TREATMENT DENIED:

Colorado Health Care "Reform" and the Mentally Ill

By Dr. Linda Gorman

Executive Summary

Colorado health care "reformers" usually claim that government control of health care raises quality and lowers cost. In fact, government involvement does just the opposite. For proof, one need look no further than the way the state Medicaid programs treat the severely mentally ill.

The severely mentally ill on Colorado Medicaid wait for care and must get their care from a monopoly provider chosen by the state. The Romer administration was so sure that it would save the state money by capitating mental health payments, paying a flat annual fee for each person enrolled in the program regardless of the amount of care needed, that it funded the state mental health care contracts at only 95% of the projected fee-for-services costs. It also required that providers offer a number of new services not specifically aimed at the severely mentally ill.

This touching faith in the miraculous powers of government cost control manifested itself again during the legislative budget process in October 2000. Under a proposed pilot project, prescription drug spending for the mentally ill would be included in the annual per-person fee for mental health care and the state and providers would split any savings that materialize. Left unmentioned was the fact that this gives both the provider and the state an incentive to withhold treatment.

As far as is known, the Romer reorganization didn’t save a dime. In October 1998, the Office of the State Auditor concluded that the costs per person served increased at a faster rate than national health care costs under the capitated mental health program, while services declined. For this, the state paid $27 million more under the capitated system of care than it would have paid under the old fee-for-service plan.

In addition to costing more, capitated care systems may be more likely to limit access to important new therapies for people with severe mental illnesses like schizophrenia. People with schizophrenia may hear voices, believe against all evidence that they are being spied upon, have racing thoughts that make thinking disorganized and fragmented, or withdraw from social interaction. Their motor coordination may be impaired, they may be unable to feel or show emotions, and they may suffer severe depression. An estimated 30% attempt suicide.

Though some people recover completely, most don't. Since schizophrenia typically 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% of U.S. schizophrenia patients are Medicaid recipients. 1

The drugs traditionally used to treat schizophrenia were developed in the 1950s. They are powerful drugs with nasty side effects that include irreversible tremors, permanent facial tics, deterioration in cognitive abilities, numbed senses, and diminished willpower. Patients often hate taking them so much that they refuse to comply with medication schemes. Aside from the high cost of inpatient hospitalization for someone who has a psychotic break, recent evidence suggests that untreated psychotic episodes are associated with slower or less complete recoveries.

The early 1990s saw the introduction of new psychoactive drugs tailored to affect certain receptors in the brain. Called "atypical" antipsychotics, the new drugs had much lower rates of irreversible muscular side effects, gave patients their feelings back, and did not cause the same cognitive losses. They helped patients who had been helped by nothing else. They also cost thousands of dollars a year more than the older ones.

State Medicaid officials, focused on their cost, immediately tried to limit their use. The Kentucky strategy was typical. Kentucky required prior approval, which was withheld until a patient suffered a psychotic break while taking the old medications. To save money, patients were kept on drugs known to cause permanent damage even though safer alternatives were available.

As is usually the case with rapidly adopted new technologies, doctors and patients who wanted the new drugs knew what they were doing. In the long run, the expensive new drugs ended up saving money. Because they made patients better, the cost of hospitalization and institutionalization fell. But declines in the rate of increases in payments for hospitalization or state mental institutions were detailed in other budgets and were, in any case, difficult to isolate.

As a result, officials continue to focus on drug costs and promote schemes designed to limit drug choice. On February 1, 2001, Colorado Access, the state's largest Medicaid contractor, informed pharmacies that prior approval would be required for more than one pill a day in certain dosages of the atypical antipsychotics Risperdal and Zyprexia. Providers were "asked to put patients on a single daily dose regimen where appropriate." Closed formularies, even those that approve all FDA-approved drugs when they are used for FDA-approved purposes, are also used to limit access. Twenty-five percent of the standard chemotherapy drugs, for example, lack FDA approval when used to fight cancer.

With government, you almost always get less than you pay for.

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Introduction

Some people appear to believe that providing excellent health care for everyone is a simple matter of empowering the state to purchase, provide, finance, define, regulate and evaluate all of the health care received by its citizens. Willfully ignorant of the copious economics literature on the impossibility of managing such a system either for quality or for low cost, and inexplicably silent on the degree of harm caused by the failures of similar experiments in Great Britain, Canada, Kentucky and Tennessee, they continue to push for the extension of state medical assistance programs and for measures that crowd out private medical care.

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In order to understand why a policy of systematically increasing government control over health care will prove an expensive failure, one must understand that treatment decisions for those who are seriously ill can be an excruciatingly complex balancing act. It is theoretically and practically impossible for government to gather and analyze the information required to do even an adequate job of making those decisions. Like every other human institution, government has limits. Bureaucrats run government, and as is the case in any bureaucracy, public or private, those who staff it are neither omniscient nor necessarily disinterested. The harm done by business bureaucracies is limited

by the fact that consumers always have the ability to find other suppliers or to forgo buying entirely and by the fact that businesses that refuse to respond to both consumers and suppliers soon go out of business. Government bureaucrats face no such limits. They can force people to buy from them regardless of cost, and, as a practical matter, are limited only by the legal or regulatory restrictions they choose to obey.

That these differences translate into enormous differences in the way private and public health systems operate has been extensively documented. In general, private systems deliver higher quality, less waste and less fraud. When all costs are included they also tend to be less expensive. The primary arguments against them are that they promote unequal "access" to medical care, that they promote high cost interventions, and that they do not produce sufficiently integrated systems of care for truly vulnerable populations. The equal access proposition has been decisively refuted by studies of waiting lists in Britain and Canada. To see how well the government approach works in other areas, one need look no further than the care of schizophrenics under state Medicaid systems.

Taxpayers were assured that costs would not increase and that care would not be compromised in any way.

A Decade of Reform: Creating a Colorado Health Care Monopoly

About ten years ago, with support from the Robert Wood Johnson Foundation, Colorado state government embarked on a radical redesign of its medical assistance programs. Reformers assured the state that by taking control of the medical marketplace it could lower the costs of its medical assistance programs, expand the population covered, and provide more services. Taxpayers were assured that costs would not increase and that care would not be compromised in any way. At bottom, all of the reform proposals shared a single assumption: letting consumers choose their medical care generated additional expenses that were unrelated to the quality of care. Reformers argued that consumers would receive better care for less money if state experts were put in charge, and numerous private institutions were consolidated under rules determined by state officials. The plan was to use the savings generated from more efficient purchasing, more widely available preventive care, and better coordinated treatment plans to expand the number of people eligible for state medical assistance. Ultimately, it was said, the state could provide universal coverage for everyone with taxpayer dollars.

State officials inspired by this vision were attracted by the promise of providing medical treatment for anyone who needed it. It was also hoped that the projected cost savings from the elimination of what was thought to be a large amount of waste in the private health care system would fund more government services. Left unmentioned were

- the possibility that the private system was in fact fairly efficient,
- the fact that government had historically been unable to manage such complex enterprises,
- the certainty that removing price constraints would require rationing in other forms, and
- the potential for capitated managed care — per-capita limits on health care expenditures proposed by the reformers as a substitute for private medicine — to pose a significant danger for patients.

Finally, there is no way to guarantee when government dictates what kind of care people will receive and determines how much providers will be paid for it, that it will be either willing or able to provide the kind of care that its citizens both want and would be willing to pay for.1[1]

The original goal of Colorado reformers was the creation of ColoradoCare, a state-run health care monopoly.

The original goal of Colorado reformers was the creation of ColoradoCare, a state-run health care monopoly. When this proved too expensive, they settled on a package of incremental reforms intended to achieve the same results by gradually extending state health insurance to larger and larger fractions of the state's population. To provide flexibility, the state sought federal

1[1] 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.

waivers exempting it from the straightjacket of federal rules governing the Medicaid program. The state's Medicaid 1915(b) waivers allowed the implementation of mandatory Medicaid managed care programs eliminating patient choice in health care. The 1915(c) waivers for home and community based services provided more flexibility in the services the state can provide, income caps, and variations in coverage.2[2]

As in most states that applied for federal waivers, Colorado chose to innovate by requiring its Medicaid recipients 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 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 its health care programs, and reshaped the market for "private" insurance.3[3]

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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, it 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% of the Federal Poverty Level, roughly $31,000 for a family of 4 in 2000,4[4] and to anyone else who would

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2[2] State of Colorado, Department of Health Care Policy and Financing, Advisory Committee Handout, January 13, 2000. *Waiver Comparison Chart.* As published on the web as of 5 February 2001, http://www.chcpf.state.co.us/icfp/advcomm/000113handout1/html.

3[3] 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.

4[4] *Federal Register,* vol. 65, No. 31, February 15, 2000. pp. 7555-7557.

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% of the federal matching funds they received for their services.5[5]

Reforms instituted without proper trials, evaluation or safeguards

In effect, the reformers sought to create a Medicaid health care monopoly modeled after Medicare, but without Medicare's fee-for-service component. Surviving documents make it clear that those involved knew that the proposed reforms could compromise the quality of care received by those on medical assistance. Though they refused to let patients vote with their feet, they devoted a great deal of effort to creating custom designed systems to measure the quality of the programs that they would eventually run. When the state sought funding from the Robert Wood Johnson Foundation in 1996, it was for an experimental program designed to "make Medicaid managed care work for vulnerable populations covered by Medicaid."6[6] In effect, the state was tacitly admitting that the new capitated managed care effort posed serious problems for those who were sickest and most in need of quality health care.

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Long before the experimental programs could be properly evaluated, reformers had urged the state 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

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5[5] Colorado Revised Statutes 26-4-531. School districts may spend up to 30 percent of the federal moneys received on "low-income" students, those whose families have an annual income less than 185% 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."

6[6] The Robert Wood Johnson Foundation. Date unknown. *Call for Proposals: Strengthening The Safety Net: The Medicaid Managed Care Program*, p. 3.

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% of those on medical assistance be enrolled in managed care programs by July 1, 2000.7[7] On June 30, 1999, the Health Care Financing Administration reported that 92% of Colorado's Medicaid enrollees received medical assistance via managed care.8[8]

Under Colorado Medicaid, managed care takes two basic forms. In non-capitated "gatekeeper" programs, case managers or primary care physicians manage patient care. The state pays providers a set fee for services delivered. Physicians in gatekeeper programs often operate under a variety of constraints, financial and otherwise, designed to control their patients' use of medical services. Under capitated care, Medicaid pays a health care organization a fixed monthly amount for all services and care. The HMO or other provider accepts responsibility for patient care and has an obligation to provide care even if its cost exceeds the amount paid. Colorado is so committed to the managed care model that rather than provide standard fee-for-service payment, it is experimenting with so-called "risk-adjusted" capitated payments in an effort to encourage HMOs to accept Medicare patients known to generate higher than average health care costs.

This allows the state to require that people receiving Medicaid mental health benefits receive their care from state providers.

Mentally ill denied Medicaid freedom-of-choice provision

Though some Medicaid recipients technically have 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

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

8[8]Health Care Financing Administration, June 30, 1999. *Medicaid Managed Care State Enrollment,* http://www.hcfa.gov.medicaid/mcsten99.htm as of February 7, 2001.

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.9[9]

By 1997, 71,142 of the 130,589 people who were enrolled in Medicaid managed care were enrolled in Medicaid HMOs.10[10] 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%) 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."11[11]

Reformers planned destruction of traditional benchmarks

When the state requires people to obtain services from a single provider, it throws away the important policing power that consumers exercise when they are free to leave a provider delivering 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 will always successfully argue that their costs are fair and their services excellent. Without competition, no one can prove them wrong.

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Reformers in favor of universal health care run by the state knew that this would be the case. A 1998 report from the state to the Robert Wood Johnson Foundation explicitly states that new

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9[9] 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.

10[10] 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 February 7, 2001.

11[11] mimeo, Robert Wood Johnson Foundation Strengthening the Safety New: Medicaid Managed Care Project Summary, Application narrative, p. 1.

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."12[12]

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. Old-style health 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. For those in favor of government run universal health care, the treatment of schizophrenics provides a cautionary tale.

Government's bitter resistance to a major medical breakthrough in 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

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.

12[12]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.13[13] 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% of U.S. schizophrenia patients are Medicaid recipients.14[14]

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

Some people lead relatively normal lives between episodes. Others remain chronically ill for decades.

13[13] L. G. Wilson. 1976. "Viral encephalopathy mimicking functional psychosis," *Am J. Psychiatry,* 133(2), 165-70.

14[14] 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.

ultimate outcome varies greatly across individuals. Some people have very few psychotic breaks, other 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% recovery rate during the first five or six years15[15] — 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 imprecise diagnoses. Recent evidence suggests that untreated psychotic episodes are associated with a slower or less complete recovery.16[16]

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…"17[17]

15[15] 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.

16[16] 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.

17[17] 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.

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.18[18] 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.

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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.19[19] 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 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% of patients using the drugs on a long-term basis will experience motor problems20[20] — that the term neuroleptic-induced deficit syndrome was coined to describe the drugs' adverse effects.21[21] A small group of researchers believes

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18[18]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.

19[19] 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.

20[20] Collaborative Working Group on Clinical Trial Evaluations. 1998. "Assessment of EPS and Tardive Dyskinesia in Clinical Trials," *J. Clin Psychiatry*, Suppl 12:23-7.

21[21] T. Lewander. 1994. Neuroleptics and the neuroleptic-induced deficit syndrome," *Acta Psychiatr Scand Suppl*, 380, 8-13.

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that they do more harm than good and is skeptical of the benefits of any neuroleptic drug treatment.22[22] 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.23[23]

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

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22[22] Seymour Fisher and Roger P. Greenberg, eds. 1997. *From Placebo to Panacea: Putting Psychiatric Drugs to the Test*. New York. John Wiley & Sons, Inc.

23[23] 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.

United States. In 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.24[24]

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 4 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

24[24] 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.

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 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."25[25]

The drug's cost provoked what can only be called a hysterical reaction from officials in charge of government mental health care programs.

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."26[26] 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 6 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

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25[25] 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.

26[26] 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.

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."27[27] 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."28[28]

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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In June 1991, the Federal Trade Commission proceeded to demonstrate the remarkable elasticity of U.S. antitrust 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

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27[27] 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.

28[28] 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.

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 6 months of treatment, and that blood monitoring be made voluntary after 1 year.29[29] 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.

Given that an estimated 30% of schizophrenics attempt suicide, such a difference is unquestionably a legitimate therapeutic consideration.

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."30[30] 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% of schizophrenics attempt suicide, such a difference is unquestionably a legitimate therapeutic consideration.31[31]

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

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29[29] 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 March 3, 2001.

30[30] 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.

31[31] 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.

favored a direct approach in which officials simply refused to buy particular drugs for anyone. Five months after Clozaril was approved for sale in the United States, the Veteran's Administration simply stopped providing the drug to its patients, saying that its cost was too high.32[32] 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. State legislatures have developed 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 closed formularies. The formularies were lists of drugs that the state would pay for. Payment was denied for all others. Concerned that restrictive state formularies denied important medicines to the poor, Congress outlawed restrictive formularies for Medicaid when it passed the Omnibus Budget Reconciliation Act of 1990. The Omnibus Budget Reconciliation Act of 1993 repealed many of the 1990 limitations. 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.

State legislatures have developed a variety of strategies to control drug budgets including formularies, prescription limits, generic substitution requirements, prior approval systems, and refill limits.

Prior approval

As one would expect if one believes that doctors prescribe drugs to help individual patients, to the extent that prior approval requirements effectively restrict patient access to expensive medicines, 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.

32[32] 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.

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 eight-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 dependent on the government were at the mercy of the whims of bureaucrats obsessed with their cost control mission.33[33]

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 to cases of therapeutic failure for almost two years after the drug was made available. Therapeutic failure occurs when a schizophrenic has a "break," a bout with uncontrolled psychosis. Current research suggests that uncontrolled psychotic breaks are associated with a poorer chance of long term recovery. Any "health care system" that requires a therapeutic break before prescribing a drug that is known to be more effective, and to produce 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."34[34]

Seriously ill patients dependent on the government were at the mercy of the whims of bureaucrats obsessed with their cost control mission.

Kentucky's lack of attention to proper patient care is typical of states in which government exercises control and consumers

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33[33]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 February 15, 2001.

34[34] 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.

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 Robert Wood Johnson inspired comprehensive health care reform. It passed sweeping legislation that guaranteed health care to all state residents and gave the state effective control of health insurance and medical practice.

As has been the case everywhere government health care has been tried, what the reformers promised never materialized. In practice, access to the latest therapies for mental illness has been degraded, and the reforms have bankrupted the state-sponsored health-insurance plan for government employees. They have destroyed the market for private health insurance.35[35] Those who blithely 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 a.m. and 6 p.m.

In spite of the evidence suggesting that state formularies increase costs and degrade quality, people who support them for state programs 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. But formulary laws may also say that the state will cover drugs only if they are used for FDA-approved, or "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. In 1993, the Boston Consulting Group estimated that it cost $500 million, in pretax 1990 dollars, to bring a drug to market in the United States.36[36] Once a drug is approved, however, 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.

Once a drug is approved, however, 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.

35[35] 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.

36[36] Hanry I. Miller. 1998. "Failed FDA Reform," *Regulation*, 21, 3, pp. 24-30.

Over time, standard medical practice may include prescribing the drug for "unapproved" uses. According to the General Accounting Office, an estimated 25% 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 that 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 the state's closed formulary law will be used to deny access to useful therapies when the state's health care budget comes under pressure.

In practice, off-label use is of such therapeutic value that more than 35 states now have laws protecting it.

Unintended consequences: state schemes increase total costs

The poor experience with closed and heavily restricted formularies is not unique to Kentucky. 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.37[37]

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

37[37] 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.

switching to the Texas system and that $5 million of the savings would have come from reduced administrative overhead.38[38]

Delays, death and suffering

This estimate does not include the pain and suffering imposed by long waits for more effective medicines. 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% of the time. This was true for all drugs, even those highly ranked for therapeutic importance.39[39]

Delays 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 hospitals. Soumerai *et al.* estimated that the additional service cost was 17 times higher than the reduction in drug costs.40[40]

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.

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.

38[38] S. Sudovar and S.D. Rein. 1978. "Managing Medicaid Drug Expenditures," *Journal Health Human Resource Administration,* 1:200-230.

39[39] 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.

40[40]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.

This is also the argument behind generic substitution, which is required in Colorado unless otherwise requested. 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, a generic and a brand name drug are considered bioequivalent or interchangeable if "the rate and extent of absorption are not significantly different (+/- 20%) from those of the innovator drug when administered under similar experimental conditions."41[41] This means that switching among generic versions of a brand-name drug could potentially result in 40% to 60% differences in the rate or extent of absorption.42[42] Individual metabolisms vary widely and generic drug bioequivalence is typically tested with groups of less than 50 people. Though most generic drugs are therapeutically equivalent, individual differences, and drug packaging and delivery systems, can make a huge difference in 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.

Debilitated or elderly patients with abnormal gastro-intestinal, renal, or hepatic function are most likely to be at risk.

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 1994 Veteran's Administration study found that serum levels of phenytoin, an antiepileptic drug, were 22-31% lower when patients were on a generic phenytoin than when the same patients were given the brand-name product Dilantin.43[43] A survey of 130 experts on cardiac arrhythmias found that a switch to generic antiarrhythmic drugs caused serious problems in over 60 cases.44[44] At present, the therapeutic categories judged most likely to be sensitive to generic substitution are cardiovascular

41[41] P.H. Rheinstein. 1990. "Therapeutic Inequivalence," *Drug Safety*, 5(Supplement) 1, 114-9.

42[42] J.L. Colaizzi and D.T. Lowenthal. 1986. "Critical Therapeutic Categories: A Contraindication to Generic Substitution?" *Clin Ther*, 8(4), 370-9.

43[43] D.H. Rosenbaum, A.J. Rowan, L. Tuchman, and J.A. French. 1994. "Comparative bioavailability of a generic phenytoin and Dilantin," E*pilepsia*, May-Jun, 35(3) 656-60.

44[44] 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.

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 patients with abnormal gastrointestinal, renal, or hepatic function are most likely to be at risk.45[45]

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.46[46]

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, marketed under the brand names Prilosec and Prevacid, belong to a class of drugs called proton pump inhibitors that are 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.47[47] To save money, many managed care

According to researchers at one VA hospital, the predicted 12% savings from the therapeutic interchange were "quickly offset" by the associated failure rate of 28%

45[45] J.L. Colaizzi and D.T. Lowenthal. 1986. "Critical Therapeutic Categories: A Contraindication to Generic Substitution?" *Clin Ther*, 8(4), 370-9.

46[46] 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.

47[47] 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 February 21, 2001.

organizations "encouraged" a switch to lansoprazole under their therapeutic interchange programs. In clinical settings, however, patients previously stabilized on omeprazole experienced more severe symptoms when switched to lansoprazole.48[48] Some patients did not respond to lansoprazole, and others could not tolerate its side effects. According to researchers at one Veteran's Administration hospital, the predicted 12% savings from the therapeutic interchange were "quickly offset" by the associated failure rate of 28%.49[49]

A number of 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.50[50] In Canada, The Fraser Institute reported on the success of British Columbia's drug control system and concluded that

> 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 of 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 and uncertainty generated by government's price control system is a clear

It became increasingly clear that physicians and patients knew what they were talking about.

48[48] 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.

49[49] 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.

50[50] Yankelovich Partners, Inc. 1996. *Effects of prescription drug access restrictions on medical practice and patient outcomes: A survey among physicians enrolled in TennCare.*

implication that the system operates for the convenience of government, not the well being of patients.51[51]

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 talking about. Even if one ignores the ethical violation 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."52[52]

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.53[53] 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.54[54] 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.

51[51] 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.

52[52] R.W. Buckman and R.D. Malan. 1999. "Clozapine for refractory schizophrenia: The Illinois experience," *J Clin Psychiatry*, 60, Suppl 1, 18-22.

53[53] 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.

54[54] G. Vaile, L. Mechling, *et al.* September 1997. Ímpact of risperidone on the use of mental health care resources," P*sychiatr Serv*, 48(9).

Statistical studies no substitute for clinical judgment

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.

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 six 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

Given that

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. People this intimately involved are unlikely to prescribe a drug unless they think it will help, and given their specialist knowledge, the odds are that they will be right. The skyrocketing demand for atypical antipsychotics has occurred precisely because clinicians observed obvious improvement in patients using the drugs.

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.55[55]

Colorado reforms shortchange the severely ill

To their credit, Colorado officials bent on putting the government in charge of health care realized early on that they could not possibly make good medical decisions and that they would have to hire others to run the health care system of their dreams. Convinced that the state's role ought to be to provide equal health care for everyone, they promoted capitated care, a system in which the state policy analysts would set appropriate per capita payment levels for medical services, another term for the

To their credit, Colorado officials bent on putting the government in charge of health care realized early on that they could not possibly make good medical decisions…

55[55] Susan D. Horn, Phoebe D. Sharkey *et al.* March 1996. "Intended and Unintended Consequences of HMO Cost-Containment Strategies: Results from the Managed Care Outcomes Project," *The American Journal of Managed Care*, II(3), p. 262.

price of a year's worth of medical care, and private firms would compete for the contract to carry out the work.

The dangers of this kind of arrangement have been known for years. To begin with, there is ample evidence that government agencies, for a variety of institutional reasons, do a rotten job of setting prices.

Projected savings never materialize

Colorado officials, assuming that state contracted Medicaid managed care for mental health would be 5% cheaper than the fee-for-service system it replaced, constructed a mental health carve-out similar to the one in Tennessee. The basis for the 5% 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% of its projections of the costs for fee-for-service care. The behavioral health organizations Tennessee contracted with then spent up to 10% of the capitation payments to meet their own administrative costs. Finally, the state withheld 10% of capitation payments for noncompliance with contractual obligations, a step that the Colorado State Auditor recommended to Colorado's Department of Human Services in 1998. The result in Tennessee, as the acting Tennessee Mental Health Commissioner acknowledged in oversight committee hearings, was that mental health and substance abuse treatments declined by 15% in one year.

Quality declines

Quality also declined. Many patients did not receive care or lost continuity of care when traditional referral networks were disrupted. Funds previously earmarked for severely mentally ill patients were spread across the whole Medicaid population. 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."56[56]

56[56] 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).

According to a 1998 report by Colorado's Office of the State Auditor, Colorado's capitated Medicaid mental health carve-out is exhibiting many of Tennessee's symptoms. Colorado has 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 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.57[57]

Colorado has had no way to determine whether its per-person expenditures for mental health care were reasonable because the necessary data simply do not exist.

Shortage of care occurs when state sets prices below costs

Other evidence that the state does a poor job of setting prices, and that when prices are politically determined program costs come first, come from the Colorado's Medicaid health care managed care program. When Rocky Mountain CEO Mike Weber criticized the state's reimbursement rates, the ***Denver Post*** reported that the then executive director of the Colorado Department of Health Care Policy and Finance, Jim Rizzuto, said that accountants have reviewed the state's 2000-2001 payment rates for Medicaid HMOs and that he believed that they were accurate. He also said that he would not let the state be pressured by HMOs to overpay health care providers. "Our responsibility is to ensure the fiscal soundness of the program," he said.58[58]

Worried about their own fiscal soundness, Rocky Mountain HMO and the Kaiser Foundation Health Plan of Colorado have sued the state for shortchanging them. According to Marsha Austin, writing in the ***Denver Post*** in May 2000, District Court District Judge Warren O. Martin found that "Richard Allen, director of Colorado's Medicaid program, underpaid HMOs beginning in 1996 and even discouraged their participation in Medicaid managed care. 'Mr. Allen undertook to achieve savings

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57[57] 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.

58[58] Marsha Austin. October 3, 2000. *Denver Post.* As posted on the web at http://www.denverpost.com/business/biz1003a.htm on February 8, 2001.

by taking them out of the hides of the HMOs,' Martin found. 'He surreptitiously, and sometimes openly hid data from the HMOs…and in essence said, "If you don't like it, get out." ' " Citing losses, Rocky Mountain reduced its service area in 1998 and the Kaiser Plan cut its Medicaid enrollment from 6,000 in 1998 to 3,000 in 1999. In 2000 it was roughly 7,200.59[59]

Based on the number of firms and individuals that have stopped providing health care to people in state-run programs, and on the number of firms that have exited the private insurance market, the private sector is pulling resources out of health care in Colorado.

Unlike accountants and government officials, economists judge industry profits by the entry or exit of firms. Large numbers of firms exiting a particular line of business is a sign that expected profits are too low to sustain the current level of activity. Based on the number of firms and individuals that have stopped providing health care to people in state-run programs, and on the number of firms that have exited the private insurance market, the private sector is pulling resources out of health care in Colorado. This suggests that Colorado officials should reassess their ability to set prices.

Monopoly capitation dangerous for the sick

Even with responsible pricing, the perverse incentives of capitated care pose a real danger to patient health. Under fee-for-service arrangements, people pay for treatment received. Though proponents of health care reform in Colorado routinely claimed that fee-for-service physicians were a danger to patients' wallets because they ordered "unnecessary" procedures, there is little hard evidence to support that claim.

Providers have an incentive to spend less on treatment

There is evidence to support the contention that capitated payment systems can endanger patients if providers seek to increase their profits by spending less on treatment. This is true even if the capitated provider is a non-profit. In that case the same behavior occurs but the spoils typically accrue to staff members in perks like better working conditions and less strict cost control rather than to stockholders in the form of cash.

Providers can control their costs by imposing costs on patients in a variety of ways that are difficult to detect. They can refuse to tell patients that more effective, but more expensive, treatments exist. Patients locked into a capitated system by

59[59] Marsha Austin. October 3, 2000. *Denver Post.* As posted on the web at http://www.denverpost.com/business/biz1003a.htm on February 8, 2001.

government edict are singularly ill equipped to counter this behavior because they rely on providers for information about their condition. Providers can require that patients try less effective, less expensive treatments first, with the result that they save money but many patients are sick longer. They can also explicitly ration procedures. This may be done by financially penalizing physicians who refer "too many" patients for certain medical or diagnostic procedures. It can also be done explicitly by making people wait, often for years, for procedures that are readily available under fee-for-service medicine.

Severely ill neglected

Capitated health care systems around the world also systematically neglect the sickest parents. Britain has Third World cancer survival rates because its bureaucrats have ruled that advanced chemotherapy drugs are "too expensive." In Canada, patients die on waiting lists for heart bypasses. One estimate suggests that Canadian elderly get such poor care that they enjoy two fewer years of active life than their American counterparts. Even simple tests like pap smears can take 7 months. In 1988, patients in Sweden's socialist paradise waited 11 months for heart x-rays and another 8 months for surgery.60[60]

One estimate suggests that Canadian elderly get such poor care that they enjoy two fewer years of active life than their American counterparts.

In Colorado's capitated Medicaid mental health system, anecdotal reports suggest that the mentally ill wait for care, and that only those suffering acute psychosis or threatening suicide get prompt appointments. People also report that high staff turnover makes therapy less helpful. As one person with schizophrenia pointed out, when you've spent two years spilling your guts to someone and they leave because they're burned out, it is really hard to just start over. According to the State Auditor's report,

> Our findings support issues raised by some Medicaid recipients and mental health advocates regarding service declines. Colorado is part of a national study on managed care. The preliminary results of this study indicate that, for both years after capitation was implemented, there were increases in the number of clients who reported that they were refused service. The study also reports that there are reductions in the probability of both inpatient and

60[60]Anikka Schildt, "In Sweden, Equality Is Tinged with Inefficiency," Washington Post, August 16, 1988. Quoted in Michael Tanner, November 24, 1992. *Health Care Reform: The Good, the Bad, and the Ugly,* Policy Analysis No. 184, The Cato Institute, Washington, D.C.

outpatient use. This indicates a reduction in the number of services provided. The study also preliminarily reports that there are no negative impacts on outcomes as a result of the change in services.61[61]

It should be noted that negative impacts on outcomes depend on what one measures. Proponents of the British National Health System claimed good outcomes for 40 years even though a large fraction of the British population chose to avoid free national health care by paying for private care. While the National Health Service considered transportation to and from the hospital an essential service, surgical waiting lists of 800,000 out of a population of 55 million were said to have no effects on measured health. Only recently have articles detailing Third World cancer survival rates and other examples of life-threatening rationing begun making British newspapers.

Politics diverts funds from severely ill to those with less expensive complaints

Since politicians respond to votes, the tendency to pull resources from the severely ill and spend them on providing relatively cheap care to large numbers of people with less serious complaints characterizes almost all politically controlled capitated care systems. Political control also changes effectiveness measures, typically relying more on statistically based utilization measures of easily quantified health outcomes or on the impressions collected with surveys and site visits than on informed clinical opinions. Statistics on the operation of the health system as a whole are of limited value. The statistical studies that have made great contributions to better and less expensive patient care are often those that focus on how individual doctors or clinics treat individual conditions.

Only recently have articles detailing Third World cancer survival rates and other examples of life-threatening rationing begun making British newspapers.

Even with spending cuts of 5%, Colorado's mental health carve-out required that providers continue treating the severely mentally ill while adding broad, untested, new services like peer counseling and support services, family preservation services,

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61[61] 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. 16.

consumer drop-in centers, and early intervention.62[62] Under existing rules, a teenager eligible for Medicaid who is feeling depressed because she broke up with her boyfriend has as much claim on state health care spending through her school-based health care center as a chronic schizophrenic who needs atypical antipsychotics simply to maintain a semblance of normal functioning.

Although capitation did give the plans unprecedented flexibility in determining how to spend the state's money to improve individual functioning, the question is whether the expected gain in efficiency was enough to fund the additional services without negatively affecting those who were seriously ill.

Evidence from Utah suggests that the expected gains from capitated systems may never materialize. 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 3 years after it was instituted.

Evidence from Utah suggests that the expected gains from capitated systems may never materialize.

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."63[63]

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

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62[62] United State General Accounting Office. September 1999. *Medicaid Managed Care, Four States' Experiences With Mental Health Carveout Programs.* GAO/HEHS-99-118, p. 16.

63[63] 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.

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.64[64]

State and contractor to split money not spent on treatment

Pharmaceuticals are not now included in capitation rates for Colorado's Medicaid mental health program. But a pilot program to include them was proposed during the October 2000 budget process. According to the report, "the pilot program promotes this goal [of capitating prescription drug spending] by creating a financing model whereby MHASAs [Mental Health Assessment and Services Agencies] are given a financial incentive to properly manage utilization of the target medications while avoiding financial harm if the calculated rate is insufficient to meet the needs of consumers." It goes on to say that the purpose of the pilot program is to give the Department of Health Care Policy and Financing "time to develop a rate development model that is financially viable for full-risk capitation." The Department, in other words, would be encouraged to extend its failed price control activities to another segment of the health care market.

Colorado's Medicaid mental health care reform boils down to a government program in which the government and its contractors conspire to split the profits that come from reducing treatment for desperately ill people who have no other choice.

Given what is known about the operation of monopoly capitated systems in Colorado and elsewhere, one aspect of the proposed pilot program is particularly revealing. The pilot contract discussed in the report would require that the MHASA contractors and the state share the gains anticipated when the roughly $16 million that was expected to be spent when reimbursement for antipsychotic medications is included in mental health plan capitation rates. The contractor would get to keep the first 5% of any savings generated. The second 5% would be shared, with 85% going to the contractor and 15% going to the state. The third 5% would be split with 60% going to the contractor and 40% going to the state. Anything above that would be evenly divided.

With this reform, Colorado's Medicaid mental health care reform boils down to a government program in which the government and its contractors conspire to split the profits that

64[64] 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.

come from reducing treatment for desperately ill people who have no other choice.

This is also the "reform" model that proponents of universal health care want to extend to every form of medical care in the state. The mentally ill are but the canaries in the coal mine. Sensible people will consider how well the state is caring for them and call for real reforms, those which put patients in charge and get state government out of the health care business.

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