninsured by a third to two-thirds . . . ."[vi]

Some states already offer tax credits for purchasing health insurance. But the credits must necessarily be small. They help, but the better solution would be for Congress to create a tax credit for the purchase of health insurance, at least for lower-income workers. Such a program would help address the tax inequity that exists today.

Exclusionary or Medical Waivers (Riders)

For the majority of people, obtaining health insurance is easy. Most applicants are issued coverage without any increase in premium or without imposing a medical waiver. Individuals who have medical conditions may have a more difficult time finding coverage – especially those with relatively minor but potentially costly medical ailments. They typically face substantially increased premiums or they are denied coverage.

Exclusionary riders provide individuals with another coverage option. Certain medical conditions, like allergies, can be expensive to cover but do not result in other health problems. An exclusionary waiver, or rider, on a health policy allows the applicant to waive coverage for the condition in exchange for coverage for all other health problems. If an applicant declines the policy with a rider, he or she can still apply to other insurers or – if available – to the state's high-risk pool. These are the same choices applicants would have if the state prohibited riders.

Reports issued by the National Association of Health Underwriters (NAHU) and the Council for Affordable Health Insurance (CAHI) debunk the perception that affordable health care is not available to persons with chronic conditions.[vii] In some cases an applicant may spend less money accepting a policy with a rider and paying for the non-covered care out of pocket. For example, a simulated applicant suffering from allergies received offers that limited coverage for her allergies. The lowest monthly premium offered with a rider was $111, and the projected average cost of her allergy medicine was $31 per month, amounting to an effective monthly cost of $142. The average monthly premium without a rider was $257.

The Health Care Choice Act

Representative John Shadegg of Arizona has introduced a new approach to the individual health-insurance market. He has recognized that one of the key problems is the lack of a nationwide marketplace. Individuals trapped in states like New York and Massachusetts, which have obliterated their individual market with guaranteed issue and community rating, cannot purchase affordable insurance. Meanwhile, nearby states like Pennsylvania and Connecticut offer policies that are much more reasonable.

Representative Shadegg's solution is to allow individuals to purchase policies approved and available in another state. While the two states (where the customer lives and where the policy is sold) split some responsibilities including certain consumer protections the bill ensures that individuals are able to purchase affordable health insurance policies by creating a nationwide market. The bill has recognized the fundamental reality missed by many legislators and regulators: health-insurance protections provide no value if they merely drive people out of the market. If Representative Shadegg's bill passes, legislators in highly regulated states will have a serious challenge if they want to maintain relevance in health-insurance markets.

Conclusion: The Path to Affordable Insurance

States have been trying to reform their health insurance markets for years, and we can now see the results of those reforms. Maine, Massachusetts, New York, and New Jersey have virtually destroyed both their individual and small group markets. But other states have thriving, dynamic markets in which people have access to a wide range of affordable policies.

The path to affordable coverage is not difficult to find, but many states have not tried it. Instead, they have implemented policies that have driven the market backward, increasing the number of uninsured. But the solution does not have to be dramatic. A few small steps forward will go a long way toward providing everyone with access to affordable health insurance.

Endnotes

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[iii] Victoria Craig Bunce, et al, *Health Insurance Mandates in the States, 2006* (Alexandria, VA: Council for Affordable Health Insurance, March 7, 2006). www.cahi.org

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3. CON Game:
It's Time to Repeal Hospital Certificate-of-Need Laws

ROY CORDATO

Key Points

- Most states prevent the building of new hospitals without government permission – a policy supported by incumbent hospitals to prevent competition.

- This leads to higher prices, communities without adequate medical resources, and money wasted on lobbying that could be devoted to patient care.

- States should repeal certificate-of-need (CON) laws in order to increase competition, reduce prices, and increase access to hospital care.

What's Wrong With This Picture?

Imagine an economic system that viewed market competition as a wasteful activity that needed to be discouraged or even prohibited by government. For example, if a Chinese immigrant family wanted to open a restaurant, it would first have to approach a government commission that would survey the economic landscape for Chinese restaurants to determine if there already were "enough" such eateries in the area.

The commission would have a formula regarding how many Chinese restaurants exist in the area, how many of those are strictly take-out

restaurants and how many are eat-in establishments, and among those that are sit-down style, how many feature buffets and how many are strictly order-from-menu. The formula might also consider variations in price to determine how many restaurants are serving lower-income families and how many are targeted to the gourmet Chinese food market.

After going through all this – a process that might take several years – the commission would decide whether this Chinese restaurant was "needed" in the area. If not, the immigrant family's request would be refused and the family would be forced to find another way to earn a living. Or, the commission might suggest that the family try another location where the authorities might determine that there were too few Chinese restaurants to serve the existing population.

If it were determined that this community did need one more Chinese restaurant, a certificate would be issued to the immigrant family stating that a restaurant of this type and size was needed and that the family had permission to open a shop. The restaurant, of course, would have to be built to the exact specifications described in the original proposal that was approved. It might not be able to offer take-out service if there were already "enough" take-out restaurants in the area. It would have to be built only to accommodate a certain number of tables because any more or any less would not fit the determined need. The menu would have to be approved, because if the restaurant were also going to serve non-Chinese foods such as pizza or hamburgers, that would fall into a different category and those menu items would have to be passed through another formula and another process.

While most people would probably think that only a Soviet central planner could be happy with such a bureaucratic nightmare, it will have its beneficiaries. Government workers charged with running the system might live well because of its existence. Existing restaurateurs who had already received one of the highly valued certificates and were operating a flourishing business would also benefit. After all, the government would deploy an entire division devoted to protecting them from competition. They would not have to worry about customers being taken by some upstart Chinese restaurant with lower prices or fancier foods.

Of course, consumers would be better off if anyone was permitted to open a new restaurant without government approval, but generally people are

not aware of what they are missing. If the town already had a couple of Chinese restaurants and there was never a wait to get in, some customers might argue that an additional restaurant would be wasteful. People might form such an opinion without a sense of what the new restaurant could be like, what menu items it might offer, what prices it might charge, and so on. This lack of knowledge might even prompt consumers, who are always hurt by monopolies, to support such a system.

As it happens, this is the kind of system found in 35 states plus the District of Columbia with respect to the market for medical-care facilities and equipment.

The Reality of Certificates for Medical Care

Under this system, health-care entrepreneurs who plan new facilities – such as adding a new wing or extra beds to a hospital, or an office that offers MRI, X-ray, or other services – require a "certificate of need" from the state (see appendix). North Carolina's CON law is typical:

> The Certificate-of-Need Law prohibits health-care providers from acquiring, replacing, or adding to their facilities and equipment, except in specified circumstances, without the prior approval of the Department of Health and Human Services … The law … limits unnecessary health services and facilities based on geographic, demographic, and economic considerations … All new hospitals, psychiatric facilities, chemical dependency treatment facilities, nursing home facilities, adult care homes, kidney disease treatment centers, intermediate care facilities for mentally retarded, rehabilitation facilities, home health agencies, hospices, diagnostic centers, oncology treatment centers, and ambulatory surgical facilities must first obtain a CON before initiating development. In addition, a CON is required before any upgrading or expansion of existing health service facilities or services.[i]

The process of obtaining a CON is time-consuming and potentially very lengthy. For example, in North Carolina, depending on the number of reviews, the process can take from 90 days to more than two years. If a denial is appealed to the state Court of Appeals, the process can go well beyond this two-year period. Two examples highlight the process.

As of the summer 2005, the CON approval process for the expansion of a small hospital in Harnett County, North Carolina, had been dragging on for more than four years. In early 2006, the CON was ultimately denied. The law fostered a contentious political and legal battle among several hospitals and local communities. While this political warfare took place, costing millions of dollars, the people of the area might have been benefiting from additional health-care facilities.

On a smaller scale, a recent news report tells of a partnership of neurologists that spent three years and more than $250,000 in an attempt to set up an MRI imaging center. The CON process led to a battle between these doctors and several hospitals. Out of frustration, the neurologists gave up and potential patients were deprived of the alternative that they were hoping to offer.[ii]

CON originated in a federal government mandate, long since repealed.

History, Justification, and Application of CON

In 1974, Congress passed the National Health Planning and Resources Development Act. The act stated that in order to receive federal funding from programs like Medicare and Medicaid, new health-care facilities and additions to existing facilities needed approval from a state agency established to issue certificates of need. All states were told to have such programs in place by 1980. This was seen as a way of controlling costs.

At the time, reimbursements for services were being made on the basis of costs of production. It was thought that facilities were being built and equipment was being purchased unnecessarily because the hospitals were bargaining that the facilities would ultimately be paid for through increased fees. In a market where health-care providers need to compete for cost-conscious purchasers of services, even if those purchasers are insurance companies, higher costs cannot simply be passed along in higher prices.

New facilities would be built or new equipment would be purchased only if the market prices for the added services could justify the added costs. Expansions would be made only if they could be justified by projected demand. This is what entrepreneurship is all about: spotting potential unfilled demand and organizing resources in new ways in order to meet it. If the demand is not there, losses will be incurred and plans have to

be revised. The government payment system at the time encouraged inefficient investment because it took the risk out of the process.

Costs were recouped regardless of any shortcomings in accurately estimating demand. Indeed the so-called "cost plus" system of reimbursement took away the need to consider future demand at all. The result was a classic case of an initial government intervention into market decision-making – in this case the Medicare and Medicaid programs – creating distortions of its own. These, in turn, were used to justify additional interventions: the CON program.

In 1987 Congress repealed its mandate. This came after the federal government abandoned its cost-based reimbursement system and switched to paying a predetermined amount based on the type of treatment used. Since that time 15 states have dropped their CON program. Unfortunately, 35 states, plus the District of Columbia, continue with centralized planning of the health-care-facilities market.

In the 1960s and early 1970s, prior to the federal mandate, more than 20 states had decided to implement CON laws independently, allegedly for cost-control reasons. According to Charles Garena, writing for the Federal Reserve Bank of Richmond, these pre-mandate laws were implemented "in response to hospital operators who favored centralized health planning."[iii] This is consistent with the economics of CON, to be discussed below, which suggest that CON is a cartel enforcement device that protects incumbent providers from new entrants and competition.

According to East Carolina University researchers Campbell and Fournier, "There are reasons to suspect that CON may have been adopted for other purposes … The states most likely to enact CON … were those with a highly concentrated hospital industry and increasing competitive pressures … Hospitals were largely in favor of CON regulation {which} protected them from competition."[iv]

In reality, the continuation of CON regulations cannot be justified either theoretically or empirically. In fact, from the perspective of sound economics, the reverse is true. If one desired to devise a policy for any market whose purpose would be to reduce efficiency, raise costs and prices, and reduce product quality, the existing CON programs would be highly recommended.

If You Like OPEC, You'll Love CON

When it comes to crude oil, it is indisputable that the ability to increase prices depends on the power to restrict production. When President Bush met with Prince Abdullah of Saudi Arabia in April 2005 to discuss high oil prices, the question immediately turned to the Organization of Petroleum Exporting Countries (OPEC), the international oil cartel that raises prices by restricting production.

Paradoxically, supporters of CON laws believe that medical-care markets operate differently, and that the way to keep costs down is to restrict the supply of medical facilities and equipment. For example, if the intent is that MRI services should be less expensive, we should have fewer MRI machines; or that if we want hospital stays to be cheaper, we need fewer hospital rooms. As pointed out by the National Academy of State Health Policy in describing CON regulations: "limitations are imposed in an effort … to hold down the volume of services provided and the cost."[v] But it is just as wrong-headed to think that limiting the supply of health-care equipment and facilities can reduce health-care costs as to think that oil prices could be reduced by limiting the supply of oil.

Cost reductions are best brought about in an environment of open competition and entrepreneurship, not monopoly. Rivalry among businesses and health-care providers is no exception: it stimulates new technologies, innovation, and more efficient ways of delivering goods and services to customers. Existing providers continuously have to keep their costs low and their products desirable in order to fend off potential competitors looking for an opportunity to earn profits.

These potential competitors, like the neurologists discussed above who wished to provide MRI services, are always looking for ways to outperform existing providers. These doctors had planned to offer newer technology and lower prices than existing MRI facilities, which are predominantly owned and operated by full-service hospitals. They planned to locate in a town that had no MRI facilities, making the services more convenient to patients and other doctors in the community.

CON laws disregard the simple economic truths about the relationship between competition and lower prices and higher quality. In large part,

the idea that increased supply leads to higher prices and costs stems from a premise that is clearly erroneous, namely that service duplication is inefficient. Again, North Carolina's law is typical. It states that "the costly proliferation of *unnecessary* health service facilities results in *costly duplication* and *underuse* of facilities, with the availability of excess capacity leading to unnecessary use of expensive resources and *over-utilization* of health-care services [emphasis added]."[v]

In a fundamental sense, this line of argument favors monopoly. Facility duplication is at the heart of competition. Indeed, the definition of a monopoly market is one in which there is no duplication. This is why in monopoly markets customers lose. They are denied the option of turning to others who are providing "duplicated" services when the monopoly providers act like monopolists.

Consider once again our team of neurologists. Would there have been "excess MRI capacity" if they had been allowed to enter the MRI market? Apparently, some state bureaucrats, not market participants themselves, believed there would have been. But the concept is meaningless. For example, the fact that because many Chinese restaurants, at a given point in time, have empty tables, or that some movie theaters have empty chairs, does not mean there is inefficient excess capacity of restaurants or theaters. The new MRI facility would lead to more choice for patients and more competition for their health-care dollars.

Indeed, at the lower prices that would result, people who might forgo MRI exams for less expensive, but less effective methods of diagnosis, might be able to take advantage of the more advanced technology. What is and is not excess capacity must be determined in the marketplace and will be revealed through the system of profit and loss. Certainly there is no way for a central planner to second-guess the ultimate result. Not surprisingly, the evidence matches the economic theory.

The Evidence on CON and Costs

Since the 1980s, when states were freed from the federal requirement to observe CON laws, numerous studies have examined the change in health care costs as states eliminated their laws. If CON were working as advertised, one would expect to see a rise in costs as the laws were eliminated. But this was not the case.

One of the most recent and widely referenced studies, written by Duke University professors Christopher Conover and Frank Sloan, shows results consistent with the economic principles involved. Output restrictions lead to higher costs and higher profits for existing providers. The authors point out that for hospitals, CON laws resulted in a two percent reduction in the supply of beds, as well as "higher costs per day and per admission, along with higher hospital profits" – exactly as economic theory would suggest. The study did find a modest reduction in per capita acute-care spending, which it attributed to CON laws. Interestingly, the study "was unable to detect a statistically significant effect of removing CON on these same expenditures." But overall, the study found no decrease in per capita health care spending attributable to CON.[vii]

An earlier study showed even more dramatic results. This study examined data through 1982 and found that CON was associated with a 20.6 percent increase in hospital spending and a nine percent increase in spending on other health care. Overall, the study found that CON was responsible for a 13.6 percent increase in per capita spending on personal health care services.[viii]

Over the last two decades, the Federal Trade Commission (FTC) has done several studies on the impact of CON laws, both nationally and for specific states. The FTC's consistent conclusion can be summarized in the language from its most recent study, released jointly with the Department of Justice in July 2004. "The agencies believe that CON programs can pose serious competitive concerns that generally outweigh CON programs' purported economic benefits. Where CON programs are intended to control health care costs, there is considerable evidence that they can actually drive up prices by fostering anti-competitive barriers to entry."[ix] As one study reports, "in researching the scholarly journals, one cannot find a single article that asserts that CON laws succeed in lowering health care costs."[x]

CON as a Hidden Health-Care Tax

While the discussion to this point has focused on the economics of CON, there are fallback arguments for CON regulations that relate to the provision of care to the indigent. Advocates argue that entry restrictions, and the higher prices and profits that go along with them, are necessary to induce providers to provide free indigent care. As summarized in a

study by Campbell and Fournier, "CON policies have … been pursued with the implicit aim of 'cross-subsidization,' that is, regulators have used their power to issue licenses and restrict competition in order to create an incentive to hospitals to provide high levels of care to the indigent population."[xi] Oddly enough, the arguments from this perspective actually contradict the "cost-saving" case for CON.

In this context CON laws are used to create a hidden tax. The cost of health care and the profits to providers are purposely kept high by granting monopoly privileges. It is then expected that these excess profits will be used to provide free care to the indigent. Customers are forced to pay a premium created by CON laws, and the proceeds from this premium are used to pay for indigent care. If nothing else, this is dishonest.

If a social and political goal is to guarantee that the needs of those who cannot afford health care be addressed, then the costs of that policy should be made explicit. Only then can the electorate make informed decisions regarding public policy. If those who are paying for health-care services must also bear the burden of paying for the indigent, then an explicit excise tax should be placed as a line item on all health-care invoices, and CON laws should be abolished. If CON laws are being used to hide this tax from the electorate, they are inconsistent with sound economics and an open and democratic political process.

CON imposes another hidden tax on the health care system, in the form of resources that hospitals and other health care entrepreneurs must devote to obtaining such a certification. The process of obtaining a CON is not only time-consuming but also expensive. As noted previously, in the case involving the group of neurologists seeking a CON for MRI equipment, more than $250,000 was spent on an ultimately futile effort – not on purchasing equipment or improving neurological services to patients, but on a bid to gain permission from the state to offer services. Like any other tax, this is an additional expense of doing business that ultimately raises health-care costs across the board.

CON and the Impossibility of Central Planning

As noted, CON regulations are an attempt at central planning of investment in health care facilities. The first underlying premise behind the law is that individuals and companies acting in a free market will

misallocate health care resources. The second premise is that the state, through centralized allocation of health care investment, can improve on market results and better serve the needs of the public. However, even after accepting the first, questionable premise, there is no reason to assume that a large-scale intervention, as authorized by CON laws, can do anything to improve the situation.

Indeed, the second assumption ignores what economic theory has demonstrated over the last 50 years regarding command-and-control methods of resource allocation and the central planning of economies. All the reasons economists typically give to explain the failure of economic central planning apply to CON regulations. In a free market, resource allocation is driven by entrepreneurs who try to predict current and future consumer demand.

Before a physicians' group invested in MRI equipment, for example, it would ascertain that the community it served could support enough business to make the MRI investment worthwhile. The physicians have powerful market incentives to make sure their market analysis is accurate, or they will lose money and their practice will suffer. In other words, the best judges of whether the service will be needed are the entrepreneurs and investors. The system of profit and loss regulates investment and furnishes the information necessary for making wise investments. In the absence of CON, these medical entrepreneurs would be operating throughout the health care market. Hospitals will continuously re-evaluate their circumstances to determine whether new birthing rooms are needed, if an expanded emergency room is necessary, or if a new helicopter evacuation unit would be useful. In each of these cases the entrepreneurs have a strong incentive to access accurately the needs of a given community.

CON laws, on the other hand, substitute bureaucratic decision-making for the market's entrepreneurial assessments. Government decisionmakers have no basis for gathering accurate market information and no incentive to make sure investments are made in the right places, at the right times, and in the right amounts. If their decisions prove misguided, they, unlike entrepreneurs, suffer no personal consequences. In fact, there is no way to determine subsequently whether or not a proper decision was made.

Conversely, a good entrepreneurial decision satisfies consumer needs at least as well, if not better, than existing and potential competitors and survives the competitive pressures of the health care marketplace.

For those granted membership in the CON-sponsored cartel, there is no real test of the marketplace, and market forces that determine whether a particular investment by a hospital, clinic, or physician's practice truly served the needs of the community are blocked. Bureaucrats who judge CON submissions do not, indeed cannot, determine whether there is a need that will best be filled by a particular applicant, because they are outside the market process that generates that information.

In "The Pretense of Knowledge," his 1974 speech accepting the Nobel Prize in economics, Friedrich Hayek argued that central planners, like those charged with determining who should and should not provide medical services, can only pretend to have the information necessary to make the kinds of decisions they make.

At best, any determination of need by such planners will be arbitrary and a poor reflection of market conditions. At worst, these planners can become witting or unwitting tools of entrenched interests who wish to keep competition out of the market. As University of Pennsylvania analyst Mark Pauly has noted, CON programs "tended to be 'captured' or dominated by the hospitals they were intended to regulate, and … those hospitals used regulation to keep out competition."[xii]

End the CON Game

Certificate-of-need laws should be repealed. The idea that free-market competition cannot work as a means of cost control in health care services is not grounded either in economic theory or empirical evidence. Indeed, in areas where competition is allowed to flourish, such as optometry, competitive pricing and an abundance of options serve customers well. The belief that CON laws and the bureaucrats that administer them can do a better job than the competitive market process is not only wishful thinking, it is the economic equivalent of flat-earth theory. Somehow, legislators have convinced themselves we can have the results of open competition by creating monopolies. As Orwell said, love is hate and war is peace.

Endnotes

[i] North Carolina Division of Facility Services, Certificate of Need Section, Overview of CON Process. http://facility-services.state.nc.us/conpage.htm

[ii] Lee Weisbecker, "Doctor claims state's CON rules favor hospitals," *Triangle Business Journal,* April 29, 2005.

[iii] Charles Gerena, "Putting on the Brakes," *Region Focus*, Spring 2004, Federal Reserve Bank of Richmond. Available at www.rich.frb.org/publs/regionfocus/spring04/brakes.html

[iv] Ellen S. Campbell and Gary Fournier, "Certificate-of-Need Deregulation and Indigent Hospital Care," *The Journal of Health, Politics, Policy and the Law,* Vol. 18, No. 4, 1993, p. 906.

[v] Ellen Jane Schneither, et al., "Rising Health Care Costs: State Health Cost Containment Approaches," National Academy for State Health Policy, June 2002, p. 4.

[vi] Article 9, Certificate of Need, p.1.

[vii] Christopher J. Conover and Frank Sloan, "Does Removing Certificate of Need Regulations Lead to a Surge in Health Care Spending?" *Journal of Health Politics, Policy and Law,* Vol. 23, No. 3, June 1998.

[viii] Joyce A. Lanning and Michael Morrisey and Robert Ohsfeldt, "Endogenous Hospital Regulation and its Effects on Hospital and Non-Hospital Expenditures," *Journal of Regulatory Economics,* Vol. 3, No. 2, 1991, cited in *Conover and Sloan's paper.*

[ix] *Improving Health Care: A Dose of Competition,* a report by the Federal Trade Commissions and the Department of Justice (July 2004). http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf

[x] Patrick John McGinley, "Beyond Healthcare Reform: Reconsidering Certificate of Need Laws in a Managed Competition System," *Florida State University Law Review*, Vol. 23, No. 1, 1995.

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[xii] As quoted by Terree Wasley, "Certificate of Need: Poor Healthcare Policy," Mackinac Center for Public Policy, June 17, 1993.

4. Malpractice Liability:
Thoughtful Tort Reform Is Good Medicine

JAMES R. COPLAND

Key Points

- Since 1975, medical malpractice costs have risen four times faster than consumer price inflation and twice as fast as medical price inflation.

- This has caused "defensive" medicine and shortages of physicians' services, sometimes in the most needy areas.

- A growing body of scholarly research supports the argument that medical-malpractice tort reform reduces physicians' insurance premiums without negatively affecting patients, and even reduces the number of accidental deaths.

- Medical-malpractice payouts and premiums vary significantly between the states, far more than can be explained by the national "underwriting cycle."

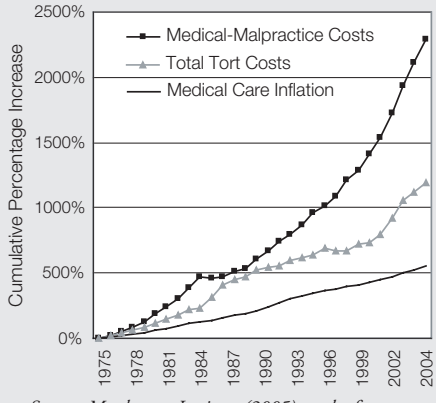
- Both proven and innovative tort reform policies are available to state policymakers who want to reduce these costs and improve patients' welfare.

Over the last few years, many state legislatures have responded to the crisis in medical-malpractice insurance rates by trying to rein in out-of-control lawsuits.[i] Several states have successfully enacted substantial reforms, but

the American Medical Association continues to list 20 states "in crisis" over malpractice litigation.[ii]

The long-term trends show a harmful, quite possibly unsustainable growth in American medical-malpractice liability. By 2004, direct liability costs for medical malpractice in the United States had reached almost $29 billion annually – a 2,000-percent increase over costs in 1975.[iii] At 12 percent per year, the growth rate since 1975 runs four times the rate of inflation, twice the rate of medical-care inflation, and almost three percentage points higher than the growth rate in U.S. tort costs overall (see Figure 1).[iv]

Figure 1. Changes in Medical-Malpractice Tort Costs, Total Tort Costs, and Medical Care Inflation, 1975-2004



Source: Manhattan Institute (2005), and references.

These direct costs of malpractice litigation significantly understate the overall cost of the tort system on American health. Medical-malpractice lawsuits tend to inflate health-care costs by encouraging "defensive medicine" – unnecessary procedures and referrals that doctors and hospitals prescribe in order to limit their exposure to potential litigation. Studies suggest that defensive medicine costs are several times higher than the direct liability costs themselves.[v]

In addition, medical-malpractice litigation adversely affects health in the United States to the extent that it creates doctor or facility shortages in certain jurisdictions and/or in certain specialties. The anecdotal evidence abounds. For instance, South Philadelphia lost its last remaining maternity ward in 2002, and Manhattan's Elizabeth Seton Childbearing Center – where 30 percent of patients were on Medicaid – shut down in 2003, when its liability premiums soared to $2 million a year.[vi]

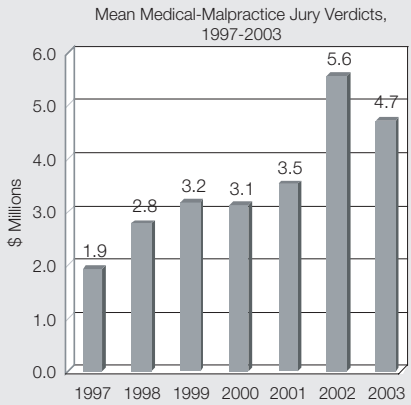
Of course, the cost of medical-malpractice litigation must be weighed against its benefits, including improvements in doctor and hospital safety. Unfortunately, there is substantial evidence that malpractice litigation is too uncertain to provide safety benefits consistent with its costs.

High Medical-Malpractice Premiums Are Caused by High Tort Awards

To many, it may seem a common sense proposition that high jury verdicts and settlements lead to high premiums for insurance against such verdicts and settlements. Nevertheless, advocacy groups allied with the trial bar – such as Public Citizen and the Center for Justice and Democracy and its subsidiary, Americans for Insurance Reform[vii] – continue to argue that rising malpractice premiums are a result of the insurance underwriting cycle,[viii] or price gouging by insurers.[ix]

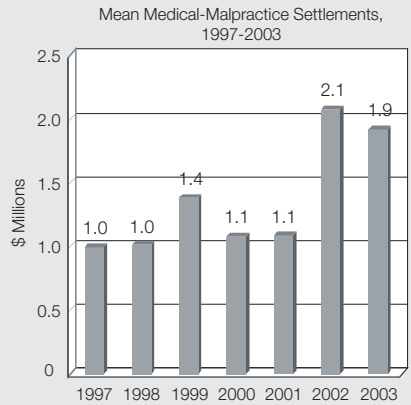
The reports issued by Public Citizen and the Center for Justice and Democracy have been thoroughly debunked, most recently by Ted Frank of the American Enterprise Institute and insurance specialist Martin Grace of Georgia State University.[x] Figure 2 shows that average medical-malpractice jury verdicts rose from $1.9 million to $4.7 million between 1997 and 2003, an increase of 147 percent. Of course, most cases settle and do not go to trial, but actual verdict levels necessarily affect expected verdict levels. And, thus, after some lag effect, they determine settlement values. Figure 3 shows that over the same time, average settlements in medical-malpractice cases rose from $1 million to $1.9 million, a 90 percent jump.

Figure 2. Average Medical-Malpractice Jury Verdicts Have More than Doubled Since 1997, to About $5 Million



Source: Manhattan Institute (2005). Data from Jury Verdict Research.

Figure 3. Average Medical-Malpractice Settlements Have Also Roughly Doubled Since 1997, to Close to $2 Million



Source: Manhattan Institute (2005). Data from Jury Verdict Research.

It strains credulity to suggest that these dramatic increases in jury verdict and settlement levels were not significantly related to the large increase in medical-malpractice insurance premiums witnessed beginning in 2000. However, that is precisely what defenders of the status quo tort system suggest. Let's address each of their arguments, the insurance cycle and price gouging.

When opponents of tort reform speak of an "insurance cycle," what do they mean? By necessity, insurance underwriting markets are cyclical, in line with the interest-rate cycle. Insurers charge premiums today, for which payouts are made in future years. When economists and financial analysts speak of "present value," they refer to the principle that a dollar today is worth more than one dollar in the future, due to opportunity cost. For example, if you are holding a dollar today, you can invest it in a risk-free instrument such as a Treasury Bill, and in one year, you will have more than that dollar.

When interest rates change over time, necessarily, the present value of an insurer's portfolio of future claims also changes. If interest rates go up, the value of those future claims, in today's dollars, goes down; if interest rates fall, the value of those future claims, in today's dollars, goes up. Over the course of 2001, the Federal Reserve Board lowered the nation's key interest rate by 4.5 percentage points. In this environment, the real value of future claims in all insurance portfolios, liability or otherwise, goes up, and premiums by necessity will rise as well.

That said, the shift in interest rates, dramatic as it was, cannot sufficiently explain the explosive growth in medical-malpractice liability premiums, which grew much faster than premiums in other insurance lines. Rather, the interest-rate environment exacerbated the problem insurers already faced from rapidly rising average jury verdicts, as shown in Figure 2.

Earlier this year, the Manhattan Institute Center for Legal Policy asked Alexander Tabarrok, an economist at George Mason University and one of the leaders in econometric research on legal issues, to examine the relationship between tort awards and malpractice insurance premiums.[xi] Tabarrok's study finds a strong statistical relationship between medical-malpractice tort payouts and medical malpractice insurance premiums. Tabarrok shows that tort awards and premiums are not only closely linked in the long run, but also that malpractice premiums track changes

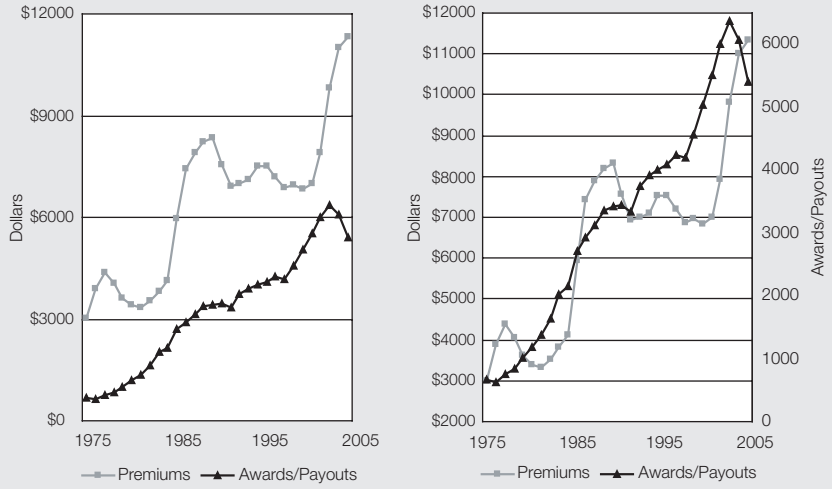
in tort awards in the short run. While this statistical relationship is hard to dispute, tort reform opponents typically assert through numerical or graphical sleight-of-hand that awards and premiums are not linked.

Consider, for instance, the left graph in Figure 4, which appeared in a *New York Times* article that concluded "legal costs do not seem to be at the root of the recent increase in malpractice insurance premiums."[xii] On its face, the graph suggests wild swings in premiums unrelated to the underlying tort awards – including periods of enormous insurer profit. The graph is highly misleading, however, in that insurers face sizable administrative costs and the legal costs of defending against all claims, win or lose. Such costs are relatively constant over time – though they have been decreasing relative to tort awards – so the graph would make much more sense if they were backed out of premiums.

The right graph in Figure 4, rescaled to reach that effect, shows clearly that premiums vacillate around awards, with insurers sometimes charging more and sometimes less than current award levels.

Premium levels vacillate so much because today's premiums must cover unknown future awards. Past awards are not very useful for prediction. The most useful awards are the most recent, especially if these suggest a

Figure 4. Medical-Malpractice Insurance Premiums Track Medical-Malpractice Tort Payouts Over Time



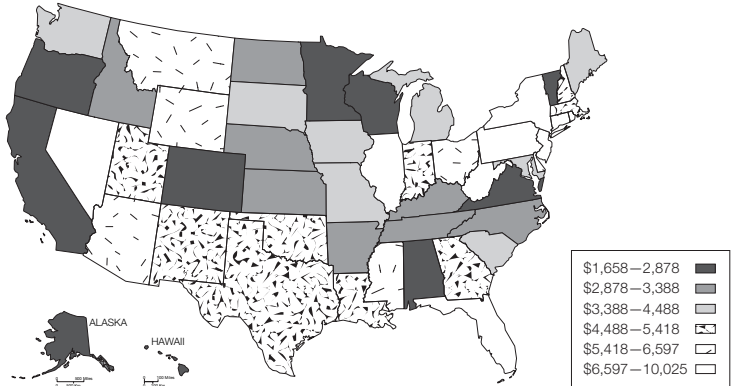
Source: Tabarrok and Agan (2006). Data from Medical Liability Monitor and National Practitioner Data Bank.

permanent change in the level of awards, but recent examples are rare. Thus, insurance companies face a very difficult job: they must forecast future awards using only a few data points. Short-term departures of premiums from awards, therefore, should be expected even when awards drive premiums.[xiii]

Moreover, state insurance regulators, who heavily control what insurers can charge, may exacerbate this tendency by preventing insurers from adjusting rates upward until long after award increases are well-established, by which time insurers' positions have reached crisis levels. If, simultaneously, falling interest rates drive up the value of future insurance claims, the premium increases passed on to doctors will be even more pronounced.

It is also useful to look at variations in tort payouts and malpractice premiums across states to understand that tort awards are the primary driver of medical malpractice premiums. As shown in Figure 5, tort payouts vary significantly across states, ranging in 1999 to 2001 from a high of $10,025 per doctor in Pennsylvania to a low of $1,658 in Wisconsin. It is highly unlikely that doctors in Pennsylvania are six times more likely to make errors than their counterparts in Wisconsin, or that doctors in Nevada, where tort payouts average $7,880 per physician, are really three times worse than those in neighboring California, where awards per doctor are only $2,589. Clearly, these dramatic variations are explained by differences in the states' tort systems.

Figure 5. Medical-Malpractice Awards Per Doctor
United States 1999-2001 Average



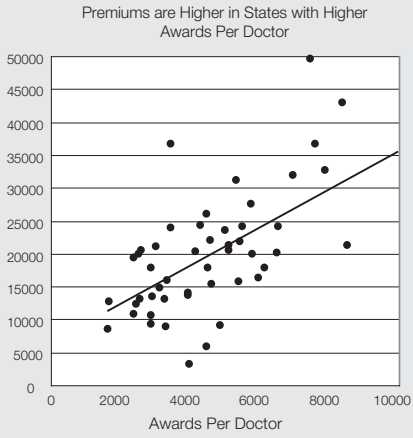
Source: Tabarrok and Agan (2006), and references.

As shown in Figure 5, medical-malpractice premiums also vary substantially from state to state. Because insurers in each state face a national interest-rate environment, interest rates cannot explain the dramatic difference in premiums across states. The correlation between higher premiums and higher tort awards, however, is clear, as is evident in Figure 6. A state's average medical-malpractice tort payout per doctor has a significant and large predictive association with the state's malpractice premium per doctor. This relationship holds when controlling for whether a state has a patient compensation fund and for insurance industry concentration.[xiv]

Interestingly, a state's insurance industry concentration has a negative, though weak, correlation with the state's medical-malpractice insurance premiums, in isolation and when controlling for other factors, including tort awards (see Figure 7). In other words, when a few big players in a state have more market share, the state tends to have lower insurance premiums.

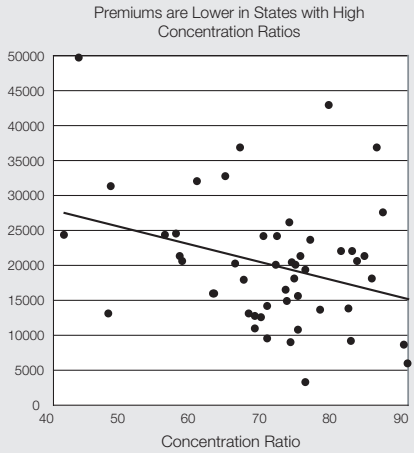
Tabarrok explains that this result makes sense if "efficient firms lower prices and increase their market shares. Wal-Mart, for example, dominates many markets because of its lower prices."[v] Put another way, the insurers'

Figure 6. States with Higher Average Medical-Malpractice Tort Awards are Much More Likely to Have Higher Medical-Malpractice Insurance Premiums



Source: Tabarrok and Agan (2006). Data from Medical Liability Monitor and National Practitioner Data Bank.

Figure 7. Medical-Malpractice Insurance Premiums are Lower in States with More Concentrated Medical-Malpractice Insurance Industries.



Source: Tabarrok and Agan (2006). Data from Medical Liability Monitor.

efficient returns to scale are larger than any pricing power they might gain through their market-share position. That very finding undercuts the anti-tort-reformers' hypothesis of price gouging.

In the first instance, the hypothesis makes little sense, given that close to 50 percent of doctors are insured through mutual (i.e., doctor-owned) insurance companies, unless we assume that doctors are price gouging themselves. Moreover, after racking up $3 billion in losses in 2001, insurers left the medical-malpractice underwriting business in droves, led by the St. Paul Companies, previously the nation's largest medical-malpractice insurer. St. Paul's and other recent withdrawals belie the current claims of price gouging.

Indeed, the price gouging hypothesis conflicts substantially with the insurance-cycle explanation, at least as such claims are articulated by reform opponents. We are asked to believe that bumbling insurance companies priced their policies too low due to "ruinous competition," but that now these same companies are exploiting doctors through collusive price gouging.

In any event, Tabarrok's finding that states with more concentrated insurance markets actually have lower medical-malpractice premiums strongly supports the commonsense notion that price gouging cannot explain malpractice premiums. Looking at rates and awards, both over time and across the states, the data tell a compelling story. The tort system does, in fact, determine the prices at which insurers write policies to cover that system's risk.

The Medical-Malpractice System's Failure to Meet Its Goals

Given that medical-malpractice insurance has grown increasingly expensive, and that the dramatic increase in tort awards has inexorably driven up those costs, we must still ask whether the system's benefits exceed its costs before deciding to support tort reform. In essence, the tort system, working properly, should compensate those injured by medical error as fairly, quickly, efficiently, and predictably as possible. And if the system is accurately punishing errors at appropriate levels of compensation, doctors and hospitals should modify their behavior consistent with improvements in patient health and safety. Unfortunately, the tort system is failing miserably in meeting those goals.

No reasonable observer would call the American tort system fair, quick, efficient, or predictable.[xvi] Litigation is a painfully slow means of reimbursing injury: plaintiffs typically wait years to recover damages. If they do ultimately recover – which happens between 30 and 40 percent of the time – they get less than 50 cents on the dollar, with lawyers' fees and administrative costs soaking up the majority of settlements and verdicts.[xvii] Little wonder that most medical-malpractice victims never sue.[xviii] The exorbitant cost and length of litigation means that for many individuals genuinely harmed by medical error, it is not worth the time or effort to seek recovery.

On the other hand, many medical-malpractice suits lack merit but, nevertheless, win staggering judgments at trial. The paradigm example is the proliferation of suits alleging that a doctor's failure to perform a cesarean section caused oxygen deprivation during delivery, which in turn caused cerebral palsy in the newborn. These suits, long a staple of the malpractice bar, have grossed millions in fees for trial lawyers such as former senator and vice presidential candidate John Edwards.[xix]

Research has shown that cerebral palsy is only rarely attributable to birth asphyxiation[xx] and that the dramatic increase in C-section rates has not led to any decrease in the percentage of infants born with cerebral palsy.[xxi] Plaintiffs' attorneys, however, continue to flog this theory to gullible juries. Jurors naturally sympathize with infants born with health problems, and they are not in a position to distinguish with any accuracy between infant birth defects that in some rare cases can be linked to medical error, and those that are unavoidable tragedies caused by genetic or other factors. As my colleague Peter Huber has noted, "jurors, who generally can reach sensible judgments about people, perform much less well when they sit in judgment on technology."[xxii]

The costs of such juror error on the availability and quality of health care can be staggering. In 2004, one of the highest jury awards ever in a medical-malpractice case – $112 million (later settled for $6 million based on a pre-verdict agreement) – was awarded to a New York couple that claimed doctors failed to act on signs of fetal distress during the mother's protracted labor.[xxiii] That verdict followed three similar New York medical malpractice verdicts in 2002 that ranked among the top 10 in the nation: of $94.5 million, $91 million, and $80 million.[xxiv]

Such potential verdicts, and juries' inability to assess medical error accurately, encourage lawyers to file suits lacking merit. The seminal 1991 Harvard Medical Practice Group study reviewed a weighted sample of 31,429 records of non-psychiatric patients discharged from non-federal acute-care hospitals in New York in 1984.[xxv] The study emerged with two striking findings.

Most persons whose claims were potentially legitimate appeared not to be filing them, whereas most claims that were filed had no evident basis.[xxvi] A more recent Harvard study concluded that 40 percent of medical-malpractice suits lacked merit.[xxvi] Clearly, a high percentage of the suits that currently clog our courts should not be there. A full 49.5 percent of medical-malpractice lawsuits are dropped, dismissed, or settled without payment.[xxviii] Nevertheless, this propensity to sue doctors who face potentially enormous verdicts, often in the form of non-economic or punitive damages, makes the tort system highly unpredictable.

Facing such pressures, doctors and hospitals understandably take precautions in response. Nearly 80 percent of doctors surveyed say they order unnecessary tests and 74 percent say they make unnecessary referrals to specialists.[xxix] The total price tag for such defensive medicine is estimated to be as much as $60 billion to $108 billion a year in unnecessary health care costs[xxx] – some two to four times higher than the total direct cost of medical=malpractice litigation itself.

These suits cost more than just dollars; they can actually lower the quality of health care. Cerebral palsy suits have not only helped spur an increase in unnecessary C-sections, at a cost to mothers' health,[xxxi] but have also succeeded in shutting down maternity wards – the tort hotbed Philadelphia has lost three in recent years[xxxii] – forcing pregnant women in certain parts of the country to travel hours for treatment. Empirical evidence is accumulating that backs up the proposition that the tort system, absent reforms, actually costs lives.

A recent study by Emory professors Paul Rubin and Joanna Shepherd examined tort reform laws passed in states over the last 20 years and found that all but one – collateral source reform – were associated with a reduction in accidental deaths.[xxxiii] The authors hypothesize that this result is largely explained by tort reforms that reduce medical-malpractice costs, which consequently make doctors and emergency rooms more available for injured persons.

In sum, the tort system as it functions in many parts of the United States today fails to meet its goals because it is a very blunt instrument. Doctors in high-risk specialties can expect to be sued: of the 46,000 members of the American College of Obstetricians and Gynecologists, 76 percent have been sued at least once, 57 percent at least twice, and 42 percent three times or more.[xxxiv] The contention of opponents of tort reform that a majority of tort awards are levied against a small percentage of doctors is accurate but misleading. Tort awards are highly concentrated among vital but risky specialties such as obstetrics and neurosurgery, both because doctors in these fields are much more likely to be sued and because the level of awards associated with these fields is much higher than those most other doctors face.

Perversely, current tort law in many states deters most medical activities that are innovative and best reduce risk or save life and limb; those activities tend to be risky although life-saving.[xxxv] As Huber has observed, "When all is said and done, the modern rules do not deter risk: they deter behavior that gets people sued, which is not at all the same thing."[xxxvi] Because American tort law fails to improve patient safety – and because litigation is expensive, slow, and unpredictable – states should continue to explore ways to improve the system.

Thoughtful Tort Reforms for Medical-Malpractice Liability

If the case for tort reform is compelling, what, then, is the appropriate agenda for reform? Among the traditional tort reforms states have enacted, statistical evidence using new techniques has shown that each reform helps to lower medical-malpractice insurance premiums, although to differing degrees.

Traditional medical-malpractice tort reforms include:

- **Limitations on non-economic damages.** Unlike most countries of the world, the United States generally allows juries to assess damages for injuries that are non-pecuniary, including pain and suffering, emotional distress, and mental anguish. In fact, such awards exceed the total value of all pecuniary damage awards in the United States. Such non-economic damage awards are difficult for appellate courts to review, since they result from jurors' impressions, rather than from calculations of lost earnings and medical care. Thus, many states have adopted limits on

jurors' non-economic damages, either across all tort cases or solely for medical-malpractice cases. Typically, such limits are set at $250,000, based largely on California's successful 1975 Medical Injury Compensation Reform Act.

- **Limitations on punitive damages.** Most American jurisdictions also permit juries to assess quasi-criminal "punitive" damages against defendants in cases that are particularly egregious. Although punitive damages are awarded relatively rarely, they are almost always pleaded and can increase plaintiffs' leverage in settlement negotiations. As a result, many states have also limited punitive damages in malpractice cases.

- **Collateral source reform.** Many states traditionally allow plaintiffs to recover damages in court even if their losses are fully insured, thus creating a type of "double recovery." A number of states have limited lawsuits in which insurers or other collateral sources cover plaintiffs' injuries, or at a minimum have allowed information about potential "double recovery" to be presented to juries.

- **Joint and several liability reform.** Many states have common law rules in which injurers – i.e., "tortfeasors" – are jointly and severally liable. In other words, each defendant in a suit can be held accountable for up to the full extent of a plaintiff's injuries if the jury determines that the defendant is even minimally at fault. Such a rule has two principal problems. First, the rule encourages plaintiffs to sue multiple defendants, even those tangentially related, to maximize chances of full recovery. Overall litigation costs across all parties are thus higher than they otherwise would be. Second, joint and several liability interferes with the tort system's ability to deter misconduct, since defendants barely responsible for the injury can bear the full extent of loss, which leads to over-deterrence, such as defensive medicine. Therefore, many states have either eliminated joint and several liability or limited it such that defendants have to be responsible for a large percentage of the injury to be liable for the full extent of damages.

- **Patient compensation funds.** Some states have enacted patient compensation funds that pay out doctor losses above a certain

> level. Such funds can be particularly effective in lowering total doctor premiums, but only in cases in which the state in effect subsidizes doctors' medical-malpractice insurance.

How have traditional tort reforms worked in practice? Early work on the effects of medical-malpractice tort reforms, led by Patricia Danzon, found that non-economic damage caps and collateral source reforms in particular led to lower tort awards in states, with impacts ranging from 11 to 50 percent.[xxxvii] Danzon's work, and that which followed, was substantially limited by a lack of data and statistical challenges.

A new study released by the Center for Legal Policy by insurance specialists Robert Hoyt and Lawrence Powell uses a "trending methodology" to correct for this problem, essentially separating trends before and after reform laws are passed.[xxxviii] Hoyt and Powell find that a significant difference exists before and after the passage of legislation, for non-economic damage caps, collateral source reform, and punitive damage caps. The result for joint and several liability reform is more ambiguous. Hoyt and Powell's study suggests that relative to the preceding trend, states should expect a drop of seven percent in malpractice premiums in the first year after passing non-economic damage caps, a six percent drop in the first year after passing punitive damage caps, and a four percent drop in the first year after passing either collateral source or joint and several liability reform. A package of all four reforms would imply a drop of 21 percent from the prior trend in the first year – with additional declines (of decreasing size) continuing to "trend in" over time.

What about the effects of tort reform on patient health? Daniel Kessler and Mark McClellan's seminal 1996 study isolated a specific heart procedure and determined that tort reforms lowered overall procedure costs five to nine percent without any statistically significant impact on health outcomes.[xxxix] More recent studies have found that the states with non-economic damage caps had about a 12 percent greater physician supply than those without,[xl] and have estimated that reduced malpractice insurer premiums would induce earlier prenatal care by about two to five percent, with a more pronounced impact in the case of African-American women.[xli]

Two important caveats are in order. First, the safety effects of tort reform may be negative for collateral source reform, a result observed by Rubin and Shepherd in analyzing accidental deaths and by Jonathan Klick looking at

infant mortality.[xlii] Second, punitive damage caps do not seem to work well when enacted in the absence of other non-economic damage caps, because jurors tend to increase non-economic damage awards as a substitute.

Finally, it is important to note that patient compensation funds do help to lower costs to physicians, but at taxpayers' expense. The evidence in fact suggests that patient compensation funds may alleviate short-run systemic pressures but encourage more litigation. For instance, Pennsylvania's patient compensation fund has helped it keep medical-malpractice premiums artificially low, although its tort awards per doctor are the highest in the nation. Nevertheless, South Philadelphia, a notorious jurisdiction that, in recent years, has had almost as many million-dollar tort awards as the entire state of California, lost all of its maternity wards in 2002.

Patient compensation funds are not, therefore, a viable long-term solution for tort systems run awry. What reforms might legislators pursue outside the traditional variety? Two deserve special mention.

First, overall medical care could be improved, and medical error reduced, if medical institutions were able to self-report mistakes and work to fix systemic (as opposed to isolated) errors. Unfortunately, the adversarial nature of the American legal system – and the dramatic costs associated with internally identified mistakes if collected for lawsuits in the discovery process – act as a strong deterrent for hospitals to review problems comprehensively with an eye toward determining "what went wrong." The Institute of Medicine has outlined a proposal to limit plaintiffs' lawyers' discovery of hospitals' internal patient safety initiatives that state legislators should strongly consider.[xliii]

Second, Philip K. Howard of Covington and Burling, the founder and chairman of Common Good, has persuasively argued for specialized health courts in malpractice cases. The United States is among only a handful of countries worldwide that use civil juries for tort litigation. Although many states may face constitutional constraints in limiting civil jury trials, legislatures could clearly pass laws making enforceable contractual provisions in which health care consumers agreed to hear cases in alternative forums, functioning similarly to the Federal Arbitration Act and similar provisions. Both special courts and limiting the discovery of internal safety reviews could much better align the tort system with its goals of providing fair and speedy compensation for injuries and proper incentives for patient care.

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5. Physicians and Non-Physician Clinicians

Where Does Quality Assurance Come From?

SHIRLEY V. SVORNY

Key Points

- Restrictive scope-of-practice laws reduce access to health services and increase health costs.
- A growing body of evidence indicates that non-physician clinicians can provide care of equal quality to that provided by physicians, in many cases.
- Innovation in practice depends upon flexibility in using the skills of all health professionals.
- "Telemedicine," which crosses state lines, makes parochial licensing laws even less relevant.
- States should eliminate "scope-of-practice" regulations and replace licensure by boards-granted state monopolies with certification by provider groups and liability insurers.

The Current Environment

In every U.S. state, health care professionals lobby for licensure or scope-of-practice laws that give them the exclusive right to perform specific tasks. Associations of physicians and non-physician clinicians hire consultants in an effort to defend or expand their legal scope of practice. All this

jockeying for turf is tolerated by consumers and consumer advocates, who view such laws as critical to health care quality. This perception could not be further from reality.

Scope-of-practice laws are sought because they limit competition, not because they ensure quality. Due to the extensive web of state licensing regulations for physicians and non-physician clinicians, qualified clinicians are precluded from undertaking tasks they could readily perform. Manpower restrictions reduce access to care, and inflate health care expenditures unnecessarily.

Once set, scope-of-practice laws are hard to change. As technology changes, creating new health care roles, licensing statutes are slow to respond. Putting politicians in the driver's seat and powerful clinician lobbies in the backseat is no way to ensure the efficient use of personnel in health care. The alternative is to take away the powers to design scope-of-practice laws that allow politicians to limit competition.

State medical professional licensing offers little protection against clinician incompetence, fraud, or malfeasance.[i] In fact, existing private sector credentialing, privileging, and malpractice underwriting is the best guarantee of quality assurance. The policy implications are direct: states should put an end to politically influenced, unduly rigid scope-of-practice laws that limit accessibility and raise the cost of health care.

What Protects Consumers

For today's consumers, quality assurance is the result of a number of factors, including hospital efforts to credential and privilege doctors and other clinicians, the reputation that accompanies the recommendations of other practitioners, screening and credentialing by health plans, a track record of effective care (recorded in state and national databanks), the scrutiny that lies behind every malpractice insurance policy issued, and private specialty board certification. Hospitals and health plans credential medical clinicians by determining whether they have the appropriate education, training, and competence, and give them privileges to consult patients in their organizations.

As with other products consumers purchase, it is not the government but the private sector that ensures medical service quality. Since 1965, when

the courts ruled that hospitals were liable for verifying the competency of clinicians,[ii] hospitals and other health care providers have taken on the task of ascertaining physician and non-physician clinician competency; and health workers can be denied hospital privileges or dropped from panels because, despite their formal training and state license, they are not suited to the task.

These organizations have their reputations and assets on the line. They have much to lose if they let incompetent individuals practice. As a result, health care providers and professional liability insurers have developed extensive protocols for establishing the competence of the individuals they hire, insure, or to whom they grant hospital privileges. Insurance underwriters use all the information they can get to avoid taking on risk that could lead to substantial loss.

We Give Up Little by Ending State Licensing

Licensing by a state medical board indicates only that an individual has completed approved coursework and passed a standardized test, perhaps many years ago. Licenses for most health care professionals in the United States do not indicate either an area of specialization or a particular expertise. Such distinctions are made by private specialty boards or certifying organizations. In fact, licensure alone does not satisfy specialty boards; surgical boards often require supervised practice as part of the certification process, in order to assess an individual's clinical skills.[iii]

Although it was not the case 20 years ago, 90 percent of physicians are privately certified by specialty boards today. Hospitals and health plans rely on the specialty-board certification in their efforts to establish the qualifications of individuals for credentialing and privileging.[iv]

Not only are the licensing efforts of state medical boards a poor indicator of practice quality, but disciplinary efforts of state medical boards do little to protect consumers. Anecdotal horror stories abound, describing incompetent individuals who are not properly sanctioned yet continue to practice.[v] Despite what consumers might think, at the state level the discipline process has never tried to address the issue of what is "good" or "bad" medicine. This is not surprising, as these are difficult calls to make when considering an individual patient's case.[vi]

Clinicians themselves think of state medical licensing as a floor, a safety net of sorts to keep the worst professionals out. But efforts on the part of health care providers to credential panels of physicians or grant practice privileges to physicians and non-physician clinicians do just as much, and more. The Joint Commission on Accreditation of Healthcare Organizations requires health care providers to verify an applicant's education, training, and board certification, and investigate actions that may have been taken against a physician. In addition, the Joint Commission requires verification of an individual's experience and competence specific to the requested privileges. This offers an assessment beyond that offered by licensure, as state boards do not evaluate practice-specific knowledge or skills. Finally, in granting privileges to practice, the Joint Commission requires consideration of malpractice judgments against the applicant. Again, state licensure offers no hint of such assessment.

By credentialing a clinician, the provider organization is exposed to malpractice risk. As a result, not only will the provider want to ensure physician quality, but the company from which it purchases liability insurance will want to vet its procedures for ensuring quality as well.

Only about 10 percent of physicians do not contract with at least one managed-care group. Many of these are older, upscale providers (often psychiatrists) who rely on reputation to attract patients.[vii] Of the physicians without contracts, such as obstetrician-gynecologists, some are credentialed and privileged by hospitals, but all those who purchase malpractice insurance must pass the scrutiny of liability insurance companies.

Non-physician clinicians are subject to the same type of evaluation by the health care providers who hire them. Rather than state licensure, it is the judgment of the supervising physician and an investigation into the specific skills of the individual that protects consumers.

The efforts of organizations that employ and insure clinicians, the need for clinicians to protect their own reputations, and individual ethics protect consumers in the United States. State efforts to regulate scope of practice are, at best, redundant.

Non-Physician Clinicians and Turf Wars

Non-physician clinicians (NPCs) – advanced practice nurses, physician assistants, midwives, and others – have taken on increasing responsibility

in the U.S. health care system over the last several decades.[viii] They substitute for physicians or provide services that are complementary to those provided by physicians. Most non-physician clinicians work in primary care, but they increasingly work in specialty practice as well. At odds with physician groups over scope-of-practice laws, organizations of non-physician clinicians lobby legislators to expand their scope of practice and limit competition.

Anyone with access to the Internet can pick up on the hotbed of activity across the country as groups of non-physician clinicians compete to secure additional protections through state licensing restrictions. It is hard to believe when reading the discussions that the underlying theme is how best to provide patient care. Clinicians, from nurses to electroneurodiagnostic (END) technologists, worry that some other group will capture a specific task within what they consider their own scope-of-practice boundaries. Each group seeks legislation to exclude others from intruding on its territory, no matter what the skills of the competing group.

For example, a white paper written for the American Society of Electroneurodiagnostic Technologists (ASET), counsels that the organization currently faces many issues. Among those, it counts the lack of a formal training program, as well as no protection for the scope of practice: "Other professions are assuming the role of the END technologist in practice," Mickie Rops writes, and "advocating for and successfully securing the END technology function within their legally protected scopes of practice."[ix]

Rops notes the "ongoing turf struggles among respiratory therapists, electroneurodiagonostic technologists, and polysomnographic technologists."[x] Legislation proposed by respiratory therapists, she cautions, could "prevent polysomnographic technologists and electroneurodiagnostic technologists from practicing in many of the areas for which they are trained."[xi]

For years, a strong nursing lobby in Mississippi blocked legislation to allow physician assistants to practice, even after every other state had passed such legislation.[xii] When Texas took steps to license surgical assistants, registered nurses objected, describing the battle between psychiatrists and psychologists over the authority to prescribe medications as "particularly bitter."[xiii]

In an article about the successful use of physician assistants in dermatologic surgery, the authors, physicians themselves, ask, "Are we training our future competitors?"[xiv] To ease the concerns of dermatologic surgeons, Leshin and Hauser note that physicians have three years of postgraduate training that gives them expertise in diseases of the skin beyond that of other clinicians. To those still worried about the encroachment on their scope of practice, the authors point out that the law requires physician assistants to practice under the supervision of a physician and not in competition with them.

To gather anecdotes about turf battles, sign up for the American Association of Physician Assistants'(AAPA) "Adventures in Lobbying, a Day on Capitol Hill." This program is offered to AAPA members bi-annually.[xv] Defending and expanding turf is a primary objective.

In addition to lobbying for scope-of-practice restrictions, efforts by clinician groups to limit competition are reflected in increasingly strict education requirements for new entrants to the profession. As late as 1986, physician assistants who had not graduated from accredited programs were allowed to take a certifying exam.[xvi] In California, nurse practitioners who begin practice in 2008 will be required to have a master's degree to practice.[xvii] Master's level preparation in the nursing specialty area is required by some certifying bodies and will be required by all by 2007."[xviii]

Of the 16 non-physician health-profession occupations examined in 2004, two have higher education requirements already on the horizon – audiologists will require a doctorate by 2012 and occupational therapists will require a master's by 2007.[xix] After 2007, experience under the supervision of a board-certified pathologist will no longer be sufficient background for pathology assistants seeking certification from the American Society for Clinical Pathology.[xx]

Pew Foundation researchers suggest that current education requirements are excessive, and point to the fact that other countries require much less education for comparable practice responsibilities.[xxi] The authors propose that practitioners learn basic competencies, and be expected to continue to learn throughout their professional lives.

One could argue that these lengthy education requirements are necessary to ensure the knowledge and skills for the position. However, health

economists have demonstrated that increasing required education and training is just one more way to limit entry and reduce competition.[xxii]

Non-Physician Clinicians

In many cases, non-physician clinicians, including advanced practice nurses, physician assistants, midwives, and others, have taken on tasks that were previously in the exclusive domain of physicians. The federal Department of Health and Human Services (HHS) reports 240,461 advanced practice nurses (APNs) in the United States (eight percent of all registered nurses).[xxiii] The number of nurse practitioner graduates has been rising every year; it is now similar to the number of new physicians graduating every year. Not all nurse practitioners go into direct patient care. Some work for insurance companies and in nursing management.

As the basis for state licensure or state or private credentialing and privileging, advanced practice nurses are certified by private certifying organizations, such as the American Academy of Nurse Practitioners.[xxiv] These private organizations have established a reputation in the medical community. For example, the Council on Certification of Nurse Anesthetists (CCNA) administers a certification examination, evaluates candidates' performance, and grants certification to those who pass and meet other requirements set by the council. The CCNA's certification program is accredited by the National Commission for Certifying Agencies (NCCA), which protects its own reputation by ensuring that organizations it accredits meet the criteria and guidelines it has set. NCCA requires a job analysis study every five years, with revisions to the scope of practice as appropriate.[xxv]

The CCNA also seeks recognition and approval from the American Board of Nursing Specialties.[xxvi] Nearly all of the advanced practice nurses surveyed by HHS reported being certified by a national organization.

Scope-of-practice rules for advanced practice nurses vary across states. For example, in 26 states, nurse practitioners may practice independent of physician collaboration or supervision. In 13 states, nurse practitioners have prescriptive authority (including controlled substances) independent of any physician oversight.[xxvii] States allow multiple paths to midwife practice.[xxviii] In many states, direct-entry midwifery – entry through an apprentice path – is legal.[xxix]

Table 1: Number and Qualifications of Advanced Practice Nurses

Nurse Practitioners (NP)	141,209	At least 3 months' training in an NP program required, but more than 65% have master's degrees
Clinical Nurse Specialists (CNS)	72,521	Master's level clinical preparation
Trained as NP & CNS	14,689	
Clinical Nurse Anesthetists	32,523	58% with post-RN certificates, 37% with master's degrees
Nurse Midwives	13,684	37% by means of a certificate program, 57% with master's degrees
Total Advanced Practice Nurses	240,461 (includes duplicate preparation)	

Source: U.S. Department of Health and Human Services, 2005.

Physician assistants are fewer in number than advanced practice nurses. The AAPA estimates that there will be 58,665 people in clinical practice as physician assistants at the beginning of 2006.[xxx] Although the ratio of physician assistants to physicians in the United States is about one to 16, the ratio for new graduates is about one to five.

In 2002, physician assistants were licensed in 36 states. Eleven states eschewed licensure in favor of certification (the private National Commission on Certification of Physician Assistants). In four states – Massachusetts, Kansas, Minnesota, and New York – physician assistants needed only to register.[xxxi] Physician assistants are generally authorized to prescribe controlled substances, except in Indiana and Ohio.

The National Commission on the Certification of Physician Assistants administers the Physician Assistant National Certifying Exam. Despite the trend towards increasing specialization, the certifying examination focuses on primary care medicine.[xxxii] In every state, physician assistants must provide services under the supervision and direction of a licensed physician. The physicians who direct the work of physician assistants

also assess their specialty skills. In addition to the health care provider organizations, the supervising physician is legally responsible for negligent acts of the physician assistant, creating incentives for oversight and direction.[xxxiii]

Good Outcomes Result from Liberty of Practice

The determination of what a physician assistant actually does on the job is a function of his or her abilities and the judgment of the physician who directs or supervises the physician assistant's work. In other words, it is the judgment of those who work with physician assistants that determines the types of positions they may hold. "A dexterous and motivated physician assistant can be trained to expertly perform numerous procedures."[xxxiv] Recent studies suggest that physician assistants can deliver up to 80 percent of the care usually provided by primary-care physicians.[xxxv]

Despite differences in the education and regulation of nurse practitioners and physician assistants, there are not "strong, unique, practice differences … between the two types of non-physician providers."[xxxvi] The ability of nurse practitioners and physician assistants to take on tasks that physicians have traditionally dominated has been documented in many cases. Mary O. Mundinger randomly assigned patients to a nurse practitioner or a physician. Patient outcomes were comparable.[xxxvii]

Summarizing the results of the literature on nurse practitioners, Professors Joanne Kelvin and Giselle Moore-Higgs report that nurse practitioners "perform as well as other health care providers."[xxxviii] However, non-physician clinicians do not simply replace physicians. Studies of collaborative physician-nurse practitioner practices suggest that these teams trump either group working alone in terms of patient satisfaction and outcomes.[xxxix] In radiation oncology, non-physician clinicians (such as clinical nurse specialists, nurse practitioners, and physician assistants) generally work with physicians, performing designated tasks under supervision, but do not independently carry caseloads.[xl]

A recent report on the use of midwives in place of physicians as first assistants in cesarean section concludes that malpractice rates did not rise, and the mothers-to-be no longer had to wait for emergency cesareans.[xli] In this case, nurses participated in on-site training in midwifery, after which the hospital's department of obstetrics and gynecology certified them.

In gastroenterology, where endoscopists are in short supply, some academic hospitals use physician assistants for flexible sigmoidoscopy (visual examination of the lower colon with a scope). Physician assistants trained for such advanced procedures are a safe and effective alternative.[xlii] In a survey of primary care physicians, researchers at Memorial Sloan-Kettering Cancer Clinic found that the vast majority of family physicians and internists were open to the idea of using physician assistants or nurse practitioners to perform cancer-screening examinations.[xliii]

More than 20 years ago, a thorough review of the empirical literature on regulating health professionals concluded, "Many studies … show that the quality of care would not suffer if licensure policies were selectively liberalized allowing mid-level practitioners to perform some tasks not reserved only for physicians.[xliv] Among the less obvious reasons for this are that scope-of-practice rules limit medical professionals' career mobility, and that licensing statutes preclude the informal transitions that are allowed in other industries as individuals gain expertise over time. Despite progress in the employment of advanced practice nurses, physician assistants, and others, it is still the case that state-level licensing statues and scope-of-practice rules constrain the efficient use of health manpower.

With respect to malpractice, claims against non-physician clinicians are rare. In a 10-year study of claims by Controlled Risk Insurance Company (CRICO), less than two-tenths of one percent of insured employees in CRICO-insured institutions had claims initiated against them. "Claims naming non-physician clinicians are relatively uncommon in the CRICO-insured institutions … Given the vast number of patient care encounters, the news is encouraging."[xlv]

Proposals for Flexibility in Employment of Allied Health Workers

The alternative to politically determined scope-of-practice rules is straightforward – shift to a system that allows hospitals and other providers the flexibility to make their own decisions about health-manpower use (under the watchful eye of liability insurers), using private market accrediting and credentialing of training and verification of experience as the basis. There have been numerous proposals to this effect, yet the political pressures to carve out practice domains show no signs of letting up.

Politicians in the Canadian province of Ontario gave lip service to increased flexibility in health-manpower use in the 1991 Regulated Health Professions Act. The act is described as a "redesigned, regulatory structure ... intended to lead to the evolution of a more flexible, rational, and cost-effective health care system...."[xlvi] No one has evaluated how well the 1991 act achieved the goal of reducing the monopoly on practice patterns granted by scope-of-practice laws.

Pew Foundation researchers note that it took quite some time to move the legislation forward and predictably, during that process, the medical professions were able to influence the legislation that was finally passed. It appears that, despite the intentions of some of the initial framers of the legislation, the regulation of health care professionals in Ontario remains much as it is elsewhere.

In 1993, as part of the Health Security Act (HSA), the Clinton Administration proposed that the federal government pre-empt state licensure laws that define scope-of-practice. The HSA said "No State may, through licensure or otherwise, restrict the practice of any class of health professionals beyond what is justified by the skills and training of such professionals."[xlvii] The Clinton health plan was defeated. Control of scope of practice remained in the hands of state legislatures and industry groups.

Pew researchers raised the idea of institutional oversight again in 1995, suggesting that the responsibility for guiding the use of health professionals should lie with institutions that hire them. The "Third Report of the Pew Health Professions Commission" calls inflexible scope-of-practice regulations a "barrier to accessible, cost-effective, and high-quality care."[xlviii] The "Third Report" suggests the possibility of "overlapping scopes of practice based on demonstrated competency."[xlix]

The "Report of the National Commission on Allied Health" argued for an expansion of scope-of-practice regulations to eliminate barriers to expanding roles for various clinicians.[l] The National Commission on Allied Health's Implementation Task Force suggested, as one of its implementation plans for education, that professional associations, credentialing agencies, accrediting agencies, payers, consumer groups, and government should undertake efforts to reduce existing barriers to clinically-effective and cost-efficient scopes of practice, particularly for those whose scope of training currently exceeds their scope of practice and for those who add new or multiple competencies in the future.[li]

Regulating Telemedicine

Telemedicine allows clinicians to provide or support care at a distance, especially across state lines. This threatens state licensing boards, which cite concerns over fraud, privacy issues, and the inability to get malpractice insurance for cross-state services as reasons to preclude distance care.[lii] By 2001, 26 states had implemented laws limiting the interstate practice of telemedicine.[liii] Some states require a full or special license to engage in out-of-state practice.[liv] Once again, it appears that turf battles will preclude access to care for millions of Americans.

Conclusion: Removing Politics from Manpower Decisions

Supporters of state medical professional licensing attribute much more competence to government agencies than the evidence supports. State governments would improve health care if they were to back off defining scope of practice for non-physician clinicians. It is, and should be, the role of hospitals, health maintenance organizations, and malpractice insurers to identify those practitioners they find competent to practice. These groups and individuals are in the right place and have the knowledge and incentive to judge quality. Given court interpretations of liability, the buck stops with the hospital administrator, health plan, or the overseeing physician now, and it will for the foreseeable future.

The premise of existing oversight of medical-professional scope of practice at the state level is that such efforts improve health care in our country. On the contrary, political decisions as to scope of practice unnecessarily restrict access to care and raise the cost. Eliminating the politics from health-manpower decisions would improve quality and allow health care to be organized and administered in a more cost-effective way.

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6. Prescription Piracy:
The Black Market in Foreign Drugs Will Not Reduce U.S. Health Care Costs

BRETT J. SKINNER

Key Points

- Foreign countries will not permit U.S. politicians to siphon off medicines their citizens need by means of a black market.
- Policies that allow this practice effectively steal intellectual property from innovative companies that operate legally in the United States.
- Many Canadian Internet pharmacies appear to be selling generic versions of medicines that are still patented in the United States.
- States should not encourage the illegal practice of "re-importing" prescription medicines.

Introduction: A Borderline Issue

Some politicians in the United States are well known for supporting the so-called "re-importation" of foreign medicines through the black market from countries such as Canada, as a way to reduce health care costs for Americans. Unfortunately for them, this black-market trade in prescription drugs will not achieve the expected outcomes.

First, it is impossible to supply the demands of American patients through the cross-border drug trade without simultaneously reducing access to

medicines for patients in the source countries. Foreign governments will ban the export of drugs to Americans before allowing American cross-border consumers to jeopardize the supply of retail drugs for their citizens. This chapter presents Canada as a case study of a major source country that has supplied the black-market trade in prescription drugs to the United States. Further, it explains the basic economic reasons why Americans will not be able to rely on foreign pharmacies to supply their medications.

Second, the black-market drug trade depends on unfair trade practices that are often illegal under international law. Many of the drugs being traded are unauthorized copies of medicines that are still under patent protection in the United States. Foreign cross-border drug retailers are engaged in the massive theft of intellectual property, because they are copy-pirating the latest drug inventions. This violation of the property rights of global drug makers could potentially reduce economic growth in the U.S. pharmaceutical industry, resulting in job loss. The violation also might discourage investment in the development of new medicines, which means that patients in the United States and around the world will not realize the benefits of future pharmaceutical improvements. This chapter discusses the role that Canadian-based cross-border Internet pharmacies are playing in the black-market copy piracy of American drug inventions.

Canadian vs. U.S. Demand for Canada's Drug Supply

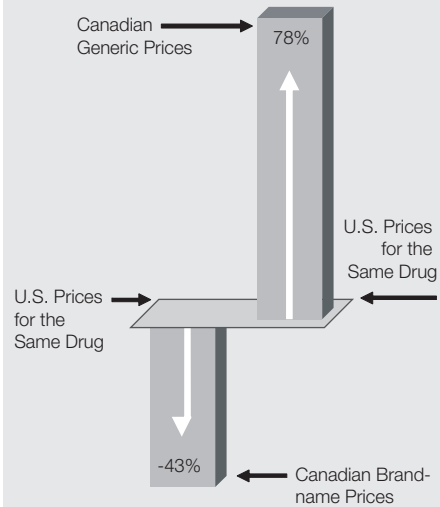
The notion that the cross-border drug trade can be relied upon to supply medicines to Americans assumes that foreign sources of supply will remain adequate to meet U.S. demand. Both the evidence and the economics of the cross-border drug trade show that this assumption is false.

The basic economic fact driving the cross-border drug trade is price differences between the United States and countries like Canada. Previous research has shown that after adjusting for currency value, prices for the 100 top-selling brand-name drugs in Canada are on average 43 percent below U.S. prices for the same drugs (Figure 1). By contrast, the 100 top-selling generic drugs are on average priced 78 percent higher in Canada than the same drugs in the United States.[i] In fact brand-name products account for about 72 percent of the value of all cross-border Internet sales to Americans.[ii]

This pattern of cross-border sales is consistent with the fact that 92 percent of the top-selling brand-name products are priced *lower* in Canada than in the United States, while nearly 75 percent of top-selling generic products are priced *higher* in Canada than in the United States.[iii] The higher relative price of most Canadian generic drugs explains why a smaller percentage of such drugs are resold to Americans through Internet pharmacies. U.S. consumers are simply able to buy most of these drugs more cheaply at home.

It is important to recognize that lower prices on Canadian brand-name drugs are not simply due to Canadian price controls, but are also the normal result of market economics. There is evidence that even in the absence of price controls, the normal Canadian free-market price for drugs would probably remain much lower than U.S. prices.[iv]

Figure 1. Average Canadian Price Differences From U.S. Prices for the Same Drugs Over the Top 100 Brand-name and Top 100 Generic Drug Products Sold in Canada in 2003 (at Purchasing Power Parity)



Source: Skinner (2005); IMS Health Inc. (2004).

There are valid economic reasons why drug companies charge lower prices in Canada than in the United States, and why they cannot afford to allow lower Canadian prices to be imported into the American market through the cross-border drug trade. Previous research indicates that across segmented free markets the prices of drugs should be positively correlated to the average incomes in each market. That is, drug prices should be higher in wealthier markets and lower in poorer markets – a pricing relationship that is consistent for many non-pharmaceutical products as well.[v]

Differential pricing between markets occurs because sellers find that the profit-maximizing price in a market depends on the level and distribution of income among buyers. A positive relationship between price and average

income in a market usually occurs because average income is an important factor in determining consumers' willingness to pay in a market.[vi] For the seller, the best price is the one that maximizes profits through an optimal combination of supply and demand within each market. The optimal price is usually higher in markets with higher incomes.[vii]

Drug manufacturers can charge lower prices in Canada relative to the United States only when the two markets are segmented; that is, price differentiation is possible when vendors can prevent customers who enjoy lower prices (Canadians) from reselling their goods to customers who pay higher prices (Americans).[viii] If the cross-border drug trade undermines North American market segmentation, Canadian prices would adjust naturally in response to the increased market demand from the growing wave of American consumers and converge toward higher American prices.

Aside from normal demand-driven price increases, the growth of the cross-border trade should create upward pressure on Canadian prices. Drug manufacturers want to prevent Canadian prices from being "imported" to the United States, thus undermining global pharmaceutical pricing strategies. Therefore, drug companies would also have an incentive to raise the price in Canada to eliminate any artificial cost savings that are driving cross-border sales. Federal Canadian drug-price controls prevent natural price movement above the status quo. As such, existing Canadian pharmaceutical policies prevent normal price adjustments from taking effect. The difference between Canadian and U.S. prices for brand-name (mostly patented) drugs has created an incentive for Canadian Internet pharmacies to buy up the Canadian drug supply at prices fixed by law in Canada. They then resell the same drugs to American consumers at a premium over the Canadian price, but still sufficiently below the U.S. market price to attract American consumers.

Those consumers represent an opportunity to capture a higher price and sell a larger quantity of drugs, thus creating a powerful profit incentive for Internet pharmacies to engage in reselling the Canadian drug supply to Americans. However, the growth in the cross-border drug trade encourages drug makers to restrict their supply of medicines in Canada to normal domestic consumption levels in order to prevent Canadian prices from being brought into the United States.

Drug Makers Choose How to Respond

Research-based drug companies cannot afford to have Canadian prices prevail in the American market because their global price differentiation strategies are designed to recover the significant research and development costs associated with bringing new drugs to market. Research indicates that on a risk-adjusted basis, inventing and developing a new drug costs on average $800 million to $900 million in U.S. dollars.[ix] The cost of this process is recovered through differential pricing strategies that match prices with demand and income conditions in each market.

In this context, drug manufacturers have only a few options with which to deal with increasing volumes of cross-border resale drugs. First, in a free market, drug makers would simply adjust Canadian prices toward the U.S. price level to eliminate the savings that are driving consumer demand for cross-border drugs. This is the easiest, most effective, and the least costly strategy. However, federal drug price controls in Canada preclude drug companies from exercising this option.

Another option is to minimize cross-border sales of drugs. Drug companies would supply the Canadian market at levels that are consistent with normal Canadian demand. The cross-border trade would become a zero-sum game: if pharmacies were to redirect substantial portions of the Canadian drug supply to American consumers, it would result in equivalent shortages for Canadian consumers. Such a strategy limits the damage that can be done to international pricing structures in pharmaceutical markets, and puts the onus for action on the Canadian government to protect its domestic drug supply. Given that price controls are the cause of the cross-border drug trade, this would seem appropriate.

In fact, evidence shows that as of June 2005 at least 10 of the largest brand-name pharmaceutical companies supplying the Canadian market have implemented policies to restrict sales of drugs in Canada to normal domestic consumption levels. These companies include Abbott Laboratories, AstraZeneca, Boehringer-Ingelheim, GlaxoSmithKline, Lilly, Merck Frosst, Novartis, Pfizer, Sanofi Aventis, and Wyeth.[x]

In fact, even under the current volume of black-market cross-border drug trade, shortages are occurring in Canada, and the Canadian government has signaled that it intends to ban the export of the domestic drug supply

to Americans. In late 2005, Canada's federal health minister introduced legislation that would allow Canada to enforce an export ban on the cross-border drug trade in the event that a drug shortage materializes. The move followed a November 2004 Canadian Pharmacists' Association report that found that 80 percent of pharmacists in Canada were experiencing one or more drug shortages weekly, and that shortages were becoming more frequent.[xi] Such shortages are not surprising when one considers the relative size of the American and Canadian consumer segments currently competing for access to Canada's retail supply of drugs.

The cross-border Internet pharmacy industry is represented by a number of trade associations, the most prominent of which is the Canadian International Pharmacy Association (CIPA). Importantly, CIPA officials identify U.S. *seniors and Americans without health insurance* as the specific target markets for its members. Based on this claim, we can estimate the size of the cross-border drug trade's target market and compare it to Canada's own population of consumers.[xii]

American seniors numbered about 36 million in 2004.[xiii] By comparison, Canada's total population is roughly 32 million and its current population of seniors about four million.[xiv] This means that there are approximately nine times as many American seniors as there are Canadian seniors in the competition for a limited Canadian drug supply. In fact, there are more U.S. seniors competing for Canada's drug supply than there are Canadians as a whole.

Some claim that the recent implementation of the Medicare Modernization Act (MMA), which extended publicly-subsidized drug benefits to most American seniors, may reduce the need for many American seniors to shop for drugs in Canada. The act created a Medicare drug benefit for seniors, beginning in 2006. The drug benefit is available on a voluntary basis to all Medicare beneficiaries. Perhaps surprisingly, eligibility for the Medicare drug benefit is more universal than existing Canadian programs for seniors, despite Canada's government health-run care system.

However, the standard drug benefit specified by the act for calendar year 2006 has a $250 annual deductible; pays 75 percent of covered drug costs between $250 and $2,250; provides no further coverage until an enrollee has incurred $3,600 in out-of-pocket drug costs for the year; and pays about 95 percent of covered drug costs beyond that catastrophic

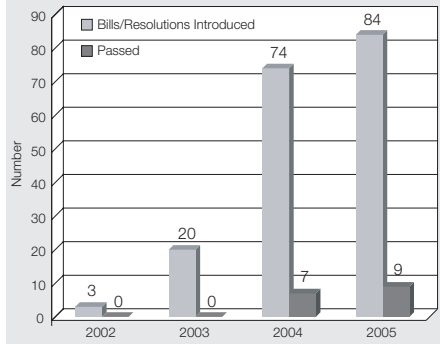
threshold. The catastrophic threshold is defined in terms of the actual out-of-pocket costs that enrollees incur.[xv] (CBO 2004: viii)

The deductible structure of the benefit and the fact that some seniors are not eligible for coverage at all under the act mean that seniors as a whole will still face significant out-of-pocket drug costs. As a result, American seniors may still demand drugs that are sold through Canadian-based Internet pharmacies. Also, as discussed later in this paper, there are accelerating legislative efforts under way in the United States to allow Medicare recipients to obtain retail drugs from Canadian pharmacies.

The other stated target market for Canadian Internet pharmacies is Americans without health insurance. According to the United States Census Bureau's *Current Population Survey* (CPS), nearly 46 million Americans lacked health insurance in 2004.[xvi] However, estimating the number of people without health insurance is the subject of much debate because of the way that the Census Bureau collects data on the issue. Government survey questionnaires overstate the uninsured population – possibly counting many responses twice.[xvii] Based on the characteristics of the individual in the uninsured survey population, the best estimate of the actual long-term uninsured population in the United States is 23 million.[xviii] Nevertheless, this group alone equals two-thirds of Canada's population.[xix]

The total current U.S. population competing with Canadians for access to their drug supply is between 59 million and 82 million people, a consumer group roughly 85 to 160 percent larger than the entire population of Canada. It is no wonder Canadian pharmacists are reporting shortages. But Canadian drug shortages would worsen dramatically if U.S. demand for Canadian medicines were to undergo an "official" expansion of the kind recommended by some American politicians.

Figure 2. Number of U.S. State and Federal Bills and Resolutions Introduced and Passed that Favored Legalizing the Cross-border Drug Trade, January 2002 to September 2005



Source: National Conference of State Legislatures (2005).

The cross-border resale drug trade is currently illegal in the

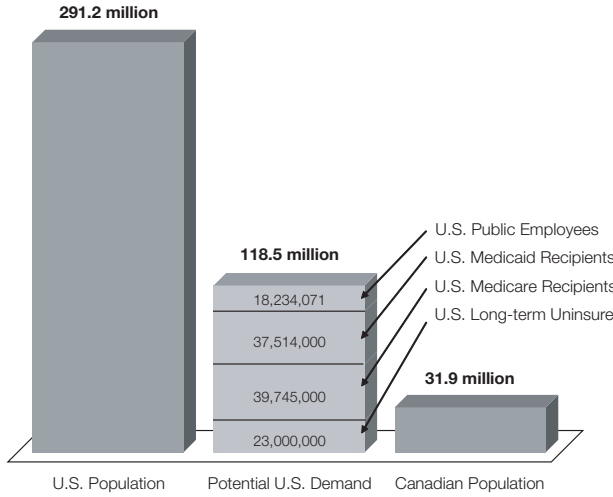
United States. Yet, since the trade began in 2002, many federal, state, and local American politicians have been attempting to legalize the purchase of resale drugs from Canadian Internet pharmacies. The number of attempts to pass legislation at the federal and state level has grown from three per year in 2002 to 84 per year by September 2005 (Figure 2). Many of the proposals allow the bulk buying of drugs from Canadian Internet pharmacies to supply federal, state, and local government employees in the United States, as well as recipients of U.S. government programs like Medicaid and Medicare.[xx]

The total scope of potential U.S. demand for foreign-sourced retail drugs under these proposals is enormous when compared to the total populations of the source countries themselves. For instance, the U.S. Census Bureau reports that the total number of full-time equivalent, federal, state, and local civilian employees of the U.S. government is approximately 18.2 million people, or approximately 57 percent of the entire Canadian population.[xxi] It is probable that the family members of these employees would be eligible to make cross-border purchases. The 2004 U.S. census reports that the average American family size was 3.18 people.[xxii] Therefore, the potential consumer segment represented by government employees and their families in the United States could be as high as 58 million, or nearly twice as large as Canada's entire population.

Additionally, the number of people enrolled in state Medicaid programs alone (37.5 million: mainly social assistance recipients) is 17 percent larger than the entire Canadian population. The number of Medicare beneficiaries (39.7 million: mainly seniors and the disabled) is 24 percent larger than the Canada's 32 million.[xxiii]

A conservative estimate of the potential individual and bulk demand for cross-border drugs shows that the number of American consumers that might compete for access to the Canadian drug supply is nearly four times the size of Canada's entire population. The enormous size of the potential American consumer demand relative to Canada's population is shown in Figure 3, and indicates that it is clearly not feasible for cross-border pharmacies to supply either their target markets (approximately 63 million customers between Medicare seniors and the uninsured populations), or potential bulk buyers (approximately 56 million customers between Medicaid and U.S. public employees, excluding family members).[xxiv]

Figure 3. Estimated Size of U.S. Consumer Groups Competing for Access to Canada's Drug Supply



Source: U.S. Census Bureau (2005); American Blue Cross-Blue Shield Association (2005); Statistics Canada (2005). To be conservative, this analysis only includes the direct employee population of 18.2 million.

This Is Not Free Trade

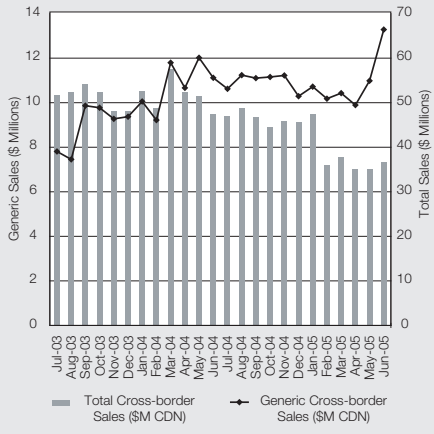
No matter what some might think, the cross-border drug trade is not free trade, which is based on respect for property rights. Yet, the evidence suggests that Canadian-based Internet pharmacies are profiting from the theft of U.S. intellectual property on a massive scale by selling to American consumers generic versions of drugs still patented in the United States.

According to the best data available there are at least 278 Canadian-based Internet pharmacies that are "confirmed or suspected" of primarily selling drugs to Americans. As of June 2005, the annualized value of drug sales to the United States through these pharmacies was an estimated $456 million (measured at manufacturer-level prices). This is down 18 percent from the previous 12 months ending June 2004 (IMS Health Inc. 2005: allowing 90 U.S. cents to the Canadian dollar). The value of sales measured at the final U.S. retail prices charged to American consumers by Canadian Internet pharmacies are certainly much higher than the figures reported above and do not include "foot traffic" sales to American consumers through regular "brick-and-mortar" border pharmacies.

What explains the recent leveling off of Canadian-based cross-border Internet drug sales to the United States? Of the 500 top-selling cross-border drugs between July 2004 and June 2005, 302 (60 percent) were brand-name products representing 72 percent of the total value of Internet sales and 198 (40 percent) were generic products representing 28 percent of the total value of Internet sales. A closer look at data on annual sales for the 500 top-selling cross-border drug products between July 2003 and June 2005 shows that relatively less expensive generic products are displacing brand-name products in the volume of drugs being traded over the Internet to Americans, thus largely explaining the drop in the overall value of sales.[xxii]

Figure 4 shows how the monthly value of all cross-border Internet drug sales declined between April 2004 and June 2005. At the same time, the monthly value of cross-border sales in specifically generic products has steadily increased. Therefore, the shrinking value of cross-border sales is not solely reflective of declining unit volumes of the drugs being traded. These data indicate that relatively lower priced generics (relative to brand drugs) have accounted for a greater share of the cross-border product mix since April of 2004, thus largely explaining the drop in the overall dollar value of sales over time.

Figure 4. Monthly Cross-border Internet Pharmacy Sales to the U.S.: Total Sales vs. Generic Sales, July 2003 to June 2005



Source: Skinner (2006); IMS Health Incorporated (2005).

The large and rising proportion of Canadian cross-border drugs accounted for by generic products is very surprising. As mentioned earlier, nearly three-quarters of the 100 most commonly prescribed generic products available in both Canada and the United States in 2003 were priced higher in Canada. The average price difference for the group of high-priced generics was 116 percent greater in Canada, while the top 100 generics as a whole were priced 78 percent higher, after adjusting for currency differences.[xxvi]

Why would Americans be buying so much of Canada's generic drug supply if these kinds of drugs were almost always cheaper in the United States? The answer is found in an analysis of the Canada-U.S. patent status of cross-border drug products. Of the top 500 drugs sold by suspected cross-border pharmacies, 198 are generic in Canada. However, 50 of these are still patent-protected in the United States. Table 1 shows that nearly half (47 percent) the value of generic sales through cross-border Internet pharmacies to Americans was accounted for by products that were not yet generic in the United States. In almost all cases, the lack of a generic equivalent in the United States means that these drugs were still under active U.S. patent protection (Table 2). The data suggest that Canadian-based Internet pharmacies are engaged in a massive theft of U.S. intellectual property, by selling drugs to Americans in violation of active U.S. patent rights.

Table 1. Distribution of Prescription Drug Sales to Americans Through 278 Identified Canadian Cross-Border Internet Pharmacies, July 2004 to June 2005, (C$, manufacturer-level prices)

Total Canadian Cross-border Internet Pharmacy Sales to U.S.	$506,642,793
Top 500 Drugs (Incl. brand and generic products) Sold Through Canadian Cross-border Internet Pharmacies to U.S.	$468,235,940
198 Canadian Generics in top 500	$131,130,748
50 of 198 Canadian Generics, Non-Genericized In U.S.	$61,203,561
Percentage of Generic Sales Violating U.S. Patents	**46.7%**

Source: Skinner (2006) using IMS Health Incorporated (2005) data.

Table 2. Drugs that are not genericized in the United States (grouped by therapeutic category and active ingredient) that are being sold in generic versions (across 50 products) from Canadian-based Internet pharmacies to Americans

Therapeutic Category*	Generic Active Ingredient	U.S. Patented Brand Name Version
Antiarthritics	Leflunomide	Arava
Antiarthritics	Meloxicam	Mobic
antihistamines, systemic	Cetirizine	Zyrtec
antihyperlipidemic agent	Fenofibrate micro	(various: Tricor, Triglide, Lofibra, etc.)
antihyperlipidemic agent	Simvastatin	Zocor

Therapeutic Category*	Generic Active Ingredient	U.S. Patented Brand Name Version
antihyperlipidemic agent	Pravastatin	Pravachol
anti-infectives	Levofloxacin	Levaquin
anti-infectives	Terbinafine	Lamisil
antispasmodic/antisecretory	Domperidone	(No equivalent brand or generic) (various:
bronchial therapy antispasmodic/antisecretory	salvent (CFC free) domperidone	similar to Albuterol) (no available product)
bronchial therapy antispasmodic/antisecretory	salbutamol hfa domperidone	(various.: similar to Albuterol) (no available product)
cardiovascular bronchial therapy	carvedilol salvent (CFC free)	Coreg (various: similar to Albuterol)
hormones bronchial therapy	desmopressin salbutamol hfa	(various: DDAVP, Stimate, Minirin, etc.) (various: similar to Albuterol)
hormones cardiovascular	alendronate carvedilol	Fosamax Coreg
neurological disorders, hormones	lamotrigine desmopressin	Lamictal (Various: DDAVP Stimate, Minirin, etc.)
psychotherapeutics hormones	sertraline alendronate	Zoloft Fosamax
neurological disorders	lamotrigine	Lamictal
Psychotherapeutics	sertraline	Zoloft

*Source: Skinner (2006); IMS Health Incorporated (2005) Notes: *USC2 description.*

These findings make it highly probable that American patent holders have legal recourse in U.S. courts to stop the cross-border trade. The federal government certainly has the legal and moral authority to ban imports of these generic drugs in order to enforce its own laws on property rights. The findings also imply that American politicians who promote the legalization of the cross-border resale drug trade are inadvertently encouraging an enormous rip-off of their own nation's intellectual property and leaves open the question of whether they might be legally liable for the losses suffered by patent holders.

Canadian-based Internet pharmacies are trading in stolen goods. The cross-border drug trade simply cannot be justified using free-market arguments, unless one uses Tony Soprano's definition of free trade.

Endnotes

[i] Brett J. Skinner, *Canada's Drug Price Paradox: The Unexpected Losses Caused by Government Interference in Pharmaceutical Markets,* (Vancouver and Toronto: The Fraser Institute, 2005).

[ii] Brett J. Skinner, *Price Controls, Patents, and Cross-border Internet Pharmacies: Risks to Canada's Drug Supply and International Trading Relations,* (Vancouver and Toronto: The Fraser Institute, 2006).

[iii] Brett J. Skinner, *Canada's Drug Price Paradox: The Unexpected Losses Caused by Government Interference in Pharmaceutical Markets,* (Vancouver and Toronto: The Fraser Institute, 2005).

[iv] Brett J. Skinner, *Canada's Drug Price Paradox: The Unexpected Losses Caused by Government Interference in Pharmaceutical Markets,* (Vancouver and Toronto: The Fraser Institute, 2005); and A. Hollis, and A. Anis, "Rx for Canada: Close the Internet Pharmacies", No. 205, ISSN 0824-8001, (Toronto, Canada: Howe Institute Commentary, October 2004); and John R. Graham, *Prescription Drug Prices in Canada and the United States—Part 2: Why the Difference?* (Vancouver, Canada: The Fraser Institute, 2000).

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[vi] However, higher prices may sometimes be observed in poorer markets if a very wide income range characterizes the market. This is because average incomes are affected by the distribution of wealth in the market. For instance, a poor country may have a small minority of its population that is extremely wealthy while the bulk of the population is extremely poor. This will lower the average income (total income divided by population). If the domestic market cannot be segmented between consumer groups based on income or if the incomes of the poor are not high enough to buy at the lowest possible price, then it will only be profitable to sell to the smaller but wealthier population whose average incomes, if considered as a separate consumer group, are much higher. Furthermore, the profit-maximizing price will be set at the equilibrium of the wealthier consumer group. If this small group of consumers has higher average incomes than the average incomes in foreign markets, then its prices will be higher as well. (Skinner 2004)

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[viii] Stuart O. Schweitzer, *Pharmaceutical Economics and Policy,* (New York, NY: Oxford University Press, 1997).

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[x] IMS Health Incorporated, Special data request, (Canada: 2005).

[xi] A.K. Woodend, J.Poston, & K. Weir, "Administrative Burden on Canadian Pharmacists Due to Drug Shortages," (Ottawa, Canadian Pharmacists Association: 2004). http://www.pharmacists.ca/content/about_cpha/who_we_are/policy_position/policy.cfm?policy_id=1

[xii] Canadian International Pharmacy Association (CIPA) News release, "CIPA discusses consequences of changes to Canadian Food and Drug Act," *CNW Group,* (November 15, 2005).

[xiii] U.S. Census Bureau, Table HI05, "Health Insurance Coverage Status and Type of Coverage by State and Age for All People: 2004", *Current Population Survey,* Annual Social and Economic Supplement. http://pubdb3.census.gov/macro/032005/health/toc.htm Last revised: July 19, 2005; and Population Division, Table 2: Annual Estimates of the Population by Selected Age Groups and Sex for the United States: April 1, 2000 to July 1, 2004 (NC-EST2004-02), Release Date: (June 9, 2005).

[xiv] Statistics Canada, CANSIM, table (for fee) 051-0001, Last modified: (October 27, 2005).

[xv] "A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit", U.S. Congressional Budget Office, (2004).

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[xvii] Brett J. Skinner, *Price Controls, Patents, and Cross-border Internet Pharmacies: Risks to Canada's Drug Supply and International Trading Relations,* (Vancouver and Toronto: The Fraser Institute, 2006).

[xviii] *The Uninsured in America,* BlueCross BlueShield Association (BCBS) (2005).

[xix] Statistics Canada, CANSIM, table (for fee) 051-0001, Last modified: (October 27, 2005).

[xx] Brett J. Skinner, *Price Controls, Patents, and Cross-Border Internet Pharmacies: Risks to Canada's Drug Supply and International Trading Relations,* (Vancouver and Toronto: The Fraser Institute, 2006).

[xxi] U.S. Census Bureau, Table HI05, Health Insurance Coverage Status and Type of Coverage by State and Age for All People: 2004, *Current Population Survey,* Annual Social and Economic Supplement, http://pubdb3.census.gov/macro/032005/health/toc.htm. Last revised: July 19, 2005; and Population Division, Table 2: "Annual Estimates of the Population by Selected Age Groups and Sex for the United States: April 1, 2000 to July 1, 2004" (NC-EST2004-02), Release Date: (June 9, 2005).

[xxii] U.S. Census Bureau, *American Community Survey,* (2004) Available at: http://factfinder.census.gov/servlet/ACSSAFFFacts?_event=&geo_id=01000US&_geoContext=01000US&_street=&_county=&_cityTown=&_state=&_zip=&_lang=en&_sse=on&ActiveGeoDiv=&_useEV=&pctxt=fph&pgsl=010)

[xxiii] U.S. Census Bureau, Table HI05, "Health Insurance Coverage Status and Type of Coverage by State and Age for All People: 2004", *Current Population Survey,* Annual Social and Economic Supplement. Available at: http://pubdb3.census.gov/macro/032005/health/toc.htm. Last revised: July 19, 2005; and Population Division, Table 2: "Annual Estimates of the Population by Selected Age Groups and Sex for the United States: April 1, 2000 to July 1, 2004" (NC-EST2004-02), Release Date: (June 9, 2005).

[xxiv] U.S. Census Bureau, Table HI05, Health Insurance Coverage Status and Type of Coverage by State and Age for All People: 2004, *Current Population Survey,* Annual Social and Economic Supplement, Available at: http://pubdb3.census.gov/macro/032005/health/toc.htm. Last revised: July 19, 2005; and Population Division, Table 2: "Annual Estimates of the Population by Selected Age Groups and Sex for the United States: April 1, 2000 to July 1, 2004" (NC-EST2004-02), Release Date: (June 9, 2005).

[xxv] IMS Health Incorporated, Special data request, (Canada: 2005).

[xxvi] Brett J. Skinner, *Canada's Drug Price Paradox: The Unexpected Losses Caused by Government Interference in Pharmaceutical Markets,* (Vancouver and Toronto: The Fraser Institute, 2005).

7. Squeezing the Balloon

The Futility of Pharmaceutical Cost Containment

JOHN R. GRAHAM

Key Points:

- Governments need to change how they account for national health spending. The Centers for Medicare and Medicaid Services (CMS) account for health spending in a largely meaningless way, and its measurements motivate popular demands that government health plans, such as Medicaid, "control" costs unproductively.

- Previous policies to contain Medicaid prescription spending have put low-income patients at risk of poor health outcomes and increased use of physician and hospital services – likely costing taxpayers more – but states are *not* measuring these outcomes.

- Fewer than five percent of Medicaid beneficiaries account for half of Medicaid costs – and these patients use significantly *less* prescription drugs than the other 95 percent of patients.

- The private sector is better than government agencies at recognizing the value of medicines, and the private sector can also provide discount drug programs to those who need them better than government can – if the government allows it.

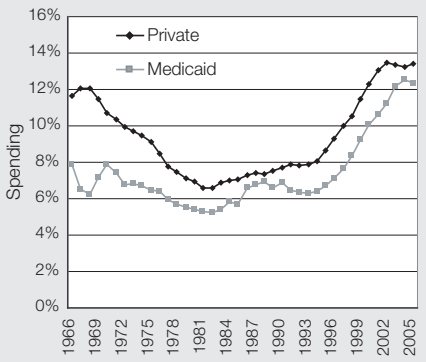
- Recent legislation gives states the opportunity to improve their Medicaid pharmaceutical policies. Specifically, the Medicare Modernization Act (2003) transfers about half of Medicaid

prescription spending to Medicare Part D, and the Deficit Reduction Act (2005) authorizes Health Opportunity Accounts for Medicaid beneficiaries and allows states more freedom to levy co-payments on Medicaid beneficiaries.

Meaningless Measurements

There is no end to hand-wringing about prescription drug prices and costs, and no end to calls for the state to minimize both. Unfortunately, many of these appeals are driven by misleading statistics.

Figure 1. Prescription Share of Total Private and Medicaid Health Spending, 1967-2005



Source: CMS National Health Expenditure data.

Every year, we hear that costs for prescription drugs dominate health care costs. CMS accounts for health spending by the type of service used: physicians' consultations, hospital procedures, nursing home care, prescription drug use, etc. These services added up to about $2 trillion for 2004. Figure 1 shows prescription spending as a share of total health spending for both Medicaid and the private market

We immediately see what is upsetting everyone. For both Medicaid and the U.S. private market, pharmaceutical spending seems to have grown disproportionately for about a decade. Having hovered between five and eight percent of health spending for about 20 years, pharmaceutical spending for both markets has sharply risen above 10 percent since the mid-1990s. Although it has plateaued in the last two or three years, the increase still makes a visual impact. In reality, this measurement is quite meaningless for two reasons. First, the figure is simply an arithmetical ratio, which we should not expect to stay constant. All components of health spending must add up to 100 percent – not a penny more or less. We expect none of the components to change their shares across time; and, if some decrease, other components must increase. It would be impossible for every component of national health spending to shrink as a share of total spending. Looking back to the 1960s and

early 1970s, we can see that prescription drugs accounted for more than 10 percent of private-sector health spending, but lost share to one or more other components of health spending until the mid-1980s.

This is not at all remarkable. If we looked at a chart showing the history of spending on artificial light, we would see that wood, oil, and candles accounted for much of it until the last quarter of the 19th century, when electricity quickly rose from zero to virtually 100 percent. Likewise, many households spend a significant fraction of dollars on diapers, baby formula, and toys at a certain point, but one could not expect that share to remain the same over decades.

Pursuing the household theme shows how meaningless this measurement is, especially as a tool for national health policy. Those who buy shoes have little regard for how much the nation spends on shoes, how such spending ranks as a share of national household spending, or how much that share has changed in the last decade. Only in health care are we mesmerized by such figures.

Second, the measurement identifies prescription drugs as a component of health spending, but neglects to specify what they are for, so we cannot judge whether the money is well spent. Dividing health spending according to its components tells us nothing about how that spending contributes to our health. Different components contribute to treating the same ailments.

For example, a patient suffering from high cholesterol may be admitted to the hospital for acute treatment of coronary heart disease, but may also take a cholesterol-lowering drug regularly as an outpatient and have a stent installed to open up his arteries. When assessing health care, it is more valuable to know how much is spent on treating coronary heart disease, diabetes, car accidents, and gunshot wounds, etc., as shares of our $2 trillion national health bill, than to know what the components are.

In fact, there is little doubt that the majority of dollars spent on prescription drugs make a valuable contribution to patients' health. Certainly there is waste in pharmaceutical spending, as there is in all areas of health care, but a misdirected focus on reducing prescription drug costs is likely to increase *total* health costs, especially for patients of lower income. This is especially the case when cost-containment efforts focus on newer medicines.

Higher Prices Have Led to Lower Costs

Columbia University Professor Frank Lichtenberg has analyzed this effect. Looking at the Medicare Expenditure Panel Surveys (MEPS) of 1996 through 1998, Professor Lichtenberg determined that people who use newer prescription drugs have better health status than those using older drugs for the same conditions. This remains true when controlling for previous health status, age, marital status, race, education, income, and even insurance coverage. Patients using newer medicines lived longer, perceived themselves as healthier than those using older medications, and experienced fewer limitations on their activities or social interactions. Lichtenberg also concluded that people without a high-school education benefited more from new medicines than patients with more education.[i]

Further, prescription medicines, especially newer ones, can substitute for more expensive interventions. For the general population, using a newer medicine reduced non-pharmaceutical spending 7.2 times more than the increased drug costs.[ii] For example, using a 5.5-year old medicine instead of a 15-year-old one was associated with an annual increase in prescription costs of $18, but a reduction in other health costs of $129, of which $80 were due to reduced hospital costs and $24 to fewer physician consultations (presumably because people did not have to return to their physicians to receive a prescription for a medicine with fewer side effects).

The real driver of Medicaid spending is high-cost enrollees, especially institutionalized beneficiaries. A full 54 percent of the people in Medicaid cost less than $1,000 per year. Indeed, 96 percent of Medicaid enrollees cost less than $25,000 per person, accounting for slightly more than half of Medicaid's costs. However, at the other end of the scale, the most expensive one percent of the Medicaid population accounts for 26 percent of total costs, while the most expensive four percent account for just under half.[iii]

This high-cost population suffers from manageable chronic illnesses such as high blood pressure, heart disease, and diabetes. Importantly, institutionalization, *not* prescription drugs, drives costs for this expensive group. For beneficiaries costing more than $25,000, prescriptions accounted for eight percent of total Medicaid costs, hospitals 15 percent, other acute care services 14 percent, and long-term institutions 64 percent. For beneficiaries costing less than $5,000, prescriptions accounted for 16 percent, hospitals seven percent, other long-term care 75 percent, and institutions only two percent.

Politicians Focus on the Wrong Things

Given Professor Lichtenberg's conclusions about the relationship between spending on prescriptions versus other health services, we must reassess our concern over out-of-control Medicaid spending. In reality, the program is probably spending too little on prescription medicines, not too much.[iv] Instead, political cadres rant about the unconscionable profits of the drug makers and how they "gouge" Medicaid. The extremity of this absurdity is demonstrated by the ever-expanding number of lawsuits against brand-name pharmaceutical manufacturers for setting "fraudulent prices" for Medicaid.

Last year, courts were expected to fine drug makers more than $1 billion for circumventing pricing rules. Ambitious state attorneys generally view this area of litigation as a growing "profit center" for their careers.[v] However, the government created this problem by mandating an unrealistic price for sales to Medicaid. The U.S. market for prescription drugs went awry as a result of the Omnibus Budget Reconciliation Act of 1990, which demanded that drug makers treat growing government programs as "most favored customers," giving them discounts from list prices that were at least as great as those granted to private buyers.

Legal force rather than negotiation created these discounts and resulted in *higher* pharmaceutical prices when it became illegal to give anyone else bigger discounts than the government enjoyed. Government programs in the United States comprised more than one-fifth of the prescription market, so drug makers had to consider the effect on prices to government agencies when they negotiated with private purchasers. Discounts to hospitals and private insurers shrank in the 1990s because of the Medicaid reimbursement rules, and HMOs saw their discounts fall from 24 percent in the first quarter of 1991 to 14 percent two years later.[vi] Even worse, the list price defined by the government steadily increased.

This "list price" is called the Average Wholesale Price (or AWP, generally referred to in the industry as "Ain't What's Paid"), which drug makers must use, but the law does not define.[vii] No wonder drug makers increased the AWP out of all proportion to costs, in order to compensate for the steep, state-imposed discounts. So drug makers have been charged with manipulating prices that do not actually exist. There has been no "gouging," only administered prices distorted by the government's inability to define the

right price of a medicine.[viii] Governments do not know this value, despite significant investment in developing "evidence-based medicine."

The best-known effort in this direction is the Drug Effectiveness Review Project (DERP), established at the Oregon Health and Science University in 2001 under the leadership of former Oregon Governor John Kitzhaber, who took over as director when he left office. Despite five years of effort evaluating the effectiveness of drugs on behalf of more than a dozen states, "there is scant evidence of the DERP's actual impact," according to a recent article in a peer-reviewed journal.[ix] When different government agencies receive and examine DERP's reports, they come to different decisions as to whether to include a medicine in preferred drug lists. Executives of the Oregon project freely state that the potential of evidence-based medicine is "not yet successful."[x] Further, the DERP does not use cost-effectiveness as a criterion in making recommendations. This may well be appropriate, because studies of cost effectiveness are subject to methodological uncertainty.[xi]

Nevertheless, taxpayers should be concerned about this initiative because state Medicaid directors use these evaluations to determine which drugs will qualify for their preferred drug lists, which are becoming more restrictive every year. Some dismiss criticism of Medicaid's increasingly restrictive reimbursement policies by noting that private insurers do the same thing in negotiating with drug companies. But this is not the case.

For example, the Oregon program has always had the goal of attracting private interest in its evaluations. However, "commercial uptake of the DERP has been spotty at best."[xii] The Oregon program's executives themselves point out significant differences between public-sector and private-sector approaches to drug benefit design. In self-defense they also note that neither has succeeded in controlling costs.[xiii]

A Big Stick That Hits the One Who Swings It

Approaches such as the Oregon project at least have the virtue of attempting to value medicines. Cruder approaches consist of using raw state power to punish the drug companies. Politicians who seek to wield this power often appear proud of their antagonistic relationship with drug makers. Unfortunately for them and their constituents, these approaches are harmful to their interests, and more successful drug-discounting programs

rely on harnessing the self-interest of the research-based pharmaceutical industry, rather than prodding it to invest millions of dollars (which could be used more productively) in defending its legitimate business interests against political attack.

As noted above, government policy has made it very difficult for drug makers to offer discounted prices to uninsured patients who cannot otherwise afford medicines. Fortunately, there is a "loophole": State Pharmacy Assistance Programs (SPAPs). SPAPs are "blessed" by CMS and immunized from the effect of the payment regulations discussed above. Basically, a SPAP offers discounted (or even free) medicines to low-income people, in return for those people identifying themselves as such to the program manager. Many of these programs are run by the drug makers. One standing complaint about SPAPs is that a person has to apply to many different programs if he takes medicines made by many different drug makers. However, this is because drug makers are not allowed to combine their programs, which would (bizarrely) violate anti-trust laws.

Nevertheless, many drug makers, coordinated by their trade association, have at least succeeded in operating a joint marketing and public awareness effort, the Partnership for Prescription Assistance, which helps low-income patients identify and enroll in programs that legally sell discounted medicines. It is *crucial* that state policymakers understand that they do *not* have to rely on drug makers' altruism to allow these programs to work; rather they are a natural extension of their commercial interest.

Most people naturally resist the explanation offered above for the high prescription drug prices that uninsured, low-income Americans often face. We tend to scoff at the notion that it is in a drug maker's corporate interest to charge discounted prices to people with lower incomes, rather than denying them medicines. It defies our understanding of their "greed." Nevertheless, a very simple arithmetical exercise demonstrates that a research-based drug maker maximizes its profits by acting in this way. This argument has also been proven formally by a number of scholars.[xiv]

Investors are willing to risk their savings in research-based drug makers because the United States and (usually to a lesser degree) other developed countries grant them patents, which give them a limited time to enjoy exclusive rights over their newly-invented medicines. These patents

prevent competitors from making exact copies of the medicine. However, if the medicine is successful, competitors have an incentive to invent other medicines that address the same illness.

Because the innovating company does not face pure competition undercutting its price, it has some power to set prices. This means that the marginal costs of manufacturing and distributing a drug are a relatively small fraction of the listed, "headline" price of a patented drug. This is obvious, because when patents on a drug expire, competitors who make high-quality generic copies are usually able to sell them in the United States at a significantly lower price than the original patented drug. Nevertheless, the generic competitors make a profit. On average, about 30 percent of the average U.S. transaction price is a close estimate of these marginal manufacturing costs.[xv]

Assume that a drug maker sells 900 million pills of a certain medicine at $1 each to earn annual sales of $900 million. With marginal costs of 30 cents per pill, it earns $630 million of gross profit. However, if that the company is only selling to 90 percent of its potential customers, because 10 percent of potential patients are unable to pay $1 for the pill, a full 100 million more pills could be pushed out the door.

The firm's marketing department analyzes the characteristics of that remaining 10 percent, and figures that three-quarters of them would be ready, willing, and able to pay 60 cents per pill. If the company could sell to those patients, it would sell 75 million more pills for $45 million, at a marginal cost of $22.5 million. It would earn a gross profit of $22.5 million (for a total of $652.5 million). It would also reduce the burden on taxpayers of funding government benefits by reducing the number of patients without access to the medicine from 10 percent to 2.5 percent. Further, the investors are able to earn a return that motivates them to continue investing in pharmaceutical research and development, which will result in even better medicines in years to come.

This results in a true win for investors, current patients, taxpayers, and future patients. How would the drug maker achieve this extremely beneficial outcome? It would launch a discount card, requiring applicants to demonstrate a need by proving that they were below a certain income level, or that the cost of the medicine was too great a share of their household income. In short, the company would do exactly what the programs that stand behind Partnership for Prescription Assistance offer.

However, once the government shows up, demanding the same discounts for 30, 50, or 100 percent of the appropriate patients, the firm has a problem. Even if the government only demands a discount for 30 percent of patients (as determined by their incomes), the firm's gross profit would drop to $572.5 million. This would be $57.5 million (or 9 percent) less than if it eliminated its discount program and only served the patients who pay $1 per pill.[xvi]

Obviously, any firm would decline to offer a discount program for low-income patients if it feared the threat of such a government intervention. This insight is critical to understanding the success of *voluntary* versus *coerced* drug discount programs. Recently, programs in two states, Maine and Ohio, have demonstrated the difference.[xvii]

In 2000, Maine's governor and legislature agreed on an ambitious and aggressive program, Maine Rx. It basically mandated price controls for all, without requiring an income test. Drug makers refused to accept this government intrusion and responded with litigation. As a result, the state was unable to launch a program at all until January 2004, after the pharmaceutical industry's suit was dismissed. It remains unclear, however, whether Maine's government has prevailed.

Although the judge dismissed the claim that Maine needed a federal waiver to implement Maine Rx Plus's Medicaid provision, the grounds were simply that the program was not "ripe." That is, because it had not actually done anything, it was not possible to say whether it had broken the rules. Further, Maine has not used its assumed power to deny drug makers access to the state's Medicaid program, MaineCare.[xviii] Indeed, Maine only implemented its program after stating that it did not plan to execute this threat anyway.

A recent pro-Maine study reported a telephone conversation with the program's manager, who claimed that discounts "*will* be seven percent to 40 percent of the usual price" [emphasis added]. Although the governor's office claims to be in the process of wrangling discounts from drug makers, it not clear that any are actually participating in the program. Nor is the program a rousing success for its beneficiaries; only 18 percent of Maine Rx Plus members even used their card in 2005.

If not the drug companies, who is giving the current discounts? There are two possible answers: the taxpayers or the pharmacies. The failure of so

many pharmacies to participate in Maine Rx Plus indicates that the state is trying to wring impossibly large discounts from them. Indeed, large chains such as Rite Aid and CVS have chosen not to participate in Maine Rx Plus. Only about half of Maine's pharmacies have opted to join. However, more than 90 percent of Ohio's pharmacies participate in Ohio's Best Rx, as well as some pharmacies outside the state that serve Ohio residents.

As a program voluntarily negotiated with the state, Ohio's Best Rx provides a gateway to a number of Pharmacy Assistance Programs recognized by the federal government. The program launched on January 11, 2005, and was so successful that by August 30, the pharmaceutical industry and its negotiating partners in Ohio announced that they wanted to increase eligibility for the program by raising the income level to 300 percent of the federal poverty level (FPL), from 250 percent.

The Ohio program is much more transparent about its discounts, publishing a monthly report. The latest, for May 2006, shows that 59 percent of brand-name drugs are now discounted by the manufacturers and the average discount is 25 percent. Ohio's Best Rx does not "crowd out" any other programs that offer discounted drug prices. According to one community activist, Ohioans are "over-saturated" with discount cards.

These dramatically different outcomes demonstrate that the correct policy to ensure discounted drug prices for those who need them is one that protects, rather than attacks, private incentives to achieve them.

Private Drug Benefit Managers Make Better Decisions

Pharmacy benefit managers in the private sector are not as focused on controlling costs as those in government programs. The evidence strongly indicates that private pharmacy benefit managers are more willing to recognize the value of new medicines than Medicaid and other government programs. Surely these private health plans do not wish to overpay for medicines; they have to watch their bottom line. That they are more willing to pay up for new prescription drugs is a strong indication that Medicaid programs are overly restrictive.

Figure 1 on page 100 shows that the private sector has always spent more on prescription drugs, as a share of total health spending, than Medicaid has. Furthermore, examining six important therapeutic categories for the

years 2001 through 2003, Professor Frank R. Lichtenberg found that Medicaid patients used prescription medicines that were older than those used by non-Medicaid patients.[xxi] For five of the categories, the difference was less than a year, but for painkillers slightly more than a year. If all states had been as restrictive as the most restrictive states, the difference would have been a little more than a year for the first five classes and 2.26 years for painkillers. Evaluating the Veterans Administration's restrictive preferred drug list, Professor Lichtenberg estimates that the restrictions on the use of newer medicines reduce the lifespan of its beneficiaries by about two months.[xxii]

A comparison of Florida Medicaid's preferred drug list with Harvard Pilgrim's three-tiered formulary in 2004 indicated that Harvard Pilgrim made better decisions than Florida, based on cost-utility ratios, the most sophisticated measure of the value of new medicines.[xxiii] Although only six percent of the drugs on the Florida preferred drug list had cost-utility analyses available, the state decided poorly: only 64 percent of the drugs on the preferred list had valuable cost-utility ratios, whereas 72 percent of the non-preferred drugs did. The figures for Harvard Pilgrim were reversed: 71 percent and 58 percent. Among drug therapies that the Harvard Center for Risk Analysis Cost-Effectiveness Registry considered to be inferior to competing alternatives, only 56 percent were on Harvard Pilgrim's preferred drug list, but 95 percent were on Florida Medicaid's.

One of the goals of a preferred drug list is to limit physicians' ability to prescribe newer, more expensive drugs. In order to prescribe newer drugs, physicians must seek (via fax or telephone) prior authorization from head office. State Medicaid programs are increasing the number of drugs subject to prior authorization, but this is not the case in the private sector. In the 1990s, UnitedHealth, now the nation's largest insurer, abolished the practice. The company had spent millions of dollars each year adjudicating prior authorizations, yet denied only two percent of the requests.[xxiv]

The scholarly literature and Medicaid cost-containment policies are undergoing a head-on collision. Despite the likelihood that increasingly restrictive Medicaid pharmaceutical management is harmful, states are not measuring the impact of these policies, despite self-congratulatory press releases describing how much money they anticipate saving.[xxv] This ignorance of the consequences of these policies can only be overcome if

states prospectively give independent scholars access to Medicaid data so that they can continuously analyze it and publish their results in the peer-reviewed literature.

Fortunately, two laws have recently changed the frame within which Medicaid operates, and both create opportunities to improve pharmaceutical use.

Opportunities for Improvement

First, the Medicare Modernization Act (2003) caused about half of Medicaid's drug spending to migrate to the new Medicare Part D drug benefit plan.[xxvi] This change is estimated to immediately cause prescription drug spending as a share of total Medicaid spending to drop from 12 percent in 2005 to seven percent in 2006. As late as 2015, only eight percent of total Medicaid spending will be on prescription drugs.[xxvii] This decrease alone will have some effect on the irrational political pressure to contain pharmaceutical costs without regard to how such actions increase other health costs.

Second, the Deficit Reduction Act (2005) (DRA) changed previous federal law that generally capped Medicaid co-payments at $3 per prescription, a price that had not changed since the 1980s. One reason that private health plans are able to avoid strict regulation over prescription drug use is that they are able to use prices to encourage the selection of lower-priced drugs where appropriate, rather than "command and control." In 2005, three-quarters of privately insured Americans were in plans that had three or four tiers of co-payment for prescription drugs. On average, co-payments were $10 for a generic prescription; $22 for preferred branded drugs (usually those without generic competition); $35 for non-preferred branded drugs (usually those with generic competition); and $74 for drugs in the fourth tier (if present).[xxviii]

The DRA gives states more freedom to increase co-payments for some beneficiaries.[xxix] For families with incomes of more than 150 percent of the Federal Poverty Level (FPL), it allows co-payments to go up to 20 percent of the full price, for non-preferred prescription drugs. (For those with incomes less than 150 percent of the FPL, the limit remains $3, but this will now increase with inflation.) However, total cost-sharing and premiums (for all health services, not just prescriptions) cannot be greater than five percent of family income.

While it is always better to use prices rather than command and control to allocate resources, steps to increase co-payments must be taken cautiously. A host of evidence recognizes that people with lower incomes, when faced with even relatively small co-payments, cut back on the use of necessary medicines and end up visiting emergency rooms and doctors' offices more often.[xxx] Thus, simply prior authorizations with higher co-payments will surely not result in superior outcomes for Medicaid patients or taxpayers.

However, the risk of higher co-payments causing Medicaid patients to forgo necessary medication can be addressed through Health Opportunity Accounts (HOAs), also created by the DRA as pilot projects in 10 states. Similar to Health Savings Accounts, they allow state governments to credit Medicaid beneficiaries with money that they can use to spend on their own health care, thereby giving them the resources required to take control of their own health spending and assume responsibility for higher prescription co-payments.

State policymakers with a sense of responsibility to their constituents, both taxpayers and Medicaid beneficiaries, will be eager to take advantage of these new tools.

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[xv] John R. Graham, *Prescription Drug Prices in Canada and the United States – Part 4: Canadian Prescriptions for American Patients Are Not the Solution,* Public Policy Source No. 70 (Vancouver, BC: The Fraser Institute, September 2003), pp. 28-29, and references.

[xvi] Only 27.5 percent of patients will buy at 60 cents per pill, because 2.5 percent still cannot afford it. The "break-even" rate is 15.625 percent. That is, if the government demands the discounted price of 60 cents for 15.625 percent of the appropriate patients, the firm will be indifferent to continuing or canceling the discount program.

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Further Reading

The Pacific Research Institute offers a number of publications that address the issues discussed in this book, all available through www.pacificresearch.org. Sally C. Pipes, the institute's president and CEO, wrote *Miracle Cure: How to Solve America's Health Care Crisis and Why Canada is Not the Answer* (2004). *Miracle Cure* outlines the negative consequences of government-controlled, single-payer health care and offers options that increase individual choice.

As a think tank based in California, PRI has produced a number of briefing papers in the "Healthy California" series, which propose state-specific reforms. In June 2006, John R. Graham wrote *Deadly Solution: SB-840 and the Government Takeover of California Health Care. Deadly Solution* addresses a current proposal to introduce government monopoly health care in California. Earlier in the year, Graham authored *California's Uninsured: Crisis, Conundrum or Chronic Condition?,* which challenged the usually quoted estimates of the number of uninsured and the often unstated assumption that Californians should enjoy health "coverage" that pays for all or most of their health expenditures. *California's Uninsured* proposed increasing Californians' freedom to purchase health insurance designed for their needs, instead of the government's preferences.

In 2006, Professor Philip J. Romero, a PRI senior fellow, wrote *The High Cost of Low-Priced Drugs to California: Lost Investment, Lost Jobs, & Lost R&D,* which estimates the negative consequences to California's welfare of the illegal piracy of prescription drugs. PRI has also published the

U.S. Tort Liability Index: 2006 Report by Lawrence J. McQuillan and Hovannes Abramyan. The *Index* ranks every U.S. state according to how its tort system affects certain factors such as job creation. It includes various measures of medical malpractice.

PRI produces a monthly publication, *Health Policy Prescriptions,* which addresses how government intervention in American health care is increasing costs and reducing the quality of care. Readers can subscribe for electronic delivery of this monthly publication at http://www.pacificresearch.org/pub/signup/index.html.

Other research materials from our partners in producing this book include:

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Author Biographies

James R. Copland is director of the Center for Legal Policy at the Manhattan Institute for Policy Research. He is the managing editor of the *PointofLaw.com* web magazine and primary author of the Center for Legal Policy's *Trial Lawyers, Inc.: Health Care – The Lawsuit Industry's Effect on American Health, 2005.* Mr. Copland has earned JD and MBA degrees from Yale University and has served as an editor of the *Yale Journal of Regulation.*

Roy Cordato is vice president for research at the John Locke Foundation in Raleigh, N.C. From 1993-2000 he was the Lundy Professor of Business Philosophy at Campbell University and from 1987-1993 he served as senior economist at the Institute for Research on the Economics of Taxation in Washington, D.C. He holds a PhD in economics from George Mason University in Virginia.

John R. Graham is director of Health Care Studies at the Pacific Research Institute in San Francisco. He is the primary author of the monthly series *Health Policy Prescriptions,* which addresses national health issues, and *Healthy California,* which proposes reforms for PRI's home state. Mr. Graham writes frequently for periodicals such as the *Wall Street Journal.* He earned his MBA from the London Business School (England) and his BA (with honors) in economics from Canada's Royal Military College.

Nina Owcharenko is a senior policy analyst at the Heritage Foundation's Center for Health Policy Studies. Before coming to Heritage, she served as

the legislative director for Rep. Jim DeMint, R-S.C., and Rep. Sue Myrick, R-N.C. She started her career on Capitol Hill working for Sen. Jesse Helms, R-N.C. Ms. Owcharenko received her bachelor's degree in political science from the University of North Carolina-Chapel Hill in 1994.

Brett J. Skinner is director of health, pharmaceutical and insurance policy research for the Fraser Institute (Toronto). He is a PhD candidate and past lecturer at the University of Western Ontario. His research is cited internationally and has been recognized for excellence by the Atlas Economic Research Foundation, the Legislative Assembly of Nova Scotia, and the Canadian House of Commons.

Shirley V. Svorny is chair of the Department of Economics at California State University, Northridge. She holds a PhD in economics from UCLA. She has written extensively on medical licensing and related health-care topics. She has published numerous academic articles and authored opinion articles for the *Los Angeles Times* and the *Los Angeles Daily News.*

J.P. Wieske is the director of state affairs for the Council for Affordable Health Insurance (CAHI) and author of the *State Legislator's Guide to Health Insurance Solutions.* After graduating from Carroll College with a bachelor's degree in political science and economics, he joined a health insurer, eventually becoming the senior government affairs specialist in 2001. He joined CAHI in 2003.

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