What Americans Should Know Before Letting Government Control Medicare's Medicine Cabinet

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Executive Summary

Contrary to popular belief, recent proposals peddled as helping two of America's most vulnerable populations—the low-income elderly and the disabled who are participating in the federal Medicare program—may actually do the opposite. Before adopting a government-controlled prescription drug program, Americans should know about and publicly debate what government control over prescription drugs could mean for these vulnerable populations.

The lessons of government-controlled health care in the United States and Canada provide enormous insights and reveal the dangers of such an approach. Touted as providing quality care for all, those without economic or political clout are often relegated to inferior care under these programs.

Take, for example, the federal government's Veterans Affairs (VA) pharmacy benefit program. Under the program's restrictive formulary, only 12 of the 31 most-common drugs used by elderly and disabled Medicare recipients are available to patients in the VA program. In fact, the program is slow to add new drugs for patients. This example of government-controlled medicine is not unique.

The government's virtual monopoly over the health care system in Canada has made it virtually impossible for its citizens to obtain high-quality drug treatments. Since the government will not approve payment for many of the newest treatments, patients lacking the means to travel outside their country for treatment wait, in some cases, years for access to the same effective treatments that many Americans receive.

The American health care system, despite its imperfections, has the best available drug innovations and treatments anywhere in the world. Government control over health care, both in the United States and in other nations, not only allows bureaucrats to interfere and override important health care decisions that rightfully belong with doctors and their patients, it consistently leaves the most vulnerable populations without access to the best available drug treatments.

Before lawmakers impose a risky plan to allow government-control over access to important prescriptions drug treatments for our nation's elderly and disabled populations, the public should know the risks and decide if they are willing to surrender control over these important health care decisions to the government.

Introduction

Propelled by the upcoming elections, the debate over whether to create a prescription drug benefit for the federal Medicare program and, if so, how it should be designed has become a highly-charged political issue in recent months. The federal Medicare program currently covers about 38 million seniors and disabled beneficiaries. The program does not currently provide coverage for outpatient prescription drugs.

In addition to several proposals in Congress, both major presidential candidates, Republican nominee George W. Bush and Democratic nominee Al Gore, have also developed their own prescription drug benefit plans.

But before the public embraces *any* proposal that would establish government control over prescription drugs for the elderly and disabled, there are several things they should know about and publicly debate:

In an effort to control costs, governments limit access to the newest, most-effective drug treatments. This paper provides examples of price controls and rationing in Canada and in the American Veterans Affairs (VA) health care program.

In fact, only 12 of the 31 drugs most used by elderly and disabled Medicare beneficiaries are currently available under the Veteran's Affairs pharmacy benefit program. There is good reason to believe that the same cost-control strategies that keep many of the newest, most-effective prescription drug treatments out of the hands of America's veterans would be used to control costs under the Medicare program.

The most frightening aspect of these proposals is that the most vulnerable populations—the low-income elderly and disabled—will actually face the greatest dangers under a government-controlled prescription drug benefit pro-

Just What the Doctor Ordered

"To help senior citizens who cannot afford medication, Congressional leaders should look at new and creative strategies to provide assistance. One possibility is to offer tax credits for contributions made to private pharmaceutical assistance programs. Doing so could encourage drug companies to replicate the GlaxoWellcome charitable prescription program, which offers certain drugs for up to 90 consecutive days at a cost of $5 to $10 to those without sufficient financial resources to pay full price."

-Twila Brase, RN, PHN, "Drug Coverage Debate Misses Real Issues,"* Heartland Institute Intellectual Ammunition, *May/June 2000.

gram. That is because government cost-control strategies will keep the most effective treatments out-of reach. The result will be unneeded and prolonged suffering for those without the economic means to seek health care services outside the government-controlled system.

Surrendering control over these important health care decisions to the government holds enormous risks, especially for the nation's low-income elderly and disabled populations. If the public considers these risky plans to allow government-control over important prescriptions drug treatments for these vulnerable populations, they should first understand how the Canadian system and the American government's own VA health care program treat their patients.

Examples of Government-Control

With numerous available examples of governments limiting access to prescription drug treatments, one has to wonder why the media and politicians have paid scant attention to these experiences. Almost exclusive attention is being devoted to the components of the proposed plans and their estimated program costs. This is premature. In order to have a fully-informed debate and to avoid repeating the failed approaches of the past, it is important to first understand how other similar attempts have fared and learn from these valuable lessons.

The American Experience

Many Americans may not be aware that some public health care programs are already providing prescription drug benefits. Take, for example, the Veterans Affairs (VA) health care program.

In order to control costs, the VA maintains a list of prescription drugs that doctors may prescribe for veterans participating in the VA health care program. This list is called a formulary. Not only does the VA generally keep a new drug off its formulary for at least one

Destroying Health Care

"If the state prevents physicians for prescribing medicines as a strategy to save costs, the system is bound to fail. The ability to prescribe medicines is a central part of practicing medicine."

-Miami physician Dr. Angel E. Garrido

year after it gains Food and Drug Administration (FDA) approval, the VA is slow to add new drugs to its formulary. (The VA policy is based, in part, on the belief that some veterans could experience drug side effects that were not identified during the drug application, review, and approval processes.)

In 1999, the VA national formulary added 43 products. During that year, however, it deleted 20 products for a net gain of 23 products. To fully appreciate the limitations of the VA formulary, it is helpful to compare it to drugs that are already commonly used.

A recent report by the White House's National Economic Council identified, using 1996 data from the U.S. Department of Health and Human Services, the 20 most used drugs for both elderly Medicare recipients and disabled Medicare recipients.[1] (See Tables 1 and 2.) After accounting for drugs that appeared in both lists, 31 drugs remained.

Even if, in 1996, some of these drugs were new, sufficient time has now elapsed to add these drugs to the VA formulary. Yet today, only 12 of the 31 drugs are listed in the VA formulary.

While the generic alternative is, in most cases, available for the most popular drugs, research indicates that these types of formulary limitations "may place the elderly at particular risk."[2] Elderly patients tend to have more side effects and tend to react less predictably to certain drugs. That is why allowing government bureaucrats to interfere with the health care decisions of doctors and their patients can create additional concerns for this vulnerable population.

In addition to the national formulary, which is the list of nationally-available prescription drugs for veterans, there are 22 Veteran Integrated Service Networks (VISN), or area-based veteran care facilities, that also maintain their own formularies. According to the U.S. General Accounting Office, the VISNs have added drugs to their formularies at varying rates. (See Table 3.)

One's geographic location is closely tied to prescription drugs available through the VISN. Given the wide variation in the number of drugs added to VISNs, one can presume that veterans in certain areas, such as Bay Pines and Omaha, have far less access to certain prescription drugs.

When a needed drug treatment is not available through the national formulary or the VISN, the treating physician may apply for a waiver for a non-formulary prescription drug. Once again, the process varies by VA medical facility.

Robert Goldberg, a senior fellow at the Washington, D.C.-based Ethics and Public Policy Center, provides an example of how the VA formulary restricts access to the most effective treatments. As Goldberg notes "VA patients with pancreatic cancer are not allowed to receive Gemzar, the newest drug for that disease, as a matter of course. They must "fail" on other drugs first."[3]

Table 1: Drugs Most Used by Aged Medicare Beneficiaries.

Drug	Treatment for:	Available under VA National Formulary?
Lanoxin	Heart failure	Yes
Furosemide[a]	Heart failure (diuretic)	Yes
Synthroid	Thyroid disease	No
Coumadin	Stroke; clot prevention	Yes
Premarin	Estrogen replacement	No
Atenolol	Heart disease; hypertension	Yes
Vasotec	Heart disease; hypertension	No*
Zantac	Stomach acid reducer	No
Norvasc	Heart disease; hypertension	No
Triamterene/HCTZ	Hypertension; heart failure	Yes
Cardizem	Heart disease; hypertension	No
Lasix	Heart failure (diuretic)	No
Zestril	Heart failure; hypertension	No
Hydrochlorothiazide	Heart failure; hypertension	Yes
Prilosec	Stomach acid reducer	No*
Zocor	High cholesterol	No
K-Dur	Potassium replacement for diuretics	No
Hytrin	Prostatic hypertrophy	No
Verapamil	Heart disease; hypertension	Yes
Procardia	Heart disease; hypertension	No

[a] Lasix generic alternative.

* No generic alternative listed on VA formulary.

Sources: U.S. Department of Health and Human Services analysis of MCBS 1996 as cited in *The White House National Economic Council / Domestic Policy Council*, "Disability, Medicare, and Prescription Drugs," July 31, 2000; *VHA National Formulary*, September 2000, at www.vapbm.org/PBM/natform.htm.

Table 2: Drugs Most Used by Disabled Medicare Beneficiaries

Drug	Treatment for:	Available under VA National Formulary?
Dilantin	Seizures	No
Furosemide*	Heart failure (diuretic)	Yes
Zantac*	Stomach acid reducer	No
Coumadin*	Stroke; clot prevention	Yes
Premarin*	Estrogen replacement	No
Prednisone	Arthritis; hormone replacement	Yes
Amitriptyline	Anti-depressant	Yes
Clozaril	Mental illness	No
Prozac	Anti-depressant	No
Lanoxin*	Heart failure	Yes
Prilosec*	Stomach acid reducer	No**
Vasotec*	Heart disease; hypertension	No**
Synthroid*	Thyroid disease	No
Zoloft	Anti-depressant	No
Benztropine	Parkinson's disease	Yes
Lasix*	Heart failure (diuretic)	No
Ibuprofen	Pain; anti-inflammatory	Yes
Paxil	Anti-depressant	No
Depakote	Manic disorder; Epilepsy	No
Trazodone	Anti-depressant	Yes

* Drug also appears in Table 1.
** No generic alternative listed on VA formulary.
Sources: U.S. Department of Health and Human Services analysis of MCBS 1996 as cited in *The White House National Economic Council / Domestic Policy Council*, "Disability, Medicare, and Prescription Drugs," July 31, 2000; *VHA National Formulary*, September 2000, at www.vapbm.org/PBM/natform.htm.

Table 3: Drugs Added to VISN Formularies, 1998 and 1999.

VISN		1998	Jan.–June 1999	Total
1	Boston	8	5	13
2	Albany	10	6	16
3	Bronx	20	2	22
4	Pittsburgh	21	0	21
5	Baltimore	6	10	16
6	Durham	22	6	28
7	Atlanta	50	9	59
8	Bay Pines	2	0	2
9	Nashville	15	0	15
10	Cincinnati	12	3	15
11	Ann Arbor	10	9	19
12	Chicago	13	9	22
13	Minneapolis	30	3	33
14	Omaha	5	1	6
15	Kansas City	13	18	31
16	Jackson	6	3	9
17	Dallas	18	8	26
18	Phoenix	7	1	8
19	Denver	16	3	19
20	Portland	52	35	87
21	San Francisco	19	5	24
22	Long Beach	36	18	54
	Total	391	155	546
	Unduplicated Total	215	53	268

Source: U.S. General Accounting Office, *VA Health Care: VA's Management of Drugs on Its National Formulary*, GAO/HEHS-00-34, December 1999, p. 11.

At that point, a physician could apply for a waiver. Of course, this is after the veteran has already needlessly suffered and delayed more effective treatment options. Not only do the VA health care program's restrictive formularies delay access to some of the most-effective treatments, the program continues to restrict access to these treatments, even when medical evidence supports the newer treatment.

The federal-state Medicaid program, which provides health care for the poor, is another government program using formularies as a cost-control measure. Because the formularies are administered on the state level, less is known about the availability of drugs in this program. However, a 1992 study did find that, during the first four years of market life, a new FDA-approved drug was available less than 40% of the time.[4]

Relatively few Americans are participating in and subject to the VA and Medicaid health care programs' restrictive formularies. If the momentum for adding a prescription drug benefit continues, however, that could change. There are about 38 million Americans participating in the federal Medicare program, including about 5 million disabled participants. Before putting these tens of millions of Americans under the same type of government-controlled health care drug program, we should also learn about the experiences of our Canadian neighbor to the north.

Canada

Most Americans have seen media accounts of elderly Americans crossing the border to purchase prescription drugs in Canada. What they fail to show, however, is the untold number of Canadians who come to the U.S. to purchase needed drugs because they cannot be obtained in Canada—at any cost.

In Canada, the government control of pharmaceuticals creates delays in approving drugs for patient use in a number of ways. First, the Therapeutics Products Program, a division of Health Canada, the federal government's health care agency, reviews the safety and efficacy of new drugs. If approved, the drug may be prescribed by physicians and dispensed by pharmacies.

Next, the federal Patented Medicines Prices Review Board (PMPRB) then determines introductory prices for patented innovative drugs. Finally, a committee in each of the nation's provinces determines if the drug should be eligible for reimbursement. If so, the drug is available on the provincial formulary for those individuals covered by the provincial government's prescription drug benefit.

The Canadian federal government takes about 7 months longer than the United States' FDA to approve a drug. (See Figure 1). One recent study published in the *Canadian*

Medical Association Journal found that, despite improvements in recent years, the process remains considerably longer than the government's own performance target.[5]

Second, the provincial government will frequently delay approval for addition to its formulary. When a drug is listed on the provincial formulary, it is paid for or subsidized for financially or medically needy patients. In an effort to contain costs, most Canadian provinces are slow to add new drugs to their formularies.

For example, in Ontario, Canada's most populous province and home to the nation's capitol city of Ottawa, the drug plan added only 12 drugs with another 23 listed on a restricted basis for a total 35 drugs over a two-year period. That is compared to the province of Quebec that added 64 drugs with another 16 added on a restricted basis for a total 80 drugs. (See Figure 2).

The Canadian system of price controls also delays entry of pharmaceutical drugs into the country. The Patented Medicines Price Review Board oversees and negotiates drug prices with drug companies. In general, a new drug cannot be sold for an amount more than the price for a similar drug treatment, even if it is more effective.

Because pharmaceutical companies pass along their research and development costs to the consumer in the price of their products, they have a financial interest in charging a price that allows them to recoup their investment costs and to make a profit. When the Canadian government imposes price controls, drug producers may choose to not sell their products in Canada. The price control system, coupled with the drug approval processes on the federal and provincial levels, leaves patients with fewer treatment options that could enhance and lengthen their lives.

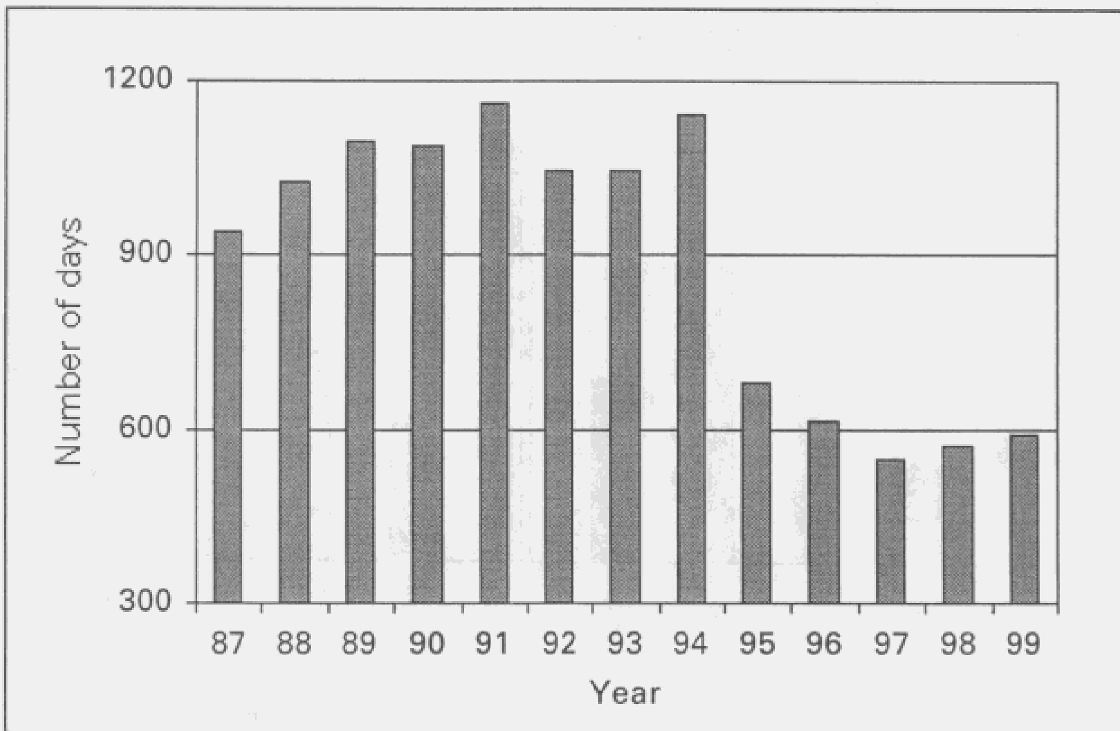
The Canadian health care system was built with the best intentions, but in order to contain drug costs,

The Bottom Line

"After year of bureaucratic delay, thousands of Canadian patients with an incurable for of non-Hodgkin's lymphoma finally got their first new weapon against the disease in nearly 15 years. Some critics say it has taken too long for (the drug), approved for use in the United States exactly two years ago to come to Canada. Non-Hodgkin's lymphoma affects about 15,000 Canadians. In 1999, an estimated 2,500 Canadians died of the disease."

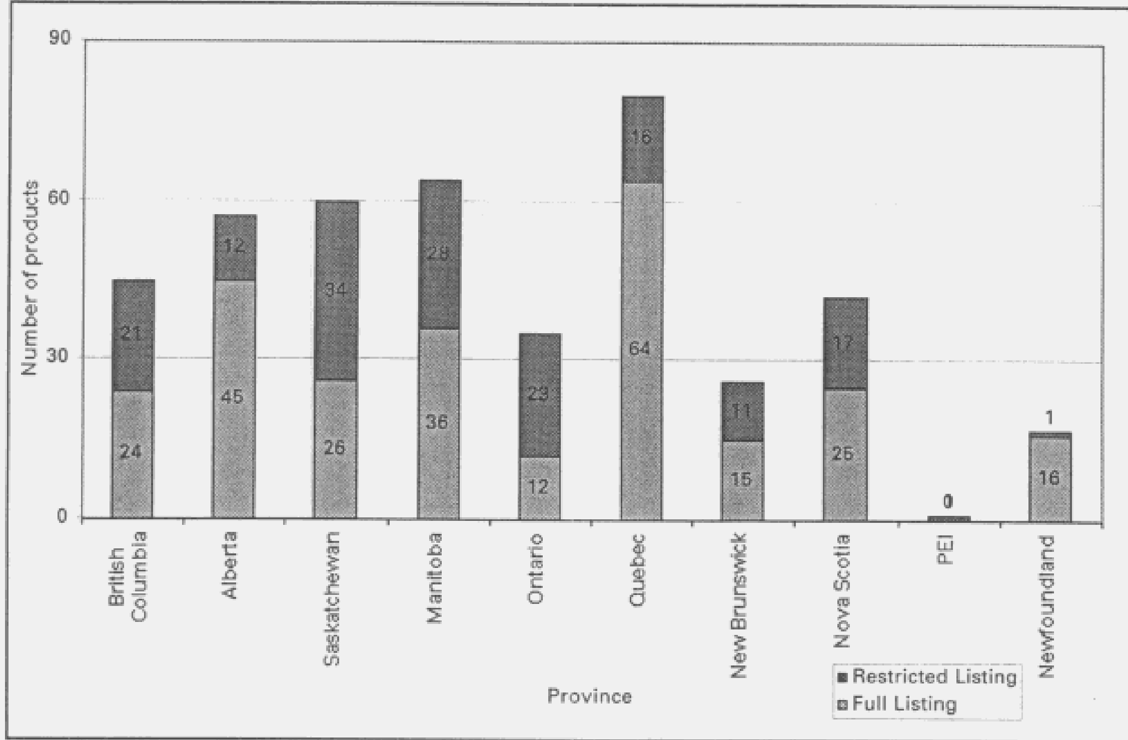
-National Post, *April 5, 2000 as cited in Canada's Research-Based Pharmaceutical Companies, Rx&D, "Impacts of Drug Cost Containment and Price Controls in Canada,"* Rx&D Issues and Backgrounders, *April 10, 2000.*

Figure 1. Days to Approval in Canada.



Source: Rx&D, Canada's Research-Based Pharmaceutical Companies, "Drug Approval Times in Canada 1999," June 2000.

Figure 2: Additions to Provincial Formularies, December 1, 1997 to November 30, 1999



Source: Rx&D, Canada's Research-Based Pharmaceutical Companies, "Drug Approval Times in Canada 1999," June 2000.

the federal and provincial governments severely limit access to prescription drugs. While more affluent Canadians are able to travel to purchase needed health care treatments and prescription drugs, low-income Canadians are relegated to continue suffering under a system that provides no options for better care.

Why Individual Choice Matters

Advocates of a universal prescription drug benefit passionately defend the proposals' principles of universality and accessibility. But even the most ardent advocates cannot deny a substantial gap between these principles and how it works in practice in Canada and in the American VA health care program. For Americans, it is more prudent to evaluate the system not by its goals and rhetoric but practical results.

In particular, observers should pay particular attention to the implications of the Canadian system and the American VA programs' approaches to the most vulnerable members of society. The value of equality may be a noble goal, but both these systems respond to mounting financial pressures by rationing care. Whatever the intent, severely limiting access results in inferior care, leaving the poor with no other options but to needlessly suffer.

Proponents of a prescription drug benefit, while well-intentioned, are advocating a risky proposal that fundamentally puts government bureaucrats, rather than doctors and patients, in control of determining to which health care options the nation's elderly and disabled populations will have access.

Doctor Bureaucrat in Canada

"In my own experience, a 64-year-old male patient had controlled peptic ulcers for more than five years when the government required that he be switched to an older, less effective drug. Within three days he required hospitalization and a lifesaving blood transfusion. After 10 days in the hospital and several more transfusions, he was discharged and placed on the same drug he had taken originally."

-William McArthur, M.D.,
"Prescription Drug Costs: Has Canada Found the Answer?" **National Center for Policy Analysis Brief Analysis,** *No. 323, May 19, 2000.*

Conclusion

Before the public allows a government takeover of the Medicare medicine cabinet, there are three things they should remember:

- To control costs, governments limit access to the newest, most-effective drug treatments. Canada and the American government's own Veterans Affairs (VA) health care program provide two excellent examples of how government rules and bureaucratic decisions can undermine important health care decisions.
- The federal government keeps 19 of the 31 drugs most used by elderly and disabled Medicare beneficiaries out of our nation's military veterans' hands. Should we let the same government "take care of" our nation's most vulnerable populations' drug needs, too?
- The low-income elderly and disabled will face the greatest dangers under a government-controlled prescription drug benefit program that, in the name of cost-control strategies, will keep the most effective treatments out-of reach.

Allowing government bureaucrats, rather than doctors and their patients, to make important health care decisions jeopardizes the health of our nation's 38 million elderly and disabled citizens. Following the same, dangerous path as Canada and the American government's own VA health care program is a prescription for disaster that should not imposed on our most vulnerable populations.

Notes

1 The White House National Economic Council / Domestic Policy Council, "Disability, Medicare, and Prescription Drugs," July 31, 2000.
2 Susan Horn, Ph.D.; Phoebe D. Sharkey, Ph.D.; and Cheryl Phillips-Harris, M.D., "Formulary Limitations and the Elderly: Results from the Managed Care Outcomes Project," *The American Journal of Managed Care*, August 1998, 4 (8): 1105–1113.
3 Robert Goldberg, "Will a Medicare Drug Benefit Be Hazardous to Your Health?" Ethics and Public Policy Center, (forthcoming 2000), p. 9. Restrictions and/or criteria for use of Gemcitabine, a generic alternative to Gemzar, must first be considered at the facility or VISN level, according to the VA Formulary.
4 Goldberg, p. 8.
5 Nigel S.B. Rawson, "Time required for approval of new drugs in Canada, Australia, Sweden, the United Kingdom and the United States in 1996–98," *CMAJ*, February 22, 2000, 162 (4): 501–504.

About the Author

Naomi Lopez Bauman is the director of the California-based Pacific Research Institute's Center for Enterprise and Opportunity. She is also author of the forthcoming book, *Perilous Prescriptions: The Lessons of Government in Canada and the United States*.