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State Medicaid Formularies: Do they Increase Costs?

By Dr. Linda Gorman, Ph.D.

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Foreword

Everyone who deals with the Virginia state budget knows we must do something about the rising cost of Medicaid in our state.

But in our efforts to reduce drug costs now, it is important that state policymakers not create a system that increases costs in non-prescription drug expenditures down the road. This unintended consequence of a restrictive drug regulatory program could create even higher medical costs for the community served by Medicaid.

Virginia is now on the verge of creating a Preferred Drug List for fee-for-service Medicaid recipients. If the state is intent on doing so, it is vital – both in legislation and regulation – that any new system take into account the experiences of other states that have gone before us.

This paper, by Dr. Linda Gorman of Colorado's Independence Institute, reviews those experiences in states like Florida, Michigan, Colorado, Kentucky and Oregon. She notes that most of these formularies, or Preferred Drug Lists, have not had the promised effect on health care costs. To the contrary, oftentimes they have had a devastating impact on the health care of many Medicaid populations, thus raising the cost of non-pharmaceutical expenses like hospitalization, nursing homes and outpatient care.

And the author points out the inconsistency of rules that allow states to spend $50,000 a year for dialysis and $66,000 a year to hospitalize schizophrenics in state institutions, even as they try to put limits on spending just $9,000 a year for drug maintenance that could allow many schizophrenics to lead a more normal and productive life without the expense of hospitalization, etc.

The points contained in this paper and in the recent newspaper column that is included, are instructive and should be carefully considered. This study is provided to the leadership in Virginia – political, business, community and media leadership – in order to generate serious discussion. This study and newspaper column does not necessarily represent the views of the Thomas Jefferson Institute or its Board of Directors. Nothing in this report is meant to influence pending legislation.

Michael W. Thompson
Chairman and President
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February 2003

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Medicaid Reform Must Protect Patients

By: Michael W. Thompson

Governor Warner is right to try to reduce Medicaid expenses. His proposal to cut the rising cost of Medicaid would create a new "prior authorization" system. His proposed Preferred Drug List program is intended to reduce prescription drug costs by creating a new gatekeeper for those who need medication.

But evidence suggests it is a fallacy to treat prescription drugs as a stand-alone cost. A growing body of research suggests that newer (and generally more expensive) drugs offer a rapid "payback" by reducing costs elsewhere in the health care system.

A recent study for the National Bureau of Economic Research by Columbia University economist Frank Lichtenberg shows that $7.20 in medical expenses is saved for every dollar spent on newer drugs.

This savings is more dramatic for the Medicare/ Medicaid population where average medical expenditures are 57 percent higher than for the general population. Here there is a savings of $8.30 in medical expenses for every dollar spent on newer drugs.

And research by the Harvard Medical School found that restricting New Hampshire Medicaid recipients to three prescriptions a month cut drug use by 35 percent, but substantially increased the number of nursing home admissions.

The Governor's Medicaid proposals would restrict the use of newer drugs. Drugs not included on the proposed Preferred Drug List (which a drug gets on by being one of two selected by a committee or by offering a rebate to the state) will require prior authorization from a Richmond bureaucrat. All drugs on the list in any given therapeutic class would be treated as equal.

But not all such drugs are equal – notably those used in mental health treatment, asthma, heart disease and especially among the elderly. And it is these ailments that are over-represented in the growing Medicaid population.

Additionally, the rebate – or "kickback" in less polite terms – results in a hidden tax on private patients. Required to supply services to Medicaid populations at below cost, providers increase prices to private patients and insurers. This leads to higher insurance premiums, driving lower paid workers to drop coverage, and increasing demand for Medicaid services.

The prior authorization requirement can also result in added expense. In a report on Michigan's Medicaid prescription drug program, the Kaiser Family Foundation noted that some

beneficiaries were actually harmed, as bureaucratic approval snafus resulted in the need for expensive hospitalization to correct untreated or improperly treated conditions.

Rising Medicaid costs are real. The Governor and General Assembly need to take effective action. Here are some ideas that could protect patients and also help ensure that cheaper, less effective drugs don't lead to higher costs in other areas:

- Patients already taking drugs covered by Medicaid should be allowed to continue doing so, thus avoiding any complications or expensive adverse health effects from shifting therapies.
- Any Preferred Drug List or prior authorizations should not apply to serious life threatening conditions when increases in non-drug health care costs (i.e., hospitalization) might overwhelm any prescription drug "savings."
- New, more effective FDA-approved prescription drugs should be immediately allowed until a drug utilization review has been performed.
- The General Assembly must build in accountability to the new system, requiring an evaluation of any drug savings vs. increased non-drug expenses.

Governor Warner has already requested a federal waiver allowing Virginia to test market-based Medicaid reforms to improve quality while bringing down cost. Similar to the successful "Cash and Counseling" pilots in other states, it allows for "patient directed" Medicaid accounts for disabled patients, allowing them to purchase cost-effective services meeting their specific needs.

Virginia's previous pilot for disease management of chronic conditions targeted doctors and patients with education and case management of both medications and treatments. The result was dramatic cost savings through reduced Emergency Room and hospital visits. This successful pilot could be expanded for further savings.

Expanding this approach to include prescription drugs or health insurance in the form of a Medicaid Health Account or insurance voucher would allow Virginia to offer a "patients first" program to its non-permanent chronic care patients. Such a plan would put patients into a more normal insurance market, gives them the means to purchase basic coverage, and permits them to devote excess MHA balances to a personal health-related benefits not covered by traditional Medicaid programs.

The former businessman now serving as Governor understands that costs reduced in one area can show up as "budget busters" in other areas. Any Medicaid "reform" must avoid this very real possibility.

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State Medicaid Formularies: Do They Increase Costs?

by Linda Gorman

Introduction

Over the last four decades, state and federal officials have continuously expanded the scope of state Medicaid programs and consistently underestimated the associated costs. Medicaid began in 1966 with an expenditure of less than $1 billion. By 1971, annual spending was $6.5 billion, more than twice the projected figure. In 2001, total expenditures were $228 billion, not including spending on children's health insurance. Long-term care, primarily for the elderly, consumes almost half of current Medicaid budgets. With the baby boomers beginning to retire in 2009, some experts predict that without fundamental changes in the program's structure, a quadrupling of long-term care costs will bankrupt state governments by 2020.[1] At present, Medicaid is second only to education in most state budgets. In FY 2001, Virginia reported spending slightly more than $1.4 billion on its Medicaid program. After federal matching funds total expenditures were slightly more than $3 billion.

Though they may be promoted as formularies, preferred drug lists, brand name drug restrictions, and "therapeutic consultation services," prescription drug price and quantity controls are the latest fad in the continuing struggle to control Medicaid expenditures. Like the construction moratoriums and certificates of need that were the fashion in the 1970s, and the mandatory managed care, block grants, and capitated care that were the rage of the 1990s, centralized control of prescription drug purchases replaces the decisions made by people intimately familiar with the problem at hand with the ill informed dictates of bureaucrats. Though such controls are sold as a way to reduce health care costs, experiences suggests that they are likely to raise them instead.

To understand why a state policy of centralized control of prescription drugs poses a danger both to taxpayer wallets and to patients, one must understand that treatment decisions for those who are seriously ill can be an excruciatingly complex balancing act and that it is theoretically and practically impossible for government to gather and analyze the information required to do an even adequate job of making those decisions. Like every other human institution, government has limits. Bureaucracies run government, and as saints are in short supply those who staff these bureaucracies are neither omniscient nor necessarily disinterested. The harm done by business bureaucracies is limited by the fact that consumers generally have the ability to find other suppliers or to appeal to the government if they feel they are being treated unfairly. Businesses that refuse to consider their customers' wants and their suppliers' needs soon go out of business. Government faces no such limits. It can require people to buy from it

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[1] Richard Teske. April 2002. *Abolishing the Medicaid Ghetto: Putting 'Patients First.'* American Legislative Exchange Council, Washington, DC, p. 3.

regardless of cost, and force suppliers to sell to it regardless of payment. It can require people to accept their choices.

The fact that these differences translate into enormous disparities in the way private and public health systems operate has been extensively documented. Private systems deliver higher quality, less waste, and less fraud. While government systems focus on managing budget categories frozen in amber by the cumbersome controls necessary to protect citizens by limiting government power, private providers are free to examine total costs, try new methods of cost control, and speedily abandon those that fail. While government systems are managed to keep politically powerful "stakeholders" happy, private systems are managed to suit their customers. Shackled by legal requirements, health care systems controlled by government may remain the same for 40 years. With patients in control, private systems deliver a constant stream of small innovations in care, and concentrate on the small improvements that lead to faster cures, more humane modes of treatment, and more active, satisfying lives for those with chronic conditions.

State Prescription Drug Spending in Perspective

Over the last ten years, many states have presided over continuous expansions in their Medicaid programs despite falling quality and skyrocketing budgets. Medicaid provides medical care assistance to four distinct populations: The impoverished elderly, many of whom are in nursing homes; people who are eligible due to disability; children who meet eligibility requirements; and some adults, primarily pregnant women near or below the poverty level. When considering the growth of prescription drug spending, it is important to keep in mind that the rapid growth of prepaid medical plans for Medicaid clients in the early 1990s obscures the true amount of spending on prescription drugs. When states pay the managed care plans a flat annual fee for each Medicaid client enrolled, prescription drugs consumed by that person are paid for by the managed care plan and are not counted in Medicaid spending on prescription drugs.

Because managed care enrollment makes sense only for relatively healthy Medicaid beneficiaries, the population responsible for reported spending on Medicaid prescription drugs includes a disproportionate fraction of elderly, blind, and disabled people, a group likely to benefit disproportionately from the fewer side effects and greater efficacy of many of the newer, more expensive, prescription drugs. In 1990, prescription drug payments for the elderly, blind, and disabled accounted for 76 percent of the $4.4 billion spent on Medicaid prescription drugs. By 1997 those groups accounted for 82 percent of the roughly $12 billion spent.[2]

For the United States as a whole, payments for prescription drugs grew rapidly in the 1990s with an annual rate of increase of 11.1 percent from 1990 to 1997. Funding for prescription drug purchases shifted dramatically. In 1988, 60 percent of all drug expenditures were paid for out-of-pocket, private health insurance paid for 24 percent, and public program picked up the remaining 16 percent. By 2000, out-of-pocket

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[2] David K. Baugh, Penelope L. Pine, and Steven Blackwell. Spring 1999. "Trends in Medicaid Prescription Drug Utilization and Payments, 1990-97," *Health Care Financing Review,* p. 79-105.

expenditures were just 32 percent of total prescription drug expenditures. Private health insurance paid for 46 percent of the total and public expenditures had risen to 22 percent.[3]

Although pronouncements from public officials might lead one to think otherwise, spending on prescription drugs is neither the largest nor the fastest growing category of health spending. Using data from the 1996 Medical Expenditure Panel Survey, Columbia University professor Frank Lichtenberg calculated that for the United States as a whole, inpatient hospital stays accounted for 41.5 percent of expenditures, office-based visits were 20.2 percent of expenditures, and prescription medicines were 13.9 percent of expenditures. Outpatient visits, dental visits, emergency room visits and other medical expenditures made up 10.2, 7.8, 3.3, and 3.0 percent of expenditures.[4]

In Virginia, Medicaid spending on hospital stays, $899 million in 1998, was almost three times as large as the $289 million spent on prescription drugs and other nondurable medical supplies. Payments for hospital stays grew at an annual rate of 12.2 percent from 1980 to 1998. The annual rate of growth of prescription drug expenditures was 14.4 percent, about the same as the average for the United States. Payments for other professional services, health practitioners other than doctors and dentists, were limited. At $465 million, spending on nursing homes was second only to spending on hospitals, growing at an average annual rate of 5.5 percent between 1980 and 1998. Nationally, Medicaid pays for almost half of all nursing home care.

As one would expect, severely ill people in hospitals and nursing homes account for a large share of Medicaid spending on prescription drugs. In FY 1998, the Centers for Medicare and Medicaid reported that 40.6 million people used the Medicaid program. About 10.5 million of them, 26 percent, were elderly, blind, or disabled.[5] In 1997, about 21 million people received at least one prescription through Medicaid, 36 percent of whom were elderly, blind, or disabled. Between 1990 and 1997, Medicaid prescription drug payments for the blind and disabled grew 6.6 percent per year. Payments for the aged grew 1.4 percent, payments for children, 3.3 percent, and payments for adults declined by 0.6 percent.[6] In Virginia, about 397,000 people received Medicaid prescription drug benefits in 1997. Roughly 16 percent of them were elderly, 21 percent were blind or disabled, 47 percent were children, and 16 percent were adults.[7] 1997 Medicaid prescription drug payments for the blind and disabled in Virginia's Medicaid program were $1491 per patient. Average 1997 prescription drug payments for the elderly were $1329. Payments for children and adults were just $140 and $228.

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[3]Office of the Actuary, National Health Statistics Group, Centers for Medicare and Medicaid Services. June 2002.

[4] Frank R. Lichtenberg. September/October 2001. "Are the Benefits of Newer Drugs Worth Their Cost? Evidence From the 1996 MEPS," *Health Affairs,* p. 243.

[5]U.S. Department of Health and Human Services, Health Care Financing Administration. September 2000. *A Profile of Medicaid, Chartbook 2000.* p. 13.

[6] David K. Baugh, Penelope L. Pine, and Steven Blackwell. Spring 1999. "Trends in Medicaid Prescription Drug Utilization and Payments, 1990-97," *Health Care Financing Review,* p. 96.

[7] David K. Baugh, Penelope L. Pine, and Steven Blackwell. Spring 1999. "Trends in Medicaid Prescription Drug Utilization and Payments, 1990-97," *Health Care Financing Review,* p. 100.

These proportions matter because to the extent that the Medicaid population is older and sicker than the general population, political attempts to arbitrarily cap prescription drug spending run the risk of sending other health care costs out of control. The elderly and disabled frequently endure multiple health problems, have more fragile health, and do better on newer drugs with reduced side effects. Attempts to arbitrarily limit the use of newer drugs may result in poorer health and increased use of health care services.

Though new drugs are typically more expensive than older ones, they play a substantial role in keeping costs down. For instance, according to economist John Calfee, the H2 antagonists that were introduced in the late 1970s reduced the need for surgery for gastrointestinal ulcers, cutting costs by more than half. Using "clot-busters" in treating strokes saves about 4 times the drug price by reducing other health care costs, and atypical antipsychotics for treating schizophrenia that cost about $4,500 a year "avoided about $73,000 a year in institutional treatment costs" according to Calfee.[8]

Misleading Health Care Claims

From a political perspective, pharmaceutical manufacturers are large companies earning millions of dollars in revenue each year. Their rising product prices make them attractive political targets. The people most likely to be harmed by the arbitrary drug denials common to Medicaid prescription drug control lists are often too poor and debilitated to protest their poor treatment. In most states, physician reimbursements have already been reduced to low levels, and officials know that lopping pharmaceutical spending by denying drug access will produce far less political heat than trimming the Medicaid program. As Frank Litchenberg has pointed out, officials can take credit for saving money no matter what happens because cost increases are lost in other budgets. "Drug costs (and changes in drug costs) are visible to the naked eye," he writes, "identification of drug benefits requires careful analysis of good data." This means that "people making drug policy decisions need to consider the full range of effects, not just the costs, of newer drugs."[9]

Nationally, the annual growth rate of Medicaid spending on prescription drugs and nondurable medical equipment was 14.2 percent between 1980 and 1998. Annual percentage increases in the Bureau of Labor Statistics price indices for prescription drugs and medical supplies were 3.7 percent in 1998, 5.7 percent in 1999, 4.4 percent in 2000, and 6.0 percent in 2001. Using these figures, a base amount of $289 million at the beginning of 1998 would have grown to about $351 million by the end of 2001.

As Medicaid prescription drug spending has grown much faster than increases in drug prices, several states have implemented Medicaid prescription drug management programs. Florida uses the Therapeutic Consultation Service, a medication management system based in Atlanta, to monitor prescriptions written under the state's Medicaid drug

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[8] John E. Calfee. 2000. *Prices, Markets, and the Pharmaceutical Revolution*. The AEI Press, Washington, DC. p. 10.

[9] Frank R. Lichtenberg. September/October 2001. "Are the Benefits of Newer Drugs Worth Their Cost? Evidence From the 1996 MEPS," *Health Affairs*, p. 250.

benefit program. The program is biased against brand name drugs, typically newer, more expensive, and more effective compounds. It requires prior approval for medications not on its preferred drug list, places arbitrary limits on the number of brand name prescriptions an individual can fill each month, and operates under a "fail-first" philosophy that prevents patients from accessing more expensive therapies before the cheaper ones have failed them.

Although proponents claim that physicians retain ultimate control over prescribing decisions, this has not necessarily been the case in Florida. Pharmacists and pharmacy technicians in Atlanta must provide prior approval before a prescription that fails to meet program specifications is filled. Denial of physicians' requests for exemption is not uncommon. In 2002, promotional material from officials in Washington State, which has just implemented the Therapeutic Consultation Service, claims that "the implementation of a similar program by the Florida Medicaid system last year—where drug increases were held to zero growth—has shown that the review and intervention techniques involved in TCS can be remarkably successful in controlling the prescription drug expenses [*sic*]." However, in its January 2002 report on the program, Florida's Agency for Health Care Administration said that Florida's Medicaid prescribed drug funding experienced a 10.3 percent growth in FY 2000-2001 and was projecting an increase of 13.9 percent for FY 2001-2002.[10]

The problem is that when government controls health care, patients have little or no influence on the kind of care they receive. The small group of people who control policy can do as it wishes, claiming that its members' expertise in the subject means that they know what is best for the average citizen. This was vividly illustrated by the State of Oregon in its Health Services Commission Report: *Prioritized List of Benefits Packages for the OHP Standard*, October 2001. On page 15 the Committee notes that "In the community forums and stakeholder meetings, the public tended to rank dental services as high or higher than mental health and chemical dependency. The Commission, however, ranked it somewhat lower on the list, determining that lack of dental care was less life threatening."

The Evaluation Flim-Flam

One way to avoid acknowledging the ill effects of a favorite plan is simply not to look for them, and experience shows that governments at all levels are fundamentally ill equipped to evaluate the programs that they promote. In February 2001, the Oregon Association of Hospitals and Health Systems issued a report by Michael McCracken Consulting that examined the performance of mental health services under the Oregon Health Plan (OHP). McCracken found that costs increased far faster than the number of clients served though poor data precluded an accurate count.

The consultants found the state's data systems are in such disarray that "administrative costs cannot be determined," and noted that "the cost increases of OHP mental health

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[10]State of Florida, Agency for Health Care Administration. January 2002. *Annual Report: Medicaid Prescribed Drug Spending Control Program.* p. 2.

services cannot be explained by a concurrent increase in numbers of people receiving services." It concludes that "mental health cost increases are likely due to the creation of new entities, Mental Health Organizations (MHOs), and the complexities of multiple subcontracts, each with added administrative expenses," that "unexplained cost increases are growing rapidly as compared to costs that are adjusted for medical inflation," and "contrary to the goal of containing growth in costs, the new system appears to have resulted in substantial cost increases beyond what can be accounted for my medical inflation."[11]

Though the Florida Agency for Health Care Administration January 2002 annual report on the prescription drug control program explicitly states on page 2 that "Initial results as the Preferred Drug List was phased into the claims edit system show reductions in projected costs, achieved while maintaining quality of care and encouraging prescribers' control over their patients' therapies," the section on the clinical evaluation of the medical effects of bureaucratic second guessing on page 17 reveals that the agency has no way of knowing whether this is true because it has only begun to discuss the parameters of an independent evaluation with researchers at the University of Florida.[12]

According to the report by the Kaiser Commission on Medicaid and the Uninsured, evaluation is not a part of the Florida prescription drug control program. "Florida has not announced plans to evaluate the specific impact of the preferred drug list on the quality of care delivered to Medicaid beneficiaries," it noted in its report, and "input from beneficiaries was noticeably absent from the legislative process."[13]

It is clear that all knowledgeable people do not share the official enthusiasm for the Florida formulary. The Formulary Study Panel that Florida convened in 1999 recommended against adopting a preferred drug list. The most knowledgeable and politically powerful patient groups, notably those afflicted with HIV/AIDS and serious mental health problems, marshaled successful lobbying efforts to exclude "their" drugs from the control program.

The first independent evaluation of the Florida program was conducted by researchers at the University of Florida's Center for Medicaid Issues and suggests that opponents' doubts were well founded. A preliminary analysis of the program found that the drugs with the highest denial rates were agents that "are often appropriate for use by patients with multiple illnesses, and persons who are medically complex and at high risk from

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[11] Michael McCracken Consulting, LLC. February 7, 2001. *Performance of Mental Health Services Under the Oregon Health Plan, Final Report to the Oregon Association of Hospitals and Health Systems.* Salem, Oregon.

[12] State of Florida, Agency for Health Care Administration. January 2002. *Annual Report: Medicaid Prescribed Drug Spending Control Program.* p. 17.

[13] Cathy Bernasek, Catherine Harrington, Rejeev Ramchild, and Dan Mendelson. February 2002. *Florida's Medicaid Prescription Drug Benefit: A Case Study.* Kaiser Commission on Medicaid and the Uninsured report 4031, Kaiser Family Foundation, Washington, DC. p. 23

adverse effects of drug therapy or inadequate treatment of their disease."[14] Substantial numbers of physicians reported that their Medicaid patients were not getting the brand name medication that they needed, and that denials had resulted in negative clinical outcomes. Physicians reported that patients denied their drugs went without medicine until the situation was resolved, and that multiple trips to the pharmacy posed a particular burden for recently discharged hospital patients and elderly patients with chronic conditions.

Florida's handling of early prescription refills provides a small example of how rigid bureaucratic orders can make life more difficult for people locked into government monopolies. Insensitive to the complexities of daily life, the state considers early refills of maintenance prescriptions "a privilege." When it found that as some pharmacy providers had automated 25-day refill policies for maintenance drugs, it stopped the practice because it considered getting 7 months of supply in a six-month period was considered waste and abuse. Apparently patients must make arrangements to avoid the "hurricane disasters and recipient travel plans" that were "the most common reasons for early refills."[15]

In a small number of cases patients sought emergency care when they could not get their prescription filled. In July 2001, the *Orlando Sentinel* reported that there had been a death associated with the program. Close associates of the dead Medicaid patient said that he took seven brand-name medications per month, and often skipped doses while waiting for approval of his physicians' prior authorization request.[16]

Also of concern, particularly at a time when low physician reimbursements are making many doctors and health plans unwilling to treat Medicaid patients at all, is the fact that physicians felt that the program was time consuming, made coordinating care more difficult, and created "just one more set of hurdles and hassles associated with Medicaid."[17] This raises physician costs and makes them less likely to participate in Medicaid. And, as the Kaiser Commission's case study on Michigan's Medicaid Prescription Drug Benefit program makes clear, these problems are by no means unique to Florida.[18]

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[14] Mary Kay Owens, Earlene Lipowski, and Renee Dubault. June 2001. *Florida Medicaid Prescribed Drug Program: Four Brand Prescription Limit Policy—Final Report, Phase 1.* Florida Center for Medicaid Issues, College of Health Professions, University of Florida, p. 9.

[15] State of Florida, Agency for Health Care Administration. January 2002. *Annual Report: Medicaid Prescribed Drug Spending Control Program.* p. 33.

[16] Groller, G. "New Medicaid Drug Policy Stirs Up Fears," *Orlando Sentinel*, July 1, 2001. Cited in Cathy Bernasek, Catherine Harrington, Rejeev Ramchild, and Dan Mendelson. February 2002. *Florida's Medicaid Prescription Drug Benefit: A Case Study.* Kaiser Commission on Medicaid and the Uninsured report 4031, Kaiser Family Foundation, Washington, DC. p. 29.

[17] Mary Kay Owens, Earlene Lipowski, and Renee Dubault. June 2001. *Florida Medicaid Prescribed Drug Program: Four Brand Prescription Limit Policy—Final Report, Phase 1.* Florida Center for Medicaid Issues, College of Health Professions, University of Florida, p. 13.

[18] Cathy Bernasek, Jeff Farkas, Helene Felman, Catherine Harrington, Dan Mendelson and Rejeev Ramchild. January 2003. *Case Study: Michigan's Medicaid Prescription Drug Benefit.* Kaiser Commission on Medicaid and the Uninsured report no. 4083, Kaiser Family Foundation, Washington, DC.

Given the existing evidence, it is clear that officials from other states should not be in too much of a hurry to copy the Florida program. It is too soon to tell how it will affect patient health, and whether or not it saves money many never be known given that the state because the state has no plans to carry out a careful evaluation.[19]

Past Formulary Failures

Though officials often prefer to ignore them, the drawbacks of draconian solutions are widely known and have proven daunting whenever government officials try to improve time tested patterns of medical practice with the imposition of cumbersome sets of one size fits all rules and regulations. Though health officials commonly defend the Florida drug control program with the comment that "if it wasn't a good idea, the Blues wouldn't have been doing it for the past twenty years,"[20] the implicit assumption that Medicaid drug restrictions are the same as those in the private insurance market suggests a lack of understanding about conditions in the private sector.

In fact, private sector plans have been dismantling strict formularies in favor of co-pay arrangements that encourage patients to evaluate their need for a particular drug in terms of its additional costs. Unlike the state Medicaid prescription drug control programs, most commercial insurance plans do not deny their customers access to the drugs that they want. They may charge higher co-pays, but people who think that the drug warrants the extra expense are free to purchase them. Patients faced with a thoroughly recalcitrant health insurer can find another one or, in extreme cases, sue for redress.

Medicaid patients have no such recourse. Because officials frequently assume that they are too poor to pay even nominal amounts for copays, there is no tiered system of copays and patients have no way to register their preferences. Though nominal copays might be a possibility, many Medicaid patients do lack the financial resources to get around program restrictions by simply buying the drugs that they need on the open market.

Numerous attempts to use formularies to control private sector prescription drug spending have failed. In 1999, the National Pharmaceutical Council reviewed the research on restrictive formularies. In general, the results suggested formularies increase costs because overruling physician prescribing decisions increases the utilization of other forms of health care.[21]

In 1992, the Health Care Financing Administration awarded two cooperative agreements for demonstration of prospective drug utilization review programs for Medicaid patients

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[19] In fact, no comprehensive set of performance measures for drug management programs have yet been developed. See Anita J. Chawla, Marjorie R. Hatzmann, and Stacey R. Long. Spring 2001. "Developing Performance Measures for Prescription Drug Management," *Health Care Financing Review,* **22**, 3, pp. 71-84.

[20] Cathy Bernasek, Catherine Harrington, Rejeev Ramchild, and Dan Mendelson. February 2002. *Florida's Medicaid Prescription Drug Benefit: A Case Study.* Kaiser Commission on Medicaid and the Uninsured report 4031, Kaiser Family Foundation, Washington, DC. p. 19.

[21] Richard A. Levy and Douglas Cocks. 1999. *Component Management Fails to Save Health Care System Costs.* National Pharmaceutical Council, Washington, D.C.

in Washington State and Iowa. The assumption was that utilization review could lower errors in prescribing, spot harmful drug interactions, and reduce costs by substituting less expensive drugs for more expensive ones, claims similar to those made for the Therapeutic Consultation Service. In general, the results provided no evidence of "any measurable effects in reducing the frequency of drug problems or on utilization of and expenditures for prescription drugs and other medical services."[22]

Colorado Medicaid Mental Health: How Government Monopolies Really Treat Vulnerable Populations

Although officials who run Medicaid programs are no doubt sincerely concerned for the welfare of the vulnerable populations they are supposed to represent, the historical record shows that government health care programs typically provide shoddy service at astronomical cost. When government controls health care, patients do not have a contractual right to receive care, practice guidelines and drug review rules may prevent physicians from using state-of-the-art techniques and there is no guarantee that government controlled working conditions and wage rates will entice providers to care for people in government programs. "Coverage" does people no good if they cannot find people willing to take care of them. Scandalously low reimbursements for physician services are driving doctors out of the Medicaid program.[23] [24] Results from other countries show that scandalously low reimbursements can produce the same response from research-intensive drug manufacturers.

Presaging the movement to save money by eliminating patient choice in prescription drugs, Colorado officials seduced by the managed care fad of the early 1990s tried to save money by eliminating patient choice in health care. Medicaid recipients were required to enroll in strict managed care. Under strict managed care, patients are at the mercy of their health care provider. Patients must see the doctors their provider tells

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[22] David Kidder and Jay Bae. Spring 1999. "Evaluation Results From Prospective Drug Utilization Review: Medicaid Demonstrations," *Health Care Financing Review,* p. 115.

[23] Note that the more recent health care "reforms," in Canada and in Medicare, have been laws making it illegal for people to buy health care with their own money. Although Britain allows private medical care to coexist with the National Health Service, Canadian reformers seeking to improve on the British system made it illegal to buy medical care outside the government system. Medicare has made it illegal for Medicare recipients to add their own money to Medicare reimbursements in hopes of obtaining a higher standard of care. Due to low pay for their work, doctors are migrating out of Canada, and U.S. physicians are refusing to accept both Medicaid and Medicare patients. The Oregon Comprehensive Health Care Finance Plan as embodied in Measure 23 on the November, 2002 ballot, continues this program by requiring that "a health service provider that accepts payment for health services from the Oregon Comprehensive HealthCare Finance Plan may not bill participants for those services. The provider must accept as payment in full amounts received from the Plan."

[24] A number of stories have appeared in local newspapers around the country. See for example, Carol M. Ostrom, March 12, 2002. "Doctors fleeing Medicare, Medicaid," *The Seattle Times.* Online corrected version as of October 12, 2002 http://seattletimes.nwsource.com/html/localnews/134418965_medicare12m.html. *The Olympian's* series on the Doctor Shortage available on line at http://news.theolympian.com/health/doctorshortage/doctor_drain/index.shtml, and Sharon Salyer, June 16, 2002. "Health care's 'big lie,'" *The Daily Herald,* Everett, Washington, Online edition as of October 6, 2002, http://www.heraldnet.com/Stories/02/6/16/15559962.cfm.

them to, follow the diagnostic procedures their provider lays out, and submit to the treatments their provider specifies. Their only alternative is to pay the entire cost out of their own pocket. With its waivers in hand, the state set up small pilot programs requiring that Medicaid recipients rely on pre-paid capitated managed care programs, promoted legislation mandating expensive private insurance policies that likely increased the number of uninsured, radically restructured the state agencies responsible for administering health care programs, and reshaped the market for "private" insurance.[25]

Under the assumption that strict managed care would produce great savings, the state also expanded both the populations eligible for medical assistance and the services offered under it. In 1997, Colorado authorized a buy-in program to extend Medicaid coverage indefinitely for former welfare recipients who return to work. It created the Children's Basic Health Plan, extending state financed health care to all children from families with incomes less than 185 percent of the Federal Poverty Level, roughly $31,000 for a family of 4 in 2000,[26] and to anyone else who would like to buy in at cost. School districts were also made eligible for reimbursement provided to Medicaid enrollees, and were authorized to keep up to 30 percent of the federal matching funds they received for their services.[27]

Reforms instituted without proper trials, evaluation, or safeguards

The haste with which statewide Medicaid prescription drug formularies are being adopted parallels the haste with which the failed Medicaid managed care programs were instituted. Long before the experimental programs could be properly evaluated, reformers had urged Colorado legislators to apply them to everybody. In 1997, legislation was passed that required all managed care contracts and pilot projects be applied statewide despite evidence that similarly structured programs were failing both at home and abroad. With little comment, the ill, the poor, and the elderly were herded into experimental programs run by those who were supposed to evaluate them.

Although there is still no evidence that managed care provides either superior long-term cost control or better care than other medical delivery models, Colorado's commitment to managed care was such that the 1997 legislation required that 75 percent of those on

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[25] For a recent history of health care reform in Colorado see Susan Wallin, *et al.*, November 1998, *Health Policy for Low-Income People in* Colorado, Highlights from State Reports, Assessing the New Federalism, Washington, DC: The Urban Institute. http://newfederalism.urban.org/html/Highlights/Cohealth.pdf as of February 5, 2000 and Linda Gorman, "Robert Wood Johnson Foundation—How its Grants Influence Colorado's State Health Policy." *Foundation Watch,* November 2000. Washington, DC: Capital Research Center, pp. 1-5. http://www.capitalresearch.org/fw/fw-1100.htm as of December 5, 2000.

[26] *Federal Register,* vol. 65, No. 31, February 15, 2000. pp. 7555-7557.

[27] Colorado Revised Statutes 26-4-531. School districts may spend up to thirty percent of the federal moneys received on "low-income" students, those whose families have an annual income less than 185 percent of the federal poverty level. There is no stipulation of how family income is to be determined. Schools may not bill for "direct" services provided to students enrolled in HMOs. Most Colorado Medicaid recipients are enrolled in HMOs. The legislation also authorizes the state to "accept and expend donations, contributions, grants, including federal matching funds, and other moneys that it may receive to finance the costs associated with this section."

medical assistance be enrolled in managed care programs by July 1, 2000.[28] On June 30, 1999, the Health Care Financing Administration reported that 92 percent of Colorado's Medicaid enrollees received medical assistance via managed care.[29]

Mentally ill denied Medicaid freedom-of-choice provision

Though some Colorado Medicaid recipients technically had a choice between a primary care case management program, HMO, or a prepaid health plan, some of the most desperately ill have no choice at all. In July 1995, the state implemented the Medicaid Mental Health Capitation and Managed Care Program. A mental health "carve-out," meaning that mental health services are provided separately from other health services, it operates under a Section 1915(b) waiver that exempts the state from the Medicaid freedom-of-choice provision. This allows the state to require that people receiving Medicaid mental health benefits receive their care from state providers. With some exceptions, this means that Medicaid mental health recipients must receive care from the Mental Health Assessment and Service Agency (MHASA) that covers their geographic district.[30]

By 1997, 71,142 of the 130,589 people who were enrolled in Medicaid managed care were enrolled in Medicaid HMOs.[31] The speed with which enrollment policies changed was outlined in a 1996 draft report from the state to the Robert Wood Johnson Foundation. By 1996, it said, "Seventy-three thousand people, or thirty percent (30 percent) of all Medicaid clients in Colorado, are enrolled in HMOs. These numbers reflect a dramatic increase over 1994, when only 11,000 Medicaid clients were served by HMOs."[32]

Reformers planned destruction of traditional benchmarks

When the state requires people to obtain services from a single provider or a single drug list, it throws away the important policing power that consumers exercise when they are free to leave a provider who delivers substandard care. It also makes it difficult or impossible to evaluate the quality and costs of existing programs. As the post office did before UPS and FedEx were allowed to compete with it, those in a protected business

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[28] See Colorado Revised Statutes, 26-4-113, as posted on the Colorado Legislature's web site on 7 February 2001. http://www.leg.state.co.us/inetcrs.nsf/caff08b8a0e34035872565e8006d65f8/2b169c388ed792ea87256930006be4c4?OpenDocument.

[29] Health Care Financing Administration, June 30, 1999. *Medicaid Managed Care State Enrollment,* http://www.hcfa.gov.medicaid/mcsten99.htm as of February 7, 2001.

[30] Agency letter, Colorado Department of Human Services, Office of Health and Rehabilitation, Mental Health Services. March 13, 1998. MA-98-3-I, cross-reference AAS-98-2-1/CW-98-6-I. As posted on the web at http://www.cdhs.state.co.us/agency/MA983I.html on February 8, 2001.

[31] State of Colorado, Department of Health Care Policy and Financing, 1998-1999 Reference Manual, part E. Division of Managed Care Contracting, p. 12. As posted on the web at http://www.chcpf.state.co.us/refmat/ref98/ref98mcc.html on 7 February 2001.

[32] Mimeo, Robert Wood Johnson Foundation Strengthening the Safety New: Medicaid Managed Care Project Summary, Application narrative, p. 1.

will always successfully argue that their costs are fair and their services excellent. Without competition, no one can prove them wrong.

Reformers in favor of universal health care run by the state often favor stringent central control precisely because they know that this will be the case. A 1998 report from Colorado to the Robert Wood Johnson Foundation explicitly states that new benchmarks would have to be created because "Medicaid HMO capitation rates are based on historical fee-for-service expenditures. As the fee-for-service base shrinks, it becomes less reliable as a basis for HMO rate setting. Therefore, the Department is moving toward competitive bidding of HMO contracts by January 1, 2000. Once the bidding system is implemented, managed care organizations will compete with one another to provide the best quality product at the lowest price."[33]

No matter how much is spent on it, the fact remains that health care is a scarce good. Scarce goods must be rationed, and the question is how, not whether, to do it. Managed care and government monopoly reformers are generally opposed to market reforms because they reduce government power. Their preferred alternative is political rationing, which is itself no panacea.

The question is whether political or market rationing produces better outcomes for patients. Under political rationing, government officials must choose between spending large sums on the small number of people who are severely ill, or relatively small amounts to alleviate the relatively minor conditions affecting large numbers of "worried well" voters. In Colorado, the experiment with Medicaid managed care for the mentally ill puts people with schizophrenia and other disabling mental illnesses at the mercy of government bureaucrats. The choices that have been made provide an illuminating case study of the outcomes produced by political rationing and highlight the dangers inherent in any system, including centralized drug approval, that leaves patients, and their doctors, at the mercy of official budgets. For those in favor of government run health care systems, the treatment of schizophrenics provides a cautionary tale.

Clozapine—Government's Bitter Resistance to a Major Medical Breakthrough

Schizophrenia

Schizophrenia is a group of conditions exhibiting similar neuropsychiatric symptoms. The set of symptoms called schizophrenia are typically severe and disabling and often afflict physically healthy young adults. Although frequently described as a "brain disease," schizophrenia has no known biological markers. In general, too little is known about the variance of brain structures in the normal population to determine whether the brains of people diagnosed with schizophrenia differ significantly from those in the

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[33]State of Colorado Department of Health Care Policy and Financing. February 27, 1998. *The Health Care Reform Initiative: Increasing Efficiency and Equity in Colorado's Health Care Market, Nine Month Progress Report to the Robert Wood Johnson Foundation, May 1, 1997-February 27, 1998.* (For a grant awarded under the Foundation's State Initiatives in Health Care Reform program), p. 11.

normal population, and there are no known neurological abnormalities shared by all schizophrenics. Though researchers have examined a large number of causal candidates, including retroviruses, the Borna disease virus, and prenatal influenza infection, schizophrenia's cause remains unknown.

Ideally, a diagnosis of schizophrenia is arrived at only after a thorough physical workup to rule out diseases, like encephalitis, known to cause similar symptoms.[34] In the United States, schizophrenia is diagnosed when a patient meets the criteria outlined in the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* (DSM-IV), a classification manual for the symptoms that characterize psychological "disorders."

DSM-IV indicators for schizophrenia include lasting episodes of persistent delusions, hallucinations, or severely disorganized speech or behavior. Afflicted people may hear voices in their heads, believe against all evidence that they are being spied upon, have racing thoughts that make thinking disorganized and fragmented, or withdraw from social interaction. Other symptoms may include impaired motor coordination, an inability to feel or show emotions, and depressions so severe that they lead to suicide. At schizophrenia's onset, those affected typically experience declines in their ability to function in their work, in their interpersonal relationships, and in their personal care. Since schizophrenia typically manifests itself during early adulthood and often completely disrupts normal social functioning, people with the disease are often dependent on public assistance. According to the U.S. Department of Health and Human Services, approximately 90 percent of U.S. schizophrenia patients are Medicaid recipients.[35]

Days or years after the first symptoms appear, people afflicted with schizophrenia may endure one or more crises, psychotic episodes characterized by severe breaks with reality. When this happens, an individual may become so agitated that he poses a danger to himself or others and requires immediate hospitalization. Like its symptoms, schizophrenia's course and ultimate outcome varies greatly across individuals. Some people have very few psychotic breaks, others have unremitting psychosis. Some people lead relatively normal lives between episodes. Others remain chronically ill for decades. Some people recover completely—German researchers in the Schizophrenia Research Unit at the Central Institute of Mental Health in Mannheim quote a 25 percent recovery rate during the first five or six years[36]—while others remain chronically ill fifteen or more years after their first hospital admission. Though the literature contains reports of schizophrenics recovering completely without treatment, this may be an artifact of

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[34] L. G. Wilson. 1976. "Viral encephalopathy mimicking functional psychosis," *Am J. Psychiatry,* 133(2), 165-70.

[35] Office of the Assistant Secretary for Planning and Evaluation, United States Department of Health and Human Services, *Market Barriers to the Development of Pharmaceuticals: LAAM, Naltrexone, Clozapine, and Nicorett,* p. 27. http://aspe.hhs.gov/health/reports/cocaine/4cases.htm as published on the web on January 17, 2001.

[36] W. an der Heiden and H. Hafner. 2000. "The Epidemiology of Onset and Course of Schizophrenia," *Eur Arch Psychiatry Clin Neurosci*, 250(6), 292-303.

imprecise diagnoses. Recent evidence suggests that untreated psychotic episodes are associated with a slower or less complete recovery.[37]

At present, standard recommendations for treatment typically include a course of drugs to control psychotic outbreaks and some form of "psychosocial" support to provide friendship, encouragement, and practical advice on handling the challenges of living with schizophrenia's symptoms. Some reports suggest that people with schizophrenia are also helped by sheltered workshops. Before the development of the neuroleptic drugs in the 1950s, severely ill schizophrenic patients were often confined in mental hospitals. The neuroleptics, which include chlorpromazine (Thorazine) and haloperidol (Haldol), affect the operation of the brain's dopamine neurotransmitters. Their discovery gave hospital psychiatrists a new tool for calming agitated inmates. According to Heinz Lehmann, a pioneer in the use of chlorpromazine in treating psychiatric patients, "Our two major therapies [in the 1940s] were insulin-induced hypoglycemic coma and electroconvulsive shock therapies (EDT) for schizophrenia and affective disorders...Paraldehyde and the barbiturates were about our only means to quell agitation and violence in addition to physical seclusion and restraint..."[38]

The drawbacks of conventional treatments for schizophrenia

Early descriptions of the effects of chlorpromazine likened it to a "chemical lobotomy," highlighting its ability to make patients indifferent to their surroundings, induce lassitude, and give the appearance, at least, of passivity.[39] Although patients intensely disliked the side effects of the drugs, their use grew rapidly due to their unparalleled ability to reduce acute and chronic psychotic disorders and calm aggressive and impulsive outbursts. It was the ability to control psychotic symptoms, according to some observers, that made it possible to deinstitutionalize many mentally ill patients.

Neuroleptics are powerful drugs with nasty side effects. These include irreversible tremors, disfiguring muscle movements in the face, limbs or trunk, involuntary muscle spasms, and neuroleptic malignant syndrome, a rare reaction to therapeutic doses of the drugs that can be fatal.[40] The movement disorders, which often persist even when the neuroleptics are discontinued, are also associated with deteriorations in cognitive function. In addition, patients taking the drugs report agitation, restlessness, weight changes, sleepiness, depression or lethargy, dry mouth, vertigo, and general physical weakness. Callers to SANELINE, a telephone help service operated by the British

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[37] John McGrath and W. Brett Emmerson. October 16, 1999. "Treatment of schizophrenia," Fortnightly review, *British Medical Journal*, 319, 1045-1048. Published on the web at http://www.bmj.com/cgi/content/full/319/7216/1045#B1 as of January 15, 2001.

[38] Quoted in David Cohen. 1997. "A Critique of the Use of Neuroleptic Drugs," *From Placebo to Panacea: Putting Psychiatric Drugs to the Test,* Seymour Fisher and Roger P. Greenberg, eds. John Wiley & Sons, New York. p. 179.

[39] David Cohen. 1997. "A Critique of the Use of Neuroleptic Drugs," *From Placebo to Panacea: Putting Psychiatric Drugs to the Test,* Seymour Fisher and Roger P. Greenberg, eds. John Wiley & Sons, New York. p. 180.

[40] See R.A. Smego and D.T. Durack. June 1982. The Neuroleptic Malignant Syndrome," *Arch Intern Med,* 142(6), 1183-5 for a brief description.

mental health charity SANE, also reported significant changes in mental outlook, saying the drugs made them feel as if their senses were numbed and their willpower was lost.

The side effects are so severe and so common—according to one estimate up to 75 percent of patients using the drugs on a long-term basis will experience motor problems[41]— that the term neuroleptic-induced deficit syndrome was coined to describe the drugs' adverse effects.[42] A small group of researchers believes that they do more harm than good and is skeptical of the benefits of any neuroleptic drug treatment.[43] Unsurprisingly, one of the biggest problems in treating schizophrenia on an outpatient basis is the fact that large numbers of patients simply stop taking their prescribed medications.

A medical breakthrough

In the face of such debilitating side effects, clozapine, the first entry in a new class of drugs called atypical antipsychotics, was considered a huge advance. First discovered and synthesized by Sandoz Pharmaceuticals in 1952, it was patented in Europe in the late 1950s. European clinical trials were begun in 1962. A United States patent was received in 1970, and U.S. clinical trials were begun in 1972. From 1973 to 1975 the drug was marketed as Leponex and was used to treat schizophrenia in Europe, Asia, and Africa. In 1975, 16 cases of clozapine-associated agranulocytosis, a condition that impairs the ability of white blood cells to fight infection, caused 8 deaths in Finland. The drug was taken off the market.[44]

From the beginning, clozapine demonstrated remarkable effectiveness in controlling psychotic symptoms. It was far better tolerated by patients, did not cause the irreversible movement disorders so commonly seen in users of conventional neuroleptics, and produced almost miraculous results in patients who had responded to nothing else. Researchers in schizophrenia treatment thought so much of clozapine's therapeutic value that they continued using it under compassionate use exemptions between 1976 and 1982.

Regulatory tradeoffs stall new treatment

Clozapine's excruciatingly slow progress in the United States market is an object lesson in how a regulatory burden intended to protect people can also harm them. In 1984, an FDA advisory committee approved further testing of clozapine in the United States. In

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[41] Collaborative Working Group on Clinical Trial Evaluations. 1998. "Assessment of EPS and Tardive Dyskinesia in Clinical Trials," *J. Clin Psychiatry,* Suppl 12:23-7.

[42] T. Lewander. 1994. Neuroleptics and the neuroleptic-induced deficit syndrome," *Acta Psychiatr Scand Suppl*, 380, 8-13.

[43] Seymour Fisher and Roger P. Greenberg, eds. 1997. *From Placebo to Panacea: Putting Psychiatric Drugs to the Test.* New York. John Wiley & Sons, Inc.

[44] Office of the Assistant Secretary for Planning and Evaluation, United States Department of Health and Human Services, *Market Barriers to the Development of Pharmaceuticals: LAAM, Naltrexone, Clozapine, and Nicorett,* p. 27. http://aspe.hhs.gov/health/reports/cocaine/4cases.htm as published on the web on January 17, 2001.

1988, a multi-center study designed to compare treatments in schizophrenic patients who failed to respond to treatment with conventional neuroleptics found that clozapine produced remarkable results. Researchers who saw patients regain control of their lives called the drug "a medical breakthrough." One patient helped by the drug compared herself to Rip van Winkle.[45]

Still, federal regulators worried about the drug's side effects. Agranulocytosis caught early enough could be reversed, but carrying out meticulous testing requires institutional arrangements focused exclusively on that. According to Sandoz, even in carefully designed clinical trials some patients inadvertently went several weeks between blood checks. FDA officials understood that approving the drug would probably result in some deaths, but were convinced that they could be minimized with careful monitoring. Concerned that physicians and health officials might ignore label directions for burdensome testing and monitoring, and that schizophrenics could not be relied upon to ensure that they got the tests, the drug was approved for sale in 1989 with the stipulation that Sandoz develop a patient monitoring system to go with it.

In February 1990, with four years left to recoup U.S. research and development costs before the drug's patent expired, Sandoz began to sell clozapine in the U.S. under the trade name Clozaril. Worried that it might be held liable if patient monitoring was not properly done, Sandoz offered the drug only in conjunction with the Colzaril Patient Management System (CPMS) run by Caremark, a laboratory company. CPMS distributed the drug in conjunction with weekly white blood cell monitoring at a price of $172 per week or about $9,000 a year in 1990 dollars. According to a report from the Department of Health and Human Services, the blood monitoring made clozapine therapy 8 to 15 times more expensive than current therapy with the traditional neuroleptics.

State officials react hysterically to cost

The drug's cost provoked what can only be called a hysterical reaction from officials in charge of government mental health care programs. Apparently unwilling to consider the possibility that this "medical breakthrough" might save money by reducing acute care costs, unwilling to confront the problem of legal liability for the drug's manufacturer that was created by the FDA monitoring requirement, and unwilling to admit that some improvements are worth the added cost solely because they improve patient outcomes, officials focused primarily on the damage the drug's immediate cost would inflict on their budgets. Only money mattered. The result, according to *The Wall Street Journal*, was that "state mental-health leaders, Medicaid officials, pharmacists, members of

[45] J. Kane, G Honigfeld, J. Singer, and H. Meltzer. September 1988. "Clozapine for the treatment-resistant schizophrenic. A double-blind comparison with chlorpromazine," *Arch Gen Psychiatry,* 45(9), 789-96. For quotes on the effect of the drug see Ron Winslow. May 14, 1990. "Wonder Drug: Sandoz Corp.'s Clozaril Treats Schizophrenia But Can Kill Patients—And Blood Tests to Prevent The Lethal Side Effects are Costly, Controversial—Who is Going to Pay $8,944?" *Wall Street Journal,* eastern edition, p. A1.

Congress and the secretary of veterans affairs...mounted an intense...effort to force Sandoz to uncouple the drug from the blood-testing program...and cut the price."[46]

The Massachusetts deputy commissioner for mental health, Mona Bennett, said, "People are desperate to use this drug...We can't not use it," but treating the state's eligible patients would cost $5 million which "we simply do not have."[47] In Texas, with a population just 3 times larger than that in Massachusetts, officials claimed a potential treatment cost of $100 million, 20 times the Massachusetts cost estimate. California mental-health officials called Clorzaril "the most expensive treatment we've encountered." They estimated their treatment costs as $300 million, a treatment cost 60 times higher than Massachusetts' estimate for a population only six times larger. Oklahoma simply claimed that the cost of treating eligible patients would exceed the state's total mental health budget.

The bizarre nature of these comments was pointed out by an official for the National Association of the Mentally Ill who wondered, in *The Wall Street Journal*, why states that routinely spent $50,000 a year to keep a single Medicaid patient on dialysis and incurred costs of about $66,000 a year to hospitalize schizophrenics in state institutions were so bitterly opposed to spending just $9,000 a year for drug maintenance that could allow many schizophrenics to lead a more normal life.

William Reid, medical director for the Texas department of mental health and mental retardation took the hyperbole to new heights, saying that "I feel like I'm being blackmailed by the company," and that the price amounted to "a ransom for taxpayers" while holding chronic schizophrenic patients "hostage to their illness."[48] In a reverse on the usual pattern of typical efficiencies of public versus private institutions, some state mental institutions even claimed that they could do the blood monitoring for less in their own labs. The executive director of the National Association of the Mentally Ill was far more realistic. Although Laurie Flynn urged Sandoz to cut the medicine's price, according to *The Wall Street Journal* "she also said her group [had] no confidence in the ability of state mental hospitals to assure the safety of patients."[49]

In August 1990, the FDA calmed the storm by ruling that Sandoz could use any patient monitoring system as long as it met certain standards. Sandoz was still required to be responsible for registering the alternative monitoring systems and ensuring their quality, meaning that it could still be held liable for any deaths associated with the drug. In January 1991, Sandoz separated the sale of clozapine from the CPMS. Without patient monitoring, a year's worth of clozapine treatment now cost $4,160.

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[46] Ron Winslow. May 14, 1990. "Wonder Drug: Sandoz Corp.'s Clozaril Treats Schizophrenia But Can Kill Patients—And Blood Tests to Prevent The Lethal Side Effects are Costly, Controversial—Who is Going to Pay $8,944?" *Wall Street Journal,* eastern edition, p. A1.
[47] Ibid.
[48] Ron Winslow. May 15, 1990. "Sandoz Urged to Lower Price Of Clozaril—Costly Monitoring System For Schizophrenia Drug Is Criticized at Meeting," *The Wall Street Journal,* eastern edition, p. B4.
[49] Ibid.

In June 1991, the Federal Trade Commission proceeded to demonstrate the remarkable elasticity of U.S. anti-trust laws by finding that Sandoz had illegally required patients to enroll in an exclusive blood monitoring program. In 1992, Sandoz settled by paying $20 million to provider groups. By 1996, after Sandoz's patent had expired, only 11,000 patients were receiving the drug.

Years later, partially as a result of the meticulous patient monitoring generated by the reviled blood monitoring program, the FDA Psychopharmacologic Drugs Advisory Committee found that it had overestimated the dangers of agranulocytosis and concluded that the weekly blood test requirement could be relaxed. In July 1997, the committee recommended that blood tests be reduced to one every other week after six months of treatment, and that blood monitoring be made voluntary after one year.[50] The FDA approved these changes in March 1998.

States Scheme to Reduce Treatment Costs By Denying Access

Though Clozaril was the first of the atypical antipsychotics, others were introduced in rapid succession throughout the 1990s including risperidone (Risperdal) in 1994, olanzapine (Zyprexa) in 1996, quetiapine (Seroquel) in 1997, and ziprasidone in February 2001. While all of these drugs are classified as atypical antipsychotics, and all cause far fewer side effects than the older neuroleptics, each affects slightly different receptors in the body with the result that clinical outcomes vary from patient to patient.

Risperidone, for example, is less sedating than clozapine and does not cause agranulocytosis. In some patients, however, it seems to cause "intolerable exacerbation of parkinsonism."[51] Patients may find olanzapine easier to take in spite of its propensity to cause weight gains, possibly because olanzapine seems to cause fewer movement disorders than resperidone. Nor are the differences necessarily immediately obvious—one multi-center 28-week double-blind study found that patients on risperidone were more likely to attempt suicide than patients on olanzapine. Given that an estimated 30 percent of schizophrenics attempt suicide, such a difference is unquestionably a legitimate therapeutic consideration.[52]

Despite the fact that experts considered atypicals like clozapine and olanzapine major therapeutic advances, government health officials worried about line items in their budgets devised a number of ways to keep them from patients. Initial responses favored a direct approach used in which officials simply refused to buy particular drugs for anyone. Five months after Clozaril was approved for sale in the United States, the

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[50] Kenneth J. Bender. May 1998. "Fed Approves Reduced Clozapine Monitoring; Increased Patient Access Versus Increased Risk," *Psychiatric Times,* 25(5). As posted on the web at http://www.mhsource.com/pt/p980513.html as of 3 March 2001.

[51] S.S. Rich, J.H. Friedman, and B.R. Ott. December 1995. "Risperidone versus clozapine in the treatment of psychosis in 6 patients with Parkinson's disease and other akinetic-rigid syndromes," *J Clin Psychiatry,* (56(12), 556-9.

[52] E.D. Radomsky, G.L. Haas, and J.H. Mann. October 1999. "Suicidal Behavior in Patients with Schizophrenia and Other Psychotic Disorders," *Am J Psychiatry,* 156(10), 1590-5.

Veteran's Administration simply stopped providing the drug to its patients, saying that its cost was too high.[53] A number of states refused to add clozapine to their Medicaid formularies. In May 1991, the Health Care Financing Administration, responding to evidence that states were denying patients access to one of the largest therapeutic advances in 40 years, ordered state Medicaid programs to include clozapine in their Medicaid programs.

Closed formularies

This did not necessarily increase access to the drug. Long before the Florida and Michigan Medicaid prescription drug control programs were developed, state legislatures used a variety of strategies to control drug budgets including formularies, prescription limits, generic substitution requirements, prior approval systems, and refill limits. Before 1990, many state Medicaid programs maintained the closed formularies that are now being recycled in the guise of preferred drug lists. Then as now, formularies were lists of drugs that the state would pay for. When it became clear that states were perfectly willing to put budgetary concerns above the improvement in patient welfare delivered by the atypical antipsychotics, Congress outlawed restrictive formularies for Medicaid in the Omnibus Budget Reconciliation Act of 1990.

Many of the 1990 limitations were repealed in the Omnibus Budget Reconciliation Act of 1993. Under the 1993 revision, one way to legally maintain a closed formulary was to include all FDA approved drugs in the formulary but require prior approval before they could be dispensed. In general, there were no regulations governing prior approval criteria as long as states responded to requests for prior approval within 24 hours and would pay for a 72-hour emergency supply of the drug under review.

Prior approval

Prior approval requirements effectively restrict patient access to expensive medicines, and they also increase health care costs. By delaying access to therapies known to improve health, such requirements ensure that sicker patients will visit doctors and hospitals more frequently. Prior approval systems are also expensive. Someone must pay for the additional staffing to ask for prior approvals, make, and track them.

In New York in 1991, patients approved for clozapine had to be at least 16 years old, had to have been diagnosed with schizophrenia, and to have failed treatment with other anti-psychotics. Recent research suggests that requiring treatment failure may reduce chances for recovery. The dispensing pharmacy had to have an 8-digit dispensing number in order to obtain reimbursement. Continuing clozapine required considerable additional data. These requirements were so burdensome, and made it so expensive to prescribe clozapine, that they have since been repealed. In the meantime, seriously ill patients

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[53] Office of the Assistant Secretary for Planning and Evaluation, United States Department of Health and Human Services, *Market Barriers to the Development of Pharmaceuticals: LAAM, Naltrexone, Clozapine, and Nicorett,* p. 30. http://aspe.hhs.gov/health/reports/cocaine/4cases.htm as published on the web on January 17, 2001.

dependent on the government were at the mercy of the whims of bureaucrats obsessed with their cost control mission.[54]

As late as 1999, Kentucky was still automatically entering every drug approved by the FDA on its prior approval list. In the case of olanzapine (Zyprexa), use was restricted by a "fail first" requirement for almost two years after the drug was made available. Therapeutic failure was defined as a "break," a bout with uncontrolled psychosis. Current research suggests that uncontrolled psychotic breaks are associated with a lesser chance of long term recovery. Any health care system requiring a therapeutic break before prescribing a drug that is known to be more effective and producing fewer irreversible side effects, is cutting costs by requiring substandard medical care. According to a 1999 report for the Kentucky Legislative Research Commission, "In the case of schizophrenia, the side effects, and the personal, medical, and social costs [of therapeutic failure] can be very substantial. In such cases of therapeutic failure, medication delayed is tantamount to medication denied."[55]

Kentucky's lack of attention to proper patient care is typical of states in which government exercises control and consumers have little choice. In 1994, seduced by the false notion that a government controlled monopoly would reduce health care costs with no effect on the quality of care, Kentucky fully embraced comprehensive health care reform. It passed sweeping legislation that promised "access" to health care for all and gave the state effective control of both health insurance and medical practice.

As is the case with all government health monopolies what the reformers promised never materialized. In practice, access to the latest therapies for mental illness was degraded, and the reforms have bankrupted the state-sponsored health-insurance plan for government employees. The reforms also destroyed the market for private health insurance.[56] Those who assume that government will protect patients when patients have no choice should take a look at Kentucky's prior approval system. Though federal Medicaid rules require action on prior approvals within 24 hours of making a request, Kentucky's prior approval office was open only on weekdays between 8:00am and 6:00pm.

Michigan and Florida provide other examples of government fecklessness when it comes to protecting patients under its care. The original Michigan Pharmaceutical Product List (MPPL) promised to protect patients by forbidding prior authorization for branded products that had no generic competition. But there is no way to make a legislature

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[54]David Blumenthal and Roger Herdman, Editors. *Description and Analysis of the VA National Formulary*, Institute of Medicine, National Academy Press, Washington, D.C. p. 164. As published on the web at http://books.nap.edu/books/0309069866/html/index.html as of 15 February 2001.

[55] Joseph Fiala and Sheila Mason Burton. May 1999. *Kentucky Medicaid Drug File and Prior Authorization System,* Research Report No. 281, Program Review & Investigations Committee, Legislative Research Commission, State of Kentucky, Frankfort, Kentucky. As published on the web at http://www.lrc.state.ky.us/lrcpubs/rr281.pdf as of March 5, 2001.

[56] Michael Quinlan. September 23, 1998. "Kentucky Kare worse off than first thought," *Courier-Journal*, as published on the web at http://www.courier-journal.com/localnews/1998/9809/23/19980923kare.html as of April 14, 1999.

honor past promises. In 2001, the Michigan legislature scrapped that protection and recreated the MPPL as a program based on prior authorization and supplemental rebates. In Florida, advocates for the program eased its passage by initially exempting patients in nursing homes. That exemption was legislated out of existence shortly after the measure passed.

In spite of the evidence suggesting that state formularies increase costs and degrade quality, people who support them argue that if a state's formulary includes all FDA approved drugs it gives the state control over drug costs without denying access to new therapeutic advances. They prefer to ignore the fact that formulary laws may also say that the state will cover drugs only if they are used for FDA approved, "on-label," uses.

Refusing to pay for "off-label" uses

On-label uses are those for which the FDA approves a drug during the clinical trials that are a part of the new drug approval process. This process is long and famously expensive. The Tufts Center for New Drug Development currently estimates that it costs $802 million, in year 2000 dollars, to bring the average new prescription drug to market in the United States. Once a drug is approved, physicians may prescribe it for any use they feel appropriate and clinical experience often shows that a drug is effective for treating conditions other than those listed on its FDA label.

Over time, standard medical practice may include prescribing the drug for "unapproved" uses. According to the General Accounting Office, an estimated 25 percent of anti-cancer drugs are off-label. Spironolactone, a drug approved to treat water retention, is another example. Thirty years after it was approved, physicians realized it might also help people with congestive heart failure. Spending millions of dollars to conduct new clinical trials to validate this makes no sense, so its use to combat congestive heart failure will continue to be officially "unapproved" standard practice.

In practice, off-label use is of such therapeutic value that more than 35 states now have laws protecting it. Medical experts are now trying to treat other serious mental illnesses with the atypical antipsychotics. The question for those who are severely ill and dependent on the state is whether a state's prescription drug list will be used to deny access to useful therapies when the state's health care budget comes under pressure.

Practice Guidelines

Practice guidelines, clinical requirements that tell doctors how to treat patients with a particular condition, can get around laws allowing off-label uses and access to the latest medications by simply adopting rules stating that "good practice" requires pursuing the least expensive treatments until a patient ceases to respond to them. How such guidelines weigh the inevitable tradeoffs in the cost benefits of such criteria is seldom made explicit. Practice guidelines also take a long time to develop and can be rapidly outdated by new discoveries.

Unintended Consequences

The poor experience with closed and heavily restricted formularies is not unique to Kentucky Medicaid. A 1993 study by W. J. Moore and R. J. Newman looked at formulary restrictions in 47 Medicaid programs. They concluded that

> . . . a restricted formulary may reduce prescription drug expenditures by approximately 13 percent, on average. Because of service substitution, however, such a policy does not translate into reductions in total program expenditures. Savings in the drug budget appear to be completely offset by increased expenditures elsewhere in the system.[57]

In addition to increasing costs by withholding treatment, restrictive formularies are expensive to administer. Sudovar and Rein compared California's rule bound Medicaid prescription policies with the less restrictive ones in Texas in 1978. They concluded that California could have saved $14 million by switching to the Texas system and that $5 million of the savings would have come from reduced administrative overhead.[58] This estimate does not include the pain and suffering imposed by long waits for more effective medicines.

Delays, death, and suffering

Grabowski *et al.* looked at the experience of nine states with Medicaid formularies between 1979 and 1985. They found that during the first four years a drug was on the market, Medicaid patients had access to new drugs less than 40 percent of the time. This was true for all drugs, even those highly ranked for therapeutic importance.[59]

Delays can also
cause deaths and suffering. Dr. Louis Lasagna, director of Tufts University's Center for the Study of Drug Development, estimated that 119,000 Americans died during the seven years it took to study beta blocker heart medicines. Although estimates are not available, an earlier approval of the atypical antipsychotics would almost certainly have prevented some of the suicides and deaths by misadventure that plague people tormented by schizophrenia.

Attempts to control health care expenditures by imposing brute restrictions on drugs have also had negative effects on the patients in state programs. When New Hampshire officials sought to control Medicaid costs by limiting prescriptions to three per person per month, schizophrenia patients made more visits to community mental health centers and

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[57] W.J. Moore and R. J. Newman. 1993. "Drug Formulary Restrictions as a Cost-Containment Policy in Medicaid Programs," *Journal of Law and Economics,* 36, 71-97.
[58] S. Sudovar and S.D. Rein. 1978. "Managing Medicaid Drug Expenditures," *Journal Health Human Resource Administration*, 1:200-230.
[59] H.G. Grabowski, S.O. Schweitzer, S.R. Shiota. 1992. "The Effect of Medicaid Formularies on the Availability of New Drugs," *Pharmacoeconomics,* Suppl 1, 32-40.

hospitals. Soumerai *et al.* estimated that the additional service cost was 17 times higher than the reduction in drug costs.[60]

The dangers of generic substitution

Defenders of closed formularies often argue that offering a variety of drugs in a particular therapeutic class simply wastes money because all therapeutic substitutes are essentially the same. This is also the argument behind generic substitution, which is explicitly required in many states unless a provider expressly indicates no substitution.[61] Though Americans have been encouraged to believe that the only difference between a brand name drug and a generic one is the price, this is not always the case.

In the United States, bioequivalency is determined by statistical trials that administer a generic drug and its branded counterpart to a small group of generally healthy volunteers. Results are compared for the drug's absorption over time, its maximum concentration in the body, and the time it takes to attain maximum concentration. Products considered interchangeable can depart from the brand-name version by up to 25%. Given the statistical constraints, the Food and Drug Administration estimates that "A generic product that truly differs by –20%/+25% or more from the innovator product with respect to one or more pharmacokinetic parameters would actually have less than a 5% chance of being approved."[62]

Statistical studies measure population differences. Individual metabolisms vary widely, however, and the average results for a group can mask the fact that particular individuals may differ substantially from the average. Furthermore, generic drug bioequivalence is typically tested on groups of less than 50 generally healthy volunteers. Though most generic drugs are therapeutically equivalent and work well, individual differences, differences in drug packaging and differences in delivery systems, can substantially affect how well a drug works for a particular patient. While one patient may do just fine on cheap over-the-counter iron pills, another may be unable to tolerate them because they cause serious constipation. In the latter case, a more expensive brand name vitamin with fewer side effects might be required.

Differences in bioavailability become more important when the difference between a therapeutic and a toxic dose is small, when a particular drug has a narrow therapeutic range, or when the inability to tolerate a substitute may have serious consequences. A

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[60] S.B. Soumerai, R.J. McLaughlin, D. Ross-Degnan, C.S. Casteris, and P. Bollini. September 1994. "Effects of a Limit on Medicaid Drug-Reimbursement Benefits on the Use of Psychotropic Agents and Acute Mental Health Services By Patients with Schizophrenia," *New Engl J. Med,* 331(10), 650-5.

[61] Wyeth-Ayerst Laboratories, May 2001. "Protect Your Prescribing Decisions." http://www.alesse.com/pdf/prescribe.pdf as of September 25, 2002.

[62] U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Management: *Approved Drug Products With Therapeutic Equivalence Evaluations.* Washington, DC, US Government Printing Office, 19th Edition, 1999. Cited in James D. Henderson and Richard H. Esham. January 2001. "Generic Substitution: Issues for Problematic Drugs," *Southern Medical Journal,* **94**, 1, pp. 20. Online edition as of November 5, 2002.

1994 Veteran's Administration study found that serum levels of phenytoin, an antiepileptic drug, were 22-31 percent lower when patients were on a generic phenytoin than when the same patients were given the brand-name product Dilantin.[63] A survey of 130 experts on cardiac arrhythmias found that a switch to generic antiarrhythmic drugs caused serious problems in more than sixty cases.[64] At present, the therapeutic categories judged most likely to be sensitive to generic substitution are cardiovascular drugs, psychotropic agents like the atypical antipsychotics, and anticonvulsants. Other potentially sensitive categories include low-dose oral contraceptives, bronchodilating agents, oral diuretics, and oral anticoagulants. Debilitated or elderly who have with abnormal gastrointestinal, renal, or hepatic function are most likely to be at risk.[65]

In testimony before the Florida Commission on Mental Health and Substance Abuse, Delores Castaldo explained what can happen to patients when bureaucrats rather than doctors have the final say on the drugs administered to patients. According to Ms. Castaldo, her son, who had schizophrenia, was doing well on Clorazil. Although his prescription stated "no generics," the pharmacist refused to comply and Florida Medicaid refused to pay for anything other than generic clozapine. When switched to generic clozapine, her son "decompensated badly." She noted that unlike her son, many patients have no family or others to advocate for them and asked the Commission to help those with mental illnesses retain access to the most effective medications.[66]

Variety of drugs needed because different patients react differently

In addition to harming patients, such problems can wipe out the savings expected to occur when bureaucrats limit doctors to one or two drugs within a particular therapeutic category. Omeprazole and lansoprazole, first generation proton pump inhibitors marketed under the brand names Prilosec and Prevacid, were commonly used to treat cases in which there is too much acid in the stomach. Initial evaluations of the pharmacology of the drugs found them similar in structure and mechanism although they were metabolized by different routes. As of July 2000, however, the average wholesale cost of a 30-day supply of a standard dosage was $116.41 for lansoprazole and $124.17 for omeprazole.[67] To save money, many managed care organizations "encouraged" a switch to lansoprazole under their therapeutic interchange programs. In clinical settings, however, patients previously stabilized on omeprazole experienced more severe

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[63] D.H. Rosenbaum, A.J. Rowan, L. Tuchman, and J.A. French. 1994. "Comparative bioavailability of a generic phenytoin and Dilantin," E*pilepsia*, May0Jun, 35(3) 656-60.

[64] J.A. Reiffel, P.R. Kowey. 2000. "Generic antiarrhythmics are not therapeutically equivalent for the treatment of tachyarrhythmias," *Am J Cardiol*, 85(9), 1151-3.

[65] J.L. Colaizzi and D.T. Lowenthal. 1986. "Critical Therapeutic Categories: A Contraindication to Generic Substitution?" *Clin Ther*, 8(4), 370-9.

[66] Florida Commission on Mental Health and Substance Abuse. December 13, 1999. Content Notes from Meeting. Westside Conference Center, University of South Florida, Tampa, Florida. As posted on the web at http://www.fmhi.usf.edu/fcmhsa/notes/december13-1999.pdf on March 7, 2001.

[67] M. Michael Wolfe, MD. *Overview and Comparison of the Proton Pump Inhibitors for the Treatment of Acid-Related Disorders,* UpToDate, an online clinical reference, http://www.uptodate.com/html/AGA_topics/jan_01/text/10094a1.htm as of 21 February 2001.

symptoms when switched to lansoprazole.[68] Some patients did not respond to lansoprazole, others could not tolerate its side effects. According to researchers at one Veterans Administration hospital, the predicted 12 percent savings from the therapeutic interchange were "quickly offset" by the associated failure rate of 28 percent.[69]

Despite growing evidence that patients do better when their physicians have access to a wide variety of drugs, legislation to resurrect state formularies appeared in a number of states in 2001-2002. The Oregon Health Plan Drug Formulary which was signed into law in 2001, is typical of this kind of legislation in that it specifically exempts drugs used to treat cancer, mental illness, and AIDS.[70] The fact that these exemptions are allowed at all shows that those in charge of government health care are perfectly aware that limiting drug choices can compromise patient care.

Cancer, mental health, and AIDS patients are not the only people whose treatment depends heavily on being able to match individual patients to the right drug. In practice, this means that the formulary laws will end up adding to health care costs. People with less politically popular illnesses will also create interest groups and hire lobbyists to ensure that they can get the care that they want. But even those who pay extra to influence the political process and succeed in getting special treatment for their conditions may still find their care compromised by practice guidelines. Suggested practice guidelines for treating schizophrenics have gone so far as to ignore the side effects associated with less expensive drugs and require that patients fail on those before allowing physicians to prescribe more expensive ones.

Other studies of the effectiveness of formulary restrictions and the costs of therapeutic substitution suggest that Ms. Castaldo's experience is not unique. A 1996 survey of 200 physicians participating in Tennessee's TennCare Medicaid managed care program found that two-thirds of the physicians who were forced to switch their patients' prescriptions reported serious adverse consequences including death, strokes, and adverse drug interactions.[71] In Canada, The Fraser Institute reported on the success of British Columbia's drug control system and concluded,

> In British Columbia, 27 percent of physicians reported that they had to admit patients to the emergency room or hospital as a result of the switching of medicines mandated by the operation of the government reference price system. Confusion or uncertainty by cardiovascular or hypertension patients due to mandated medicine switching was reported by 68 percent of doctors while 60 percent observed a worsening or accelerating symptoms. British Columbia doctors for other types of patients reported similar problems with the result being an increase of patients who stop taking their medications and increased emergency room admissions. This patient confusion

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[68] W.W. Nelson, L.C. Vermeulen, E.A. Guerkink, D.A. Ehlert, and M. Geichelderfer. Sep. 11, 2000. "Clinical and humanistic outcomes in patients with gastroesophageal reflux disease converted from omeprazole to lansoprazole," *Arch Intern Med*, 160(16), 2491-6.

[69] P.B. Amidon, R. Jankovich, C.A. Stoukides, and A.F. Kaul. May, 2000. "Proton pump inhibitor therapy: preliminary results of a therapeutic interchange program," *Am J Manag Care*, 6(5), 593-601.

[70] Mary Bellotti. July 13, 2001. "Governor expands health care plan," *PortlandTribune.com* as of September 24, 2002. http://www.portlandtrubune.com/archview.cgi?id=5028.

[71] Yankelovich Partners, Inc. 1996. *Effects of prescription drug access restrictions on medical practice and patient outcomes: A survey among physicians enrolled in TennCare.*

> and uncertainly generated by government's price control system is a clear implication that the system operates for the convenience of government, not the well being of patients.[72]

Ironically, in the years following the hysteria over the cost of the atypical antipsychotics, it became increasingly clear that physicians and patients knew what they were about. Even if one ignores the inhumanity inherent in keeping patients on drugs known to cause permanent damage when newer ones with far fewer side effects are available, subsequent data suggests that state officials would have saved money by immediately embracing the new drugs. One startling estimate of the savings from using the new drugs came from a study by Illinois officials on the costs of treating refractory schizophrenia with clozapine. With clozapine, the state was able to discharge 243 of 518 patients. The savings from those patients alone was estimated to be "approximately $20 million per year."[73]

Moderating the Illinois findings are several others that find modest savings. In a one-year study of treatment refractory patients in Veterans Administration hospitals treated with clozapine and the traditional neuroleptic haloperidol, Rosenheck *et al.* concluded that clozapine treatment saved $2,734 per patient per year.[74] Vaile *et al.* used data from the California's Santa Clara County Mental Health Department to measure the cost of medications and inpatient and ambulatory services to assess the difference in accumulated cost for 139 patients before and after treatment with risperidone, the least expensive of the atypical antipsychotics.[75] They found a slight increase in expenditures with risperidone after 14 months of follow-up, although outcome measures suggested that the extra spending did make patients better off.

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[72] *Canadian Health Care—A System in Collapse*. January 27, 1999. The Fraser Institute, Vancouver, British Columbia. As posted on the web at http://www.fraserinstitute.ca/publications/backgrounders/20000127/index.html as of January 15, 2001.

[73] R.W. Buckman and R.D. Malan. 1999. "Clozapine for refractory schizophrenia: The Illinois experience," *J Clin Psychiatry,* 60, Suppl 1, 18-22.

[74] R. Rosenheck, J. Cramer *et al.* September 1997. "A Comparison of clozapine and haloperidol in hospitalized patients with refractory schizophrenia. Department of Veterans Affairs Cooperative Study Group on Clozapine in Refractory Schizophrenia," *New Engl J Med*, 337(12), 809-15.

[75] G. Vaile, L. Mechling, *et al.* September 1997. "Ímpact of risperidone on the use of mental helath care resources," P*sychiatr Serv,* 48(9).

Statistical studies no substitute for clinical judgment

These results show the difficulties faced by those who argue that taxpayer money should not be spent on new forms of treatment until research studies demonstrating their effectiveness have been completed. In the real world, statistical study designs always have weaknesses. These range from small sample sizes with short follow-up periods to primitive outcome measures. They also include the problem of matching treatment and non-treatment groups when people have different genetic structures and different treatment histories. With a disease like schizophrenia, further complications include a disease with an unknown cause and relatively subjective measures of severity. Cost analyses are even more difficult because direct and indirect costs vary from person to person and are difficult to measure. The studies cited above, for example, need to be interpreted in light of suggestions from longer follow-ups suggesting that the major benefits from treatment with the atypical antipsychotics may not show up until a year or more after patients are stabilized on the drugs.

The problem with relying exclusively on statistical results can be summarized by the following example. Suppose that two people diagnosed with schizophrenia are discharged from the hospital on two different drugs after acute psychotic breaks. For the next six months both avoid additional hospitalization. Person number one has never been hospitalized before and is given the less expensive, less advanced drug. When he is discharged, he continues living independently and holds down a job. Because he does not like the side effects and feels just fine, he stops taking his medication at the end of 6 months without telling anyone. The other patient, who has been in and out of the hospital and on and off various drugs for years, is discharged on a much more expensive drug. He drifts in and out of his parents' home but continues taking his medication. An inexperienced policy analyst applying simple statistics to the data contained in the medical record might well use these data to conclude that the more expensive drug is not worth its cost. Patients and clinicians familiar with the disease, who know that discontinuing medication will likely result in a future psychotic break, might legitimately come to a different conclusion.

Given that physicians act in the best interests of their patients, it comes as no surprise that attempts to second-guess their decisions often do harm. Doctors in traditional practices generally know more about their patients' lives and preferences than remote government officials. Psychiatrists who specialize in schizophrenia, for example, claim that personal familiarity with an individual patient makes them able to detect subtle changes that give them advance warning of an impending psychotic break. This means that they can take steps to prevent or manage it. Physicians this intimately involved with their patients are unlikely to prescribe a drug unless they think it will help. Given their specialist knowledge, the odds are that they will be right. In fact, the demand for atypical antipsychotics has skyrocketed precisely because clinicians observed obvious improvement in the patients who used them.

In constraining physicians' drug choices by closing formularies, limiting prescriptions, or requiring therapeutic substitutions, government officials implicitly substitute the judgment of a bureaucracy for that of a physician. Lacking the information that physicians have, it is no wonder that the bureaucrats trying to substitute for them end up

making costly mistakes. The problem, as researchers from the Managed Care Outcomes Project so delicately put it, is that

> A causal relationship between stricter HMO cost-containment practices and increased resource use also is supported by previous studies reporting shifts to more-expensive resources when restrictions are placed on the availability of drugs in Medicaid programs. These shifts are not inconsistent with prevailing economic theory based on findings that greater choice enhances consumer satisfaction and economic efficiency. Likewise, systems theory predicts that often unforeseen effects are found when complex systems (such as the healthcare system) are perturbed.[76]

Projected Savings Never Materialize

Serious harm is also done when government officials act on the unreasonable optimism generated by the expected success of reform proposals. In the heyday of Medicaid managed care, Colorado officials assumed that state contracted Medicaid managed care for mental health would be 5 percent cheaper than the fee-for-service system it replaced.

The basis for the five percent assumption is unclear. According to a 1998 JAMA article, Tennessee officials made the same assumption. Sure that savings would occur and intent on keeping them for itself, Tennessee funded its mental health managed care carve-out at 95 percent of its projections of the costs for fee-for-service care. The behavioral health organizations Tennessee contracted with then spent up to 10 percent of the capitation payments to meet their own administrative costs. Finally, the state withheld 10 percent of capitation payments for noncompliance with contractual obligations. The result, as the acting Tennessee Mental Health Commissioner acknowledged in oversight committee hearings, was that mental health and substance abuse treatments declined by 15 percent in one year.

Evidence from Utah also suggests that the expected gains from disease management programs have been problematic. In the early 1990s, some Utah counties had fee-for-service Medicaid mental health and some had capitated plans. Popkin *et al.* examined the medical records of 200 Medicaid beneficiaries in the state's capitated plans and compared them with those of 200 beneficiaries who remained in the fee-for-service system. Records were examined before the adoption of the prepaid plan in 1990 and followed for three years after it was instituted.

The authors found that traditional therapeutic encounters were de-emphasized under capitation. They also found that "the probability of a patient's terminating treatment or being lost to follow-up increased, the probability of having a case manager increased, the probability of a crisis visit decreased (but still exceeded that at the nonplan sites), and the probability of treatment for a month or longer with a suboptimal dosage of antipsychotic medication increased."[77]

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[76] Susan D. Horn, Phoebe D. Sharkey *et al.* March 1996. "Intended and Unintended Condequences of HMO Cost-Containment Strategies: Results from the Managed Care Outcomes Project," *The American Journal of Managed Care*, II(3), p. 262.

[77] M.K. Popkin, N. Lurie, W. Manning, J. Harman, A. Callies, D. Gray, and J. Christianson. 1998. "Changes in the process of care for Medicaid patients with schizophrenia in Utah's Prepaid Mental Health Plan," *Psychiatr Serv,* 49(4), 518-23.

Manning *et al.* compared outcomes for Utah Medicare beneficiaries with schizophrenia under the two systems of care. Between 1991 and 1994, they found that the average beneficiary's mental health status improved, but that the improvement was less under the carve-out program. No doubt some of the improvement was due to the fact that atypical antipsychotics were just coming onto the market during this period. Still, schizophrenia patients improved less under the capitated carve-out than under fee-for-service, and the difference was greatest for those who were sickest when the comparison began.[78]

According to the Kaiser Commission, when Michigan officials created their state prescription drug list they also acted on the assumption that projected savings would materialize. "Confronted by the growing budget deficit...[they] sought savings from Medicaid—particularly the pharmacy program." The savings goal was set at $42.8 million. The legislature was so sure that the savings would materialize that it subtracted the same amount from the year's Medicaid appropriation.[79] Just months after the program began, the state agency in charge reported savings of about $800,000 a week, almost exactly what was necessary to achieve the goal set by the legislature. Such statements are common in centrally planned enterprises in which people know they must satisfy the plan. Further details about the exact sources of these savings, and what the state is doing with them, have not been forthcoming.

Quality declines

Cuts made in anticipation of savings that fail to materialize can generate substantial quality declines as desperate officials cut services across the board. When Tennessee's referral networks were disrupted, many patients stopped receiving care. Funds previously earmarked for severely mentally ill patients were spread across the whole Medicaid population, and providers who had specialized in treating those with severe mental illness went bankrupt. As financial stresses increased, charity care diminished. "Many CMHCs [Community Mental Health Centers] also stopped providing non-TennCare enrollees with services, especially substance abuse treatments, that had previously been subsidized by state funds."[80]

According to a 1998 report by Colorado's Office of the State Auditor, Colorado's capitated Medicaid mental health carve-out exhibits many of Tennessee's symptoms. As is the case in many of the hastily conceived prescription drug programs, the state had no way to determine whether its per person expenditures for mental health care were reasonable because the necessary data simply do not exist. The data that did exist suggested worrisome declines in quality and service. Before capitation, the percentage of

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[78] W.G. Mannin, C.F. Liu *et al.* November 1999. "Outcomes for Medicaid beneficiaries with schizophrenia under a prepaid mental health carve-out," *J Behav Health Serv Res*, 26(4) 442-50.

[79] Cathy Bernasek, Jeff Farkas, Helene Felman, Catherine Harrington, Dan Mendelson and Rejeev Ramchild. January 2003. *Case Study: Michigan's Medicaid Prescription Drug Benefit.* Kaiser Commission on Medicaid and the Uninsured report no. 4083, Kaiser Family Foundation, Washington, DC. p. 11-12.

[80] Cyril F. Change, Laurel J. Kiser *et al.* March 18, 1998. "Tennessee's failed managed care program for mental health and substance abuse services, *JAMA,* 279(11).

Medicaid recipients receiving mental health services was increasing. After capitation, costs per Medicaid person served increased at "a faster rate than national health care costs," the percentage of Medicaid recipients served declined, and services per person probably decreased. In 1997, the auditor estimated that the state paid $27 million more under the capitated system than it would have under fee-for-service.[81]

In government formulary systems legislative management routinely compromises patient health by making cost the central concern. In Canada, where the Patented Medicines Price Review Board controls drug approvals, officials simply refuse to approve new drugs that are priced higher than the most effective drug currently in use no matter how effective the new drug is. As a result, Canadians may wait years for access to new drugs that are available in the United States. The Board also tries to control costs by dragging out approvals. Between 1994 and 1998 it considered 400 drugs and approved only 24.[82]

Patients who do not do well on the drug chosen but who might do better on one of the other compounds in a particular class are out of luck. When government formularies respond to a lower price by substituting one medication for another, patients must change their medication regimes. This can cause problems. In one survey, 27% of doctors in British Columbia reported admitting patients to hospitals as a result of problems created by government mandated prescription drug substitutions.[83]

In the United States, the Veterans Administration formulary is famous for its lack of choice. As of 2002, the Veterans Administration carried only 7 of the drugs that were the 20 most popular drugs for elderly Medicare recipients in 1996.[84] In 2000, patients with pancreatic cancer were required to "fail first" on other drugs before being given access to Gemzar, the newest drug for that disease. Whether fail first is an ethical option given that treatment with 5-FU, the only other alternative, has been described as "palliative" with "dismal outcomes," remains an open question.

In 2001, the Florida prescription drug list covered 83 of the most commonly prescribed brand-name drugs, but the list did not include any of the popular thyroid replacement agents Synthroid, Levoxyl, or Levothryod. All of the generic equivalents that were included were rated "BX" by the FDA. BX means that there is inadequate clinical data to establish the highest level of brand-generic equivalency.[85] The Kaiser Foundation's analysis of the Michigan preferred drug list showed that it was considerably more

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[81] State of Colorado, Office of the State Auditor. October 1998. *Department of Human Services Medicaid Capitation for Mental Health Services Financial Review*, Report number 1160, p. 17.

[82] William McArthur. May 19, 2000. *Prescription Drug Costs: Has Canada Found the Answer?* National Center for Policy Analysis Brief Analysis No. 323. Accessed on the web at http://www.ncpa.org/ba/ba323/ba323.html on February 2, 2003.

[83] William McArthur. January 21, 2000. "Memo to Al Gore: Canadian Medicine Isn't Cheap or Effective," *The Wall Street Journal, p. A19.*

[84] Naomi Lopez Bauman. March 2002. *Playing Doctor in Tallahassee: How Lawmakers' Efforts to Save Money May Threaten Quality Care for Mentally Ill Medicaid Patients.* Policy Report #37, James Madison Institute, Tallahassee, Florida.

[85] Cathy Bernasek, Catherine Harrington, Rejeev Ramchild, and Dan Mendelson. February 2002. *Florida's Medicaid Prescription Drug Benefit: A Case Study.* Kaiser Commission on Medicaid and the Uninsured report 4031, Kaiser Family Foundation, Washington, DC. p. 18.

restrictive than private plans in drugs used to treat cardiac conditions, depression, and diabetes.

States Profit By Denying Treatment

Supplemental rebates are the centerpieces of both the Michigan and Florida Medicaid drug restriction program. Supplemental rebates are cash payments from drug manufacturers for the privilege of selling their products to state Medicaid drug programs. According to the Kaiser Commission Michigan case study, "Drugs not selected as "best in class," or whose manufacturers would not offer supplemental rebates to the states, were excluded from the MPPL [the drug control list] and subject to prior authorization."[86]

Florida statute allows the Agency for Health Care Administration to "negotiate supplemental rebates from manufacturers of at least 25% of average manufacture price"(AMP).[87] "For an brand-name product to be considered by the [Pharmaceutical and Therapeutics Committee] for inclusion on the [Preferred Drug List], the manufacturer must offer a minimum 25% of the AMP rebate."[88] In Florida, manufacturers can choose to run disease management programs "in lieu of cash rebates." Why officials think that citizens will benefit when a drug manufacturer's attention is shifted from finding new cures to disease management programs remains a mystery.

Ironically, both programs fine the producers who fund the research and development leading to new medicines and favor the producers of copycat generics. Money, not patient outcomes, drives the process, a situation that health expert Merrill Matthews has labeled "Prescription Drug Payola."[89]

In other contexts, payments to state officials in exchange for using a specific product or hiring a specific contractor are called kickbacks. Kickbacks are against the law because they put manufacturers who price their products fairly at a disadvantage and they create asymmetric incentives that promote irresponsibility with the public purse. In the Medicaid case, these kickbacks encourage state and federal officials to ignore the fact that Medicaid expenditures are out of control because the Medicaid program itself is a dysfunctional, 40-year-old program in need of drastic reform.

The irresponsibility engendered when state officials are allowed to extort money from the stockholders of legal businesses who refuse to make special deals with the state was most

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[86] [86] Cathy Bernasek, Jeff Farkas, Helene Felman, Catherine Harrington, Dan Mendelson and Rejeev Ramchild. January 2003. *Case Study: Michigan's Medicaid Prescription Drug Benefit.* Kaiser Commission on Medicaid and the Uninsured report no. 4083, Kaiser Family Foundation, Washington, DC. p. 11.

[87] State of Florida, Agency for Health Care Administration. January 2002. *Annual Report: Medicaid Prescribed Drug Spending Control Program.* p. 10.

[88] State of Florida, Agency for Health Care Administration. January 2002. *Annual Report: Medicaid Prescribed Drug Spending Control Program.* p. 12.

[89] Merrill Matthews, Jr. April 19, 2002. *Prescription Drug Payola Scam Breaks Wide Open.* Independence Institute Issue Backgrounder #2002-E, Golden, Colorado.

recently illustrated by the way in which state officials manipulated public opinion to challenge tobacco companies. When state officials were pursuing the tobacco companies, they sought public approval by claiming that the money merely made up for the health costs that smoking imposed on taxpayers. Once state officials received huge sums of money from tobacco companies in exchange for dropping the lawsuits against these businesses, they diverted the money to programs designed to increase their political stature or their ability to attract votes.

Successful state attempts to claim the assets of cigarette companies merely increased the price of legal cigarettes and created, in some areas, a whole new industry devoted to cigarette smuggling. In health care, the stakes are much bigger. As William Orzechowski and Robert C. Walker point out, price control schemes like those in Florida and Michigan are little more than state officials' attempts to avoid paying their fair share of drug research and development.[90] If they succeed, Medicaid patients will be denied access to new therapies, state health care spending will climb, and drug research and development will be retarded. As the most effective way to control health care costs is to find cures for cancer, arthritis, diabetes, and all of the other ills that afflict us, the official enthusiasm for prescription drug formulary lists demonstrates yet again that government monopolies in health care are a sure prescription for poor results and unintended consequences.

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[90] William Orzechowski and Robert C. Walker. December 2001. *Florida's Folly: The Darker Side of the Sunshine State's Drug-Pricing Scheme.* The National Taxpayer's Union, Washington, D.C. *www.ntu.org.*

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"... a wise and frugal government, which shall restrain men from injuring one another, shall leave them otherwise free to regulate their own pursuits of industry and improvement, and shall not take from the mouth of labor the bread it has earned. This is the sum of good government, and this is necessary to close the circle of our felicities."

Thomas Jefferson

1801

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