Executive Summary
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Compromising Quality: The High Cost of Government Drug Purchasing

Edmund F. Haislmaier

Revised estimates of the new Medicare prescription drug benefit's projected cost have re-ignited congressional debate about the merits and design of the recently enacted Medicare legislation. One argument in particular has received renewed attention: the contention that the new drug benefit will be unnecessarily costly because the legislation does not allow the government to use the "enormous market clout" of the 41 million Medicare beneficiaries to drive down the price of drugs.

The truth is that the legislation's authors knew of Medicare's history of distorting the delivery of medical care by setting prices for hospitals and physicians. To prevent that from happening with drugs, they included "non-interference" provisions in the law to prohibit Medicare from interfering in negotiations between private plans, pharmacists, and drug companies or from imposing a national formulary or single-price schedule.

Success of Private Insurers and PBMs. Striking the right balance between drug price and availability is difficult. Unlike commodities such as wheat or oil, drugs are not easily substitutable for all patients, and there are varying degrees of price competition in the pharmaceutical market.

That is why the authors of the new Medicare law gave the job of striking the right balance to those with the most experience in doing it—private insurers and pharmacy benefit managers (PBMs). The private plans devised by PBMs and private insurers employ proven strategies for reducing the cost of prescription drugs while also promoting better patient outcomes and constraining overall health system costs.

Government Limitations. Critics argue that as a single, large purchaser, Medicare could do a better job of obtaining the best prices for drugs than PBMs and private insurers. Such assumptions are empirically wrong.

- **Less Market Clout.** Medicare is not as large as the critics believe. The number of enrollees in each of the three largest PBMs far exceeds the current 41 million Medicare enrollees. Thus, simply on the grounds of relative market share, having Medicare beneficiaries obtain drugs through existing PBMs would seem sound. After all, Medicare enrollees would be able to join large, private buying groups that already successfully provide drug benefits for millions of Americans.
- **Market Inexperience.** Unlike the managers of private drug benefit plans, who have decades of experience in managing prescription drugs, Medicare's managers have no previous experience buying outpatient prescription drugs and

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are notorious for inefficient bureaucracy. Thus, in order to obtain the necessary expertise, Medicare would likely have to rely on private PBMs anyway.

Harmful Government Strategies. As a sole purchaser of drugs for seniors, the government could employ four additional strategies that are not available to private insurers or PBMs in order to extract further discounts from drug makers. The unintended consequences of those strategies, however, could be to:

- **Impose increased substitution.** Unlike private insurers and PBMs, who must maintain a careful balance between encouraging drug substitution and satisfying consumers, the government can impose a single, restrictive drug formulary that puts price considerations ahead of patient benefit or clinical appropriateness. This would leave patients with no alternatives—at least none for which the government will help to pay the costs.
- **Restrict market access.** If a manufacturer refuses to charge prices that are acceptable to the government, the government can simply deny seniors access to those drugs. Yet patients denied access to drugs under a government program cannot simply choose a different plan as they could in the private sector.
- **Control intellectual property and limit pricing freedom.** Governments establish patent laws to reward manufacturers for developing innovative products. Such laws grant those manufacturers market exclusivity for a period of time. But a government intent upon coercively controlling costs could decide to reduce or eliminate a company's patents, thereby allowing others to copy the innovation and impeding a company's ability to recover its investment costs. Such a move would seriously undermine future innovation, as well as international patent laws, and restrict the flow of new products to consumers.
- **Extract price concessions by non-market means.** Government can also use its powers over aspects of a manufacturer's business that are not directly related to its products—such as tax policy, financial market access, and a host of other regulatory regimes—to extract price concessions. For example, pending legislation would penalize any drug company that limited sales of its products to wholesalers who re-import them to the U.S. from countries with drug price controls. It does so by prohibiting the manufacturer from deducting advertising and marketing expenses, which are normal deductible business expenses under corporate tax law. Yet such moves would undermine market confidence in the fairness and predictability of corporate tax laws among other companies and industries. It could also spark trade conflicts between the U.S. and other countries if drug makers responded by refusing to sell their products in those countries.

Conclusion. While there is much to criticize about the design of the new Medicare prescription drug benefit, the basic structure of coverage provided by competing private plans, free of government interference, is actually a commendable feature of the legislation. Any attempt by the government to circumvent those market mechanisms out of a desire to pay even lower prices would have an unfavorable impact on pharmaceutical investments, research, and development while also diminishing the quality of health care received by America's seniors.

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Recently revised estimates of the projected cost of the new Medicare prescription drug benefit have re-ignited congressional debate about the merits and design of the recently enacted Medicare legislation. One particular argument that has received renewed attention, both in and out of Congress, is the contention that the new drug benefit will be unnecessarily costly because the legislation does not allow the government to use the "enormous market clout" of 41 million Medicare beneficiaries to drive down the cost of drugs.

Proponents of this argument point to a provision in the new law that prohibits the federal government from interfering in price negotiations between drug makers and the private plans that will provide the new drug coverage to seniors.[1] Legislation has been introduced to repeal the provision.[2]

This criticism sounds reasonable at first blush. After all, if the government is now going to help pay for seniors' drugs, should it not use its new purchasing power to get the elderly a better deal on their medicines?

A Flawed Argument

This argument, however, fails to recognize that drugs are not a commodity like wheat, sugar, or oil. What makes something a commodity is that all the suppliers are offering essentially the same product; therefore, price is what matters most to the buyer when choosing between suppliers.

This is not the case with drugs. Thanks to pharmaceutical innovation, doctors can choose from a

Talking Points

- The Medicare drug entitlement is deeply flawed both in its structure and in its financing, but its reliance on competing private plans guarantees a better performance than does reliance on the Medicare bureaucracy in the pricing and delivery of prescription drugs.
- Medicare's assumed "market clout" is considerably less than that which already exists among large, private-sector pharmacy benefit managers, and Medicare has no experience whatsoever in managing prescription drug benefits.
- The government should refrain from reducing the quality of drug coverage available to seniors by imposing drug substitution, restricting market access, limiting intellectual property rights or pricing freedom, or extracting price concessions by non-market means.

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number of different drugs when treating high blood pressure, diabetes, depression, elevated cholesterol, bacterial infections, HIV, and many other medical conditions. The drugs available to treat a given condition are not necessarily interchangeable. One drug will work better for some patients, and another will work better for others.

Thus, if the government decides—based mainly on price—which drugs to buy for 41 million Medicare enrollees, it may very well limit what it spends on drugs, but it will do so at the expense of treating some patients' illnesses. Such a practice could even result in Medicare's spending *more* on doctor and hospital visits by substituting less effective drugs for more effective ones.

Government's Limitations. Striking the right balance between drug price and availability is difficult. That is why the authors of the new Medicare law gave that job to those who are already doing it and who have the most experience doing it—private insurers and pharmacy benefit managers (PBMs).

The traditional Medicare program has certain inherent limitations in managing a drug benefit. Specifically:

- **Medicare's market clout is inferior to that of the largest existing PBMs.** For example, Advance PCS covers 75 million individuals, Medco Health Solutions covers 65 million, and Express Scripts covers 57 million—in each case, far more than the existing 41 million covered by Medicare. By allowing Medicare beneficiaries to buy into these and other existing PBMs, Congress will enable millions of these beneficiaries to take advantage of the even larger "market clout" of the private sector, in which PBMs are already successfully providing drug benefits for additional millions of Americans. The real question is: Could the government do a better job? The answer is that it could not—at least not without adversely affecting the quality of patient care for Medicare beneficiaries.
- **Medicare's experience in managing drug benefits is inferior to that of private-sector alternatives.** Unlike private plans with decades of experience in managing drug programs, Medicare has no experience buying outpatient prescription drugs. Unlike traditional government management of drug programs—which relies on such negative strategies as market access restrictions—the new Medicare law allows Medicare beneficiaries to choose between competing private prescription drug plans. In that way, the plans will have to respond to consumer pressure both to keep costs down and to maintain access to a broad range of drug therapies. Medicare patients can have the best access to the right drugs at the best prices through real, competitive market forces.
- **Government intervention will undermine quality and patient choice.** If the government were to step into the middle of negotiations among PBMs, pharmacies, and drugs companies, it would override their decisions—effectively making the PBMs irrelevant. In order to be more effective than PBMs, the government would have to tell drug makers, "Accept what we're willing to pay or we won't make your drug available in Medicare." This would leave some patients without the drug that works best for them. In that case, they could no longer choose a different plan that covered the drug they needed, because none would be available. Instead, the patients (with the drug makers right behind them) would have to lobby Congress to overrule Medicare.

There are ample grounds for criticizing the new Medicare drug provisions. Although the problem of access to drug coverage was limited to a minority of seniors, Congress and the Administration

1. Sec. 1860D–11(i) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108–173.
2. Recently introduced bills that would, among other provisions, repeal Sec. 1860D–11(i) of P.L. 108–173 include S. 1950, sponsored by Senator Richard Durbin (D–IL); S. 1992, sponsored by Senator Edward Kennedy (D–MA); S. 1994, sponsored by Senator Thomas Daschle (D–SD); and S. 2053, sponsored by Senator Olympia Snowe (R–ME).

insisted on creating a universal entitlement. This entitlement expansion will cause an explosion in costs and will displace existing drug coverage, including employment-based retiree coverage. However, Congress and the Bush Administration wisely decided against government pricing—or the monopsony purchasing of drugs.

The Economic Rationale for Drug Price Discounts

To understand the rationale behind the design of the new Medicare drug benefit and the reasons the authors included "non-interference" provisions in the legislation, it is first necessary to understand the basic economics of price discounting. It is then necessary to understand how price competition works in pharmaceutical markets. Finally, it is necessary to consider the ways in which direct purchasing of drugs by Medicare would differ from the way drugs are currently purchased by private insurers and PBMs, and the likely effects that could result from those differences.

Degrees of Price Competition in Markets

As the popularity of wholesale stores attests, even those with a limited understanding of economics have experience in obtaining reduced unit prices for larger-volume purchases of goods. Wholesale discounts are the product of both supply-side and demand-side considerations.

- On the *supply side*, producers can afford to accept discounted prices without incurring much impact on profitability when lower revenues are compensated for by equivalent reductions in packaging, shipping, and production costs.
- On the *demand side*, large-volume purchasers can command lower unit prices from producers when they account for a proportionately larger share of the producer's business. The producer has a proportionately greater interest in accommodating such purchasers.

However, economists recognize that the phenomenon of price discounting in exchange for volume purchases is ultimately a function of two other factors: competition and substitution.

- If *competition* among producers does not exist because one producer has a monopoly, or because there are only a few producers who are operating in a cartel, a producer has little or no incentive to offer discounts for volume purchases. If even a big-volume buyer cannot get the goods from another supplier at a lower price, why should the producer offer a discount? Instead, the producer can pocket as added profit any savings from manufacturing efficiencies or bulk shipping.
- A closely related factor that reinforces competition and works against the interests of producers is *substitution*. For competition to work—and price discounting to occur—it is not always necessary that several producers be selling identical goods. It is often sufficient that competing producers sell goods that are similar enough that consumers can substitute one for the other without being greatly inconvenienced.

Hence, economists recognize natural gradations in price discounting that conform to different degrees of competition and substitution. The greatest discounting—and thus the thinnest profit margins for producers—occurs when there are multiple producers for the same good and buyers can easily substitute the goods of one producer for those of another because there are few, if any, differences in quality. Examples would include items such as flour, sugar, oil, or copper. Economists call such goods commodities.

The next level, which features less discounting and substitutability, is made up of goods that are largely similar, but not identical: for example, buying Pepsi instead of Coke. Many consumers treat those goods as substitutable, but others clearly prefer one to the other.

At the next level are products that are decidedly different but still similar enough to be considered substitutable by some buyers under the right circumstances. For example, increased beef prices might lead some shoppers to buy chicken instead. Yet the price difference would have to be significant for significant numbers of consumers to make that substitution.

Finally, there are those goods for which it is very difficult—or, in the case of a monopoly, impossible—for buyers to find a satisfactory substitute.

Those goods face the least price competition and thus generate the highest profit margins for producers. Producers of these goods have little incentive to offer discounts, and consumers have little leverage with which to demand discounts (no matter how large a quantity they buy) because there are no alternative products that they can reasonably substitute for the product in question.

Dynamics of Pharmaceutical Markets

To understand the dynamics of pharmaceutical markets, and the extent and limits of price competition for prescription drugs, it is first necessary to determine where various drugs fall on the scale of product substitution and competition. The place to begin is with the patent system that stimulates the development of new drugs.

Patent Policy. Governments encourage all types of innovation by granting time-limited monopolies to inventors and authors through the legal instruments of patents and copyrights. Political theorists have long recognized that granting such limited monopolies benefits all of society.

First, they are powerful incentives for creativity and invention, since they give authors and inventors time to recoup their investment before others may copy their work. Thus, patents and copyrights help to generate a steady stream of new and improved products for sale to the general public.

Second, they encourage the creation of useful products because only products that people view as desirable or beneficial will sell.

Third, the public further benefits because, once the patent or copyright expires, additional producers can legally enter the market and prices will drop as a result of the ensuing competition. Indeed, America's Founding Fathers considered such incentives important enough to provide for them in the U.S. Constitution.[3]

Pharmaceuticals are a prime example of the wisdom and benefits of encouraging innovation through the granting of patents. Virtually all Americans today live longer, healthier, more productive, and more enjoyable lives thanks to the invention and use of hundreds of pharmaceuticals, most of which were developed only in the past 50 years.

Today, half of all drugs consumed in the United States are generic drugs. In some cases—at a cost of pennies per pill—the very poorest of Americans can now be spared death from illnesses that claimed the lives of even the wealthiest in previous centuries. Yet none of those drugs would be available today had not patents granted years ago given researchers and companies the necessary incentives to discover and produce them.

Other drugs consumed today are still on-patent, and manufacturers can command much higher prices for them. While many complain that those prices are too steep, it would not be difficult for any American to find in his or her family history a relative whose life could have been saved by some drug that is currently on-patent. The prices of these drugs may be high, but so too can be the cost of not having them. Over time, these drugs will lose their patents and drop dramatically in price as generic competition begins.

Drug Categories. Although patents are essential to the ongoing cycle of pharmaceutical innovation, they also affect the prices charged for different drugs. Hence, the next step in understanding the economics of the pharmaceutical market is to divide all drugs into four broad categories, based on their relative substitutability and price competitiveness.

1. Generic products. Strictly speaking, generic products are identical to each other in all important respects. That is, the active ingredient is the same, the dosing is the same, and the bioavailability (the length of time that the drug is absorbed, present in the body, and then excreted) is the same.

True generics are the commodities of the pharmaceutical market. They are easily substitutable, and price is their only real difference. Thus, pricing

3. One of the powers of Congress enumerated in Article I, Section 8 of the U.S. Constitution is "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

pressure on manufacturers is greatest for generic drugs, and they are the cheapest of all drugs.

2. Products with the same compound but different bioavailability. For many patients, these products are safely substitutable. However, for some patients with some drugs, such substitution is not medically appropriate. A common example would be two drugs with the same compound (or active ingredient), one with a dosing regime of three times a day and the other with a once-a-day dose.

To the patient, the main difference may seem to be one of convenience. In fact, as the physician knows, the difference in bioavailability between two different dosing regimes can sometimes be important to the success of the treatment.[4]

As with true generics, there is considerable leeway for substituting drugs when the active ingredient is the same but the bioavailability is different. The exception occurs when an innovator company uses a patented drug delivery technology to create a new version of an existing drug. In fact, there are at least 47 U.S. biotechnology companies that currently specialize in developing new drug delivery technologies.[5]

In such cases, while the drug may be available as an off-patent, low-price generic, the manufacturer of the new version can charge more because the delivery technology used by the drug is still on-patent. The greater the benefit from the new formulation of the drug, the more scope the manufacturer has to charge higher prices for the new version. Yet if the outcome for the patient is likely to be much better, the use of this more expensive drug may actually reduce the total cost of treatment—even though the new drug costs more than its generic competitors.[6]

3. Therapeutically similar products. These drugs have different active ingredients but treat the same condition in a similar manner. A good example is the half-dozen drugs currently available to regulate cholesterol levels. All of the drugs in a therapeutically similar class may be on-patent, or some may be on-patent while others are off-patent generics. When doctors can safely substitute one of these drugs for another in a particular patient (a practice known as "therapeutic substitution"), relative price differences can become a consideration in deciding which drug should be used.[7]

However, for some patients, such substitution is not medically appropriate. For example, if a doctor has different patients with the same condition but with different severities of the illness and/or with other medical conditions present (called "comorbidities"), it is medically appropriate for the doctor to prescribe whatever drug best treats each patient from among those available in a given therapeutic class. Also, different drugs in a therapeutic class may have different side effects, and individual patients will differ in their abilities to tolerate

4. Chemists can plot a bioavailability curve starting at zero (when the dose is first taken) and rising (as the drug is absorbed). Once the body has absorbed most of the drug, the curve falls off as less and less of the dose is available. Finally, the curve reaches zero again once the entire dose has been consumed and excreted. In cases in which it is important to have a consistent level of the drug in the body over a sustained period, the timing of doses is scheduled so that the curve of each new dose overlaps with that of the previous dose.
5. Rachel Zimmerman, "New Ways to Take Old Drugs Help Patients, Extend Patents," *The Wall Street Journal*, March 15, 2004, p. B1.
6. For example, naltrexone, for which the patent expired in 1998, helps treat alcohol and opiate addictions by reducing cravings and negating the effects of alcohol. Taking naltrexone for several months as part of an addiction treatment program increases the chances that a patient will achieve sustained sobriety. However, because naltrexone is taken as a daily tablet, if the patient skips a dose, relapse can occur. Consequently, its success in treating addictions in the clinical setting has been limited. However, the biotechnology company Alkermes is now in late-stage testing of a monthly injectible version of naltrexone. If approved by the Food and Drug Administration, the new formulation will be much more likely to help patients successfully complete an addiction treatment program. Instead of relying on the patient to take a pill every day, the physician would be able to administer a monthly injection and thus ensure that the patient is benefiting from the drug. See *Ibid.* See also *www.nlm.nih.gov/medlineplus/druginfo/medmaster/a685041.html.*
7. Technically, substituting drugs with the same compound but with different bioavailability is also therapeutic substitution.

those side effects. Again, the appropriate course is for the doctor to prescribe the drug that does the best job of treating the condition with the least potential for otherwise harming the patient.

If therapeutic substitution is medically appropriate, the relative prices among drugs within a therapeutic class can be a legitimate consideration in deciding which drug is most appropriate. Yet the size of the price differences among those drugs—and the extent to which competition will force down prices for most, or all, drugs in a class—is a function of the degree of appropriate substitutability among the various drugs. When two or more drugs in a therapeutic class are very similar (and thus appropriately substitutable for most patients), significant price competition occurs, and prices for all the drugs in that class drop as similar drugs enter the market. Indeed, this price discounting occurs even if all the drugs in a given class are on-patent and, theoretically, their manufacturers could thus charge monopoly-level prices.[8]

Conversely, the fewer the similarities and the greater the differences in relative therapeutic benefit and side-effect profiles among drugs in the same class, the fewer the number of patients for whom therapeutic substitution is medically appropriate, and the less will competitive pressure induce manufacturers to offer discounts.

4. Unique innovator products. These are products that not only are on-patent, but for which there is also no reasonably substitutable drug, either on- or off-patent. In some cases, there may actually be no previous treatment for the condition at all. That was the situation when the first drugs to treat HIV entered the market in the 1980s. In other cases, the new drug may offer such a significant advance, either in effectiveness or in reduced side effects, that substituting an older drug for the new one would be inappropriate.

It is only in these fairly limited circumstances that the maker of a new drug has real freedom to charge monopoly-level prices. But, again, such monopoly pricing power lasts only until such time as the patent on the new drug expires—or, as is more often the case, another company introduces a drug similar to the first one—and therapeutic substitution for some patients becomes a possibility.[9]

Thus, price competition in pharmaceuticals occurs at several levels and is principally a function of the degree of substitutability. As with other goods, volume purchasers can leverage drug substitution to extract discounts from manufacturers. It was this insight that led to the rapid growth during the past two decades of new companies specializing in reducing pharmaceutical costs: pharmacy benefit managers, or PBMs.

PBMs and Discounting in Pharmaceuticals

The basic business strategy behind a PBM is to aggregate a large number of drug consumers and use the resulting purchasing power to extract discounts from drug makers. Yet while volume purchasing encourages manufacturer discounting, it is not—in and of itself—sufficient to extract large discounts. Manufacturers will offer substantial discounts only if the buyer combines the "carrot" of volume purchasing with the "stick" of being able to substitute one supplier's goods for those of another.

However, compared to other businesses that purchase goods in large volume (such as a bakery that buys flour in bulk), PBMs face five obstacles to wielding the "stick" of substitutability to extract large discounts from drug makers:

- The patient, not the PBM, is the end user of the product.
- The ultimate purchaser is the patient or the patient's insurer, not the PBM.

8. For example, in the early 1990s, even before their patents expired, the makers of the very similar anti-ulcer drugs Zantac and Tagamet battled for market share by offering substantial discounts to large-volume purchasers who encouraged substitution of one drug for the other on the basis of price.
9. An example would be when Eli Lilly first brought Prozac to market. Prozac not only was more effective in treating depression than previous anti-depressants, but also had a much better side-effect profile. However, it was not long before other drug makers brought to market other new anti-depressants that were similar to Prozac, and Lilly lost some of its monopoly pricing power.

- The PBM does not fully control product demand. Ultimately, demand is a function of the specific drugs prescribed by doctors for patients enrolled in the PBM.
- The PBM cannot legally make substitution decisions on its own authority. Only a physician may legally prescribe one drug instead of another.
- Drugs are not commodities. They have differing degrees of substitutability.

Existing Private-Sector Strategies

Confronted with these limits on traditional volume purchasing power, PBMs have developed various tools and strategies to reduce the cost of drug benefits. Those strategies can be grouped into four basic categories:

1. Promoting system efficiencies. The first set of strategies centers on reducing costs through system efficiencies. An early step was to cut transaction costs by introducing computerized systems for filling prescriptions and processing claims. PBMs also leveraged their economies of scale by creating large-volume mail order pharmacies to handle refills for "maintenance therapies"—drugs that patients take regularly over a period of months or years.

In addition, PBMs developed networks of retail pharmacies to service their enrollees. In exchange for the PBM steering more patients to a particular pharmacy, the pharmacy agrees to reduce its per-prescription dispensing fee. The theory behind this is that providing a pharmacy with a larger share of customers will enable it to achieve its own economies of scale and pass some of the savings back to the PBM and its customers.

2. Providing substitution incentives. Although costs can be reduced somewhat through system efficiencies, much greater savings can be achieved by substituting lower-priced drugs for more expensive ones. As noted, the greatest savings can be achieved by substituting a generic drug for a branded drug. Substituting one on-patent drug for another similar on-patent drug can also yield savings, though they are generally not as great as those from generic substitution.

However, a PBM cannot legally make such substitutions on its own authority. It needs agreement from the patient or the doctor, both of whom are mainly concerned about the relative benefits of the drugs in question. Thus, PBMs devised a strategy to create incentives for doctors and patients to weigh cost as well as benefit in prescribing and purchasing drugs.

At the heart of this strategy is the concept of a drug "formulary." Essentially, a drug formulary is a list of drugs grouped according to therapeutic class. Within each class, specific drugs are then ranked by preference. The considerations in determining a drug's rank within its class are its effectiveness and its cost. Thus, a drug that should be effective for a substantial subset of the population being treated (a criterion called "clinical appropriateness") and that also has a lower price would rank as the preferred drug in its class.

However, designing a drug formulary is more of an art than a science. For each class of drugs, there are a number of variables to consider that require judgment calls—including the relative effectiveness and side-effect profiles of different drugs. Indeed, even cost comparisons may not be straightforward. For example, if drug B is twice as effective in managing cholesterol as drug A but costs 50 percent more, a "bang-for-the-buck" calculation would conclude that the more expensive drug is the better buy. In addition, once it has constructed a formulary, a PBM must constantly update it to reflect the introduction of new drugs, both on-patent and generic.

To make the decisions involved in constructing and updating its drug formulary, the PBM assembles a Pharmacy and Therapeutics (P&T) Committee consisting of independent outside experts: physicians, pharmacists, and others with particular clinical expertise.[10] This helps the PBM to ensure that clinical appropriateness, as well as price, is factored into decisions about drug preferences within its formulary.

With a formulary in place, the PBM next creates incentives for doctors and patients to follow the formulary preferences when prescribing and purchasing drugs. Those incentives typically include

charging the patient lower co-pays for a generic drug than for an on-patent drug and charging lower co-pays for a preferred on-patent drug as opposed to a non-preferred on-patent drug. The PBM will also have pharmacists call doctors to get physician approval to substitute one drug for another.

3. Seeking manufacturer discounts and rebates. Although the use of formularies and related incentives as a stand-alone strategy can generate substantial savings, it also gives PBMs another lever with which to further reduce drug costs. If the PBM has a large market share, its programs to encourage drug substitution will have a follow-on effect on the relative market shares of the different drugs in each class. That phenomenon, of course, is a powerful tool with which to induce drug makers to offer the PBM further discounts or rebates as a way to get better formulary placement for its drugs.

However, because many drugs are not perfectly substitutable, a PBM must be careful when pursuing this strategy. While doctors and patients want the PBM to obtain drugs at lower prices, they naturally resist having the PBM interfere too much in decisions about the clinical appropriateness of specific drugs for specific patients. If patients perceive the PBM's formulary to be driven mainly by cost considerations, they will then seek another avenue for purchasing drugs. This natural market check on PBMs again reinforces the incentive to seek savings only within the context of clinical appropriateness.

4. Developing health care quality assurance systems. To provide further value for their customers, PBMs have also developed strategies to reduce health care costs through better prescribing and dispensing practices. One such tool is called "drug utilization review," or DUR. The basic insight behind DUR is that the PBM is often in the unique position of having all of the relevant data about a given patient's drug consumption. When a patient sees different doctors for different ailments, each doctor knows only what the patient tells him or her about any other drugs the patient is taking. Similarly, without PBM involvement, a retail pharmacist knows only about the particular prescriptions a particular patient has had filled at that pharmacy.

In contrast, the PBM can see the total picture. PBMs quickly realized that they could use that information to improve the quality of care while also reducing costs. For example, a basic DUR strategy is to identify any potential harmful interactions between a drug the patient is already taking and a new drug that has been prescribed—*before* the new drug is dispensed. Armed with this information, the PBM can then call the doctor, warn him or her about the potentially harmful drug interaction, and suggest prescription alternatives. Another common flag is to check whether the prescription is appropriate for the patient's age, or whether the dose should to be adjusted.

While these interventions benefit the patient's health, they may at times increase total drug costs. However, they can also result in much greater savings by avoiding adverse events that result in additional doctor visits or hospitalization. Thus, the greatest benefit to be derived from PBMs' practicing DUR is when it is done in the context of managing the drug component of a comprehensive health insurance plan that pays for the patient's total care.

Other related strategies that PBMs use to enhance quality of care include patient and physician education programs, disease management programs, and patient compliance programs. Such programs can increase the effectiveness of drug regimens for patients with chronic conditions (such as diabetes) and avoid costly doctor visits and hospitalizations. The same results can also be achieved through patient compliance programs, which help to ensure that patients take their medications as directed.

Finally, PBMs can use the data in their systems to generate prescribing profiles for individual physicians. If a PBM identifies a doctor whose prescribing patterns vary substantially from the norm,

10. Health Policy Alternatives, Inc., "Pharmacy Benefit Managers (PBMs): Tools for Managing Drug Benefit Costs, Quality, and Safety," prepared for the Pharmaceutical Care Management Association, August 2003, at *www.pcmanet.org/research.asp* (May 19, 2004).

it may target that physician for one of its education programs because the doctor's atypical prescribing pattern may be the result of unfamiliarity with the latest drug-effectiveness research. Recognizing that it is difficult for physicians to keep abreast of new information and that drug company representatives, while providing doctors with valuable information, have an incentive to emphasize their company's products, PBMs use physician education programs to give doctors a more comprehensive picture of information on the latest and best clinical practices for prescribing medications.

Success of PBMs

Using these various strategies, PBMs have demonstrated through their success in the competitive private market that they provide value for patients in the health care system. That value takes the form not only of reduced costs for pharmaceuticals, but also of better use of prescription drugs to achieve improved patient outcomes and constrain overall health system costs.

The creation and growth of PBMs is an example of the genius of a decentralized, private market in health care. In essence, the private market "invented" PBMs both as a way to increase health system efficiency and as a mechanism for balancing conflicting incentives within the pharmaceutical marketplace. By acting as advocates for patients and payers, PBMs exert countervailing pressure on drug makers and doctors. One set of what economists call "learned intermediaries" (PBMs) interacts with other sets of learned intermediaries (drug makers and doctors), and the product of their interactions is a balanced approach that seeks optimum quality at optimum cost for a complicated set of services and products about which the average consumer has little expertise.

To be sure, PBMs can be subject to their own biases. The perennial temptation for a PBM is to overemphasize cost considerations to the detriment of benefit considerations. However, to the extent that a PBM functions as part of a comprehensive health plan that is responsible for the total cost of patient care—and particularly to the extent that consumers are free to choose the health plan and/or PBM in which they have the greatest confidence—the competitive marketplace will check this temptation on the part of PBMs. Thus, through its complex system of natural checks and balances, the private market seeks the most clinically appropriate care for the individual patient at the best price.

Why the Government Will Not Do a Better Job

A prominent criticism of the recently passed Medicare prescription drug benefit is that by designing the new program to rely on private plans to purchase drugs for seniors, the legislation fails to ensure that the government and seniors will get the lowest prices for drugs. In particular, critics argue that as a single large purchaser, Medicare could do a better job of obtaining the best prices for drugs. The question for policymakers then becomes: Can the government do a better job of purchasing drugs than the private sector?

As the previous discussion illustrates, the prescription drug market is highly complex from both the medical and economic perspectives. The authors of the Medicare prescription drug benefit recognized both of those complexities—as well as the success of PBMs in managing them—in the legislative design of their new program. The legislation provides for Medicare enrollees to obtain their drugs either through a stand-alone drug plan managed by a PBM or through a comprehensive, private Medicare Advantage plan using either an in-house or outside PBM to manage the plan's drug benefit.

Medicare's Pricing History

The bill's authors were also aware of Medicare's history of distorting the delivery of medical care by setting prices for hospitals and physicians. When Medicare has set the price that it will pay for a service too high, it has encouraged the provision of more of that service than is medically appropriate. Conversely, when Medicare has set the price that it will pay for a service too low, the result has been greater reductions in the availability of the service in question than is medically appropriate.

Thus, not only did the authors of the legislation provide for the new drug benefit to be delivered through private plans, but they also included a provision in the bill that prohibits Medicare from interfering in negotiations among the private plans,

pharmacies, and drug manufacturers. They also prohibited Medicare from imposing a national formulary or single-price schedule on the private plans.

Congressional and other critics have attacked these "non-interference" provisions as "expressly prohibiting the Federal Government from negotiating the best possible price for prescription drugs,"[11] adding that the new bill "disallows the Secretary any real authority to negotiate for lower priced drugs for the 41 million seniors that will be eligible for this program."[12] These critics argue that the legislation should be amended to strike the "non-interference" provisions. Essentially, the critics ask: If the government is now going to help pay for seniors' drugs, shouldn't it use its newfound purchasing power to get a better deal?

However, the first question that needs to be asked about this critique is: Does Medicare's purchasing power substantially exceed that of existing PBMs? Although critics and their audiences assume this to be the case, the empirical answer is actually "no."

Medicare's Market Clout

When it comes to market share or purchasing power, 41 million Medicare enrollees may sound like a lot, but Medicare is only a second-tier player in this huge sector of the health care market. If Medicare ran its own PBM to buy drugs for all its beneficiaries, it would still be only the country's fourth largest PBM. Last year, Advance PCS covered 75 million individuals, Medco Health Solutions covered 65 million, and Express Scripts covered 57 million—in each case, far more enrollees than the entire Medicare population. In addition, the next three largest PBMs had enrollments of 32 million, 24 million, and 11 million individuals.[13]

Furthermore, of the 41 million Medicare beneficiaries, about 30 million already have some kind of drug coverage—either through a former employer plan, a Medicare HMO, a Medi-gap policy, or the state-run Medicaid program. Additionally, most Medicare beneficiaries get their drugs through a PBM. That leaves just 10 million Medicare beneficiaries currently without drug coverage.

Simply on grounds of relative market share, having Medicare beneficiaries obtain their drugs through an existing PBM would seem to be a sound strategy. After all, under such a system, Medicare enrollees would be joining buying groups that are similar to—or in several instances much larger than—the total size of Medicare. This strategy enables enrollees to leverage the even larger market clout of private PBMs.

Medicare's Lack of Experience

Furthermore, Medicare has no previous experience buying outpatient prescription drugs, while private plans have almost two decades of such experience—during which they have developed sophisticated expertise and systems. In fact, if Medicare were to buy drugs directly, it would have to contract with one or more existing PBMs to obtain the expertise needed to make such a program work.

Thus, if it were simply a question of market size (as the critics imply), Medicare would be—at best—a second-tier player with no particular advantage. If it were a question of expertise, Medicare would actually be at a substantial disadvantage. So the next question is: If Medicare would not have a clear advantage in either market size or expertise, might it possess other comparative advantages over existing, private PBMs?

To answer that question, it is necessary to consider other tools the government could use to obtain drugs at even lower prices—tools that are not available to PBMs.

What a Government Drug Strategy Might Look Like

Governments essentially have four sets of tools—not available to private entities—by which they can extract discounts from drug makers. Those tools are the government's unique powers to (1) impose increased substitution of drugs; (2)

11. Senator Joseph Lieberman, *Congressional Record*, November 24, 2003, p. S15683.

12. Senator Tim Johnson, *Congressional Record*, November 25, 2003, p. S15901.

13. Health Policy Alternatives, Inc, "Pharmacy Benefit Managers."

restrict market access; (3) limit manufacturers' pricing freedom; and (4) extract price concessions by non-market means.

1. Imposing Increased Substitution

Encouraging the substitution of cheaper drugs is an important lever that PBMs use to extract price discounts, but there are limits on how far a PBM can go in encouraging drug substitution. The most important limitation is that PBMs must compete for the business of consumers who, while they like paying less for drugs, still want access to the drugs they need.

If a PBM attempts to get deeper discounts by making its formulary too restrictive or by making it too costly or difficult for physicians to prescribe "off-formulary," then customers will be inclined to switch their business to another, less restrictive PBM. Thus, the market power PBMs can exert over drug makers is limited by the market power being exerted over PBMs by their customers.

Monopsony Purchasing and Quality. By contrast, when the government is the sole, or "monopsony," purchaser for a group of individuals (such as the Medicare population), it is free to pursue a strategy that puts price considerations ahead of patient benefit or clinical appropriateness. That is because patients have no alternative purchasing avenues—or at least none for which the government program will help to pay the costs. PBMs are also tempted to act that way but, unlike the government, must compete for business by satisfying consumers who want access to the drugs that benefit them.

Thus, as a monopsony purchaser, the government can impose a single, restrictive drug formulary in a program like Medicare. Because manufacturers no longer have other avenues to reach that market, they must offer significant discounts to ensure placement of their drugs on the formulary—and even deeper discounts to get preferred placement.

Such a policy can further drive down drug prices, but would do so at the expense of quality patient care. Under a single formulary, doctors are more likely to be forced to prescribe drugs that are cheaper. Yet those drugs may not be as effective for the patient as others. This is the situation with single, government-set formularies in other programs such as Medicaid, the Veterans Administration (VA) health system, and foreign national health systems.

Indeed, a government-imposed, single, restrictive formulary may also come at the price of higher program costs. Forcing patients to accept lower priced, less effective drugs can actually result in increased total drug spending as the volume of drugs prescribed increases. This is, in fact, what happens in other countries with drug price controls.[14]

Furthermore, even if such a formulary does lower total drug expenditures, it may still backfire on the government. The savings it achieves in drug spending could be more than offset by added costs for hospitalization and physician visits due to the fact that the prescribed drug treatment course is sub-optimal.

For example, a major 1996 study of the effects of restrictive formularies in private managed-care plans found that "more restrictive drug formularies were correlated with an increase in patients' use of more expensive medical services, treatment in emergency rooms and hospitals, and visits to doctors' offices."[15] The study also found that the adverse effects of restrictive formularies were greater for the elderly than for the non-elderly, even after adjusting for differences in the severity

14. See Robert Goldberg, Ph.D., "Ten Myths About the Market for Prescription Drugs," National Center for Policy Analysis, *Policy Report* No. 230, October 1999.

15. Susan Horn, Ph.D., Frederick Goodwin, M.D., and Robert Goldberg, Ph.D., "What Seniors Should Know About Government Restrictions on Prescription Drugs," Heritage Foundation *Backgrounder* No. 1611, November 6, 2002. See also S. D. Horn, P. D. Sharkey, D. M. Tracy, C. E. Horn, B. James, and F. Goodwin, "Intended and Unintended Consequences of HMO Cost-Containment Strategies: Result from the Managed Care Outcomes Project," *American Journal of Managed Care*, Vol. 2, No. 3 (March 1996), pp. 253–264.

of illness: "In comparison with younger patients, seniors who were faced with formulary restrictions were twice as likely to be hospitalized or to go to the emergency room for treatment."[16]

Medicare Fee Schedules. The same effects occur when the government uses a related tool—imposing a single fee schedule for covered drugs. In this case the government simply tells manufacturers what it will pay for drugs and refuses to cover those for which the manufacturer will not accept the government's set price.

However, such a system must be enforced or the costs will simply be shifted back to patients. For example, if Medicare refused to cover a specific drug, the patient could instead use his or her own money to buy it. Similarly, if the government decided to pay only half the market price of a particular drug, the patient could still obtain the drug by paying the balance out of pocket. Any purchaser, even the government, that does not control a captive market will lack the necessary stick with which to enforce lower *real* prices.

Faced with a similar situation with respect to physician fees, Congress restricted balance billing in the Medicare physician payment reforms enacted in 1989. As part of the 1997 Balanced Budget Act, Congress then made "private contracting" with Medicare enrollees by physicians virtually illegal. Under current law, a doctor who contracts with a Medicare enrollee, and who agrees to bill the patient and not Medicare, must forgo any payments from Medicare for *any* Medicare patients for two years.

As that experience shows, Medicare *could* extract deeper discounts from drug makers than from PBMs, but only if it is willing to limit or deny patients drug coverage from a manufacturer that will not "play ball." Thus, the government's power to extract additional discounts is purely a function of its willingness to limit market access to drugs—for both patients and drug makers.

2. Restricting Broad Market Access

Unlike private PBMs and health plans, governments have the power to impose broad market access restrictions on drugs if manufacturers refuse to limit the prices they charge to levels that are deemed acceptable by the government.

A private plan can refuse to cover a drug as a way to extract price concessions from the manufacturer, but that option is limited by the plan's need to satisfy customers who want the drug covered. A government program faces no such pressure from consumers. Patients denied access to drugs under a government program cannot simply choose a different plan. Instead, they must lobby the government to change its reimbursement policy—a much more difficult, lengthy, and costly undertaking.

Thus, a government that is willing to deny patients access to drugs can extort lower prices by threatening to deny manufacturers access to a major market segment.[17] This occurs in countries with government-run health systems. It also occurs in the United States, and a number of congressional critics argue that it should now be applied to Medicare.

During the debate on the Medicare bill, Senator Barbara Mikulski (D–MD) summarized the argument as follows:

> The VA uses its buying power to negotiate with drug companies for lower prices. That means we get a 25-percent reduction. It is not price control. It doesn't shackle innovation. It is good management. By the VA negotiating those prices, it is good for

16. Horn, Goodwin, and Goldberg, "What Seniors Should Know About Government Restrictions on Prescription Drugs." See also S. D. Horn, P. D. Sharkey, and C. Phillips-Harris, "Formulary Limitations in the Elderly: Results from the Managed Care Outcomes Project," *American Journal of Managed Care*, Vol. 4, No. 8 (August 1998), pp. 1105–1113. For a good overview of recent research on the effects of restrictive drug formularies on health system costs, see Richard A. Levy, Ph.D., and Douglas Cocks, Ph.D., "Component Management Fails to Save Health Care System Costs: The Case of Restrictive Formularies," National Pharmaceutical Council, 1999, at *www.npcnow.org/resources/PDFs/componentmanagement.pdf* (May 19, 2004).

17. In such a situation, the distinction between threatening refusal to cover a drug and actually refusing to cover the drug is largely irrelevant because, without a genuine willingness to deny coverage, any such threat would be meaningless.

> the VA to be able to afford to provide drugs, and it is good for the veteran to be able to afford to buy their drugs. Why can't we do this everywhere?[18]

The VA Model. Senator Mikulski is correct in saying that the VA's practices are not, strictly speaking, price-control mechanisms. However, she is incorrect in implying that the VA's practices are "negotiation" in the proper sense of the word. In fact, the VA does not "use its buying power to negotiate with drug companies for lower prices."

The more accurate description is that the government, acting through the VA, uses its power to deny manufacturers market access as a way to extort lower prices.[19] To answer the Senator's question, it is necessary to understand how the government threatens to restrict market access as a tool to extract price concessions.

The system works as follows. The Federal Supply Schedule (FSS) lists the drug prices the government will pay for the VA and several other programs. Under the rules set by Congress, for a drug to be included on the FSS, its manufacturer must sell it to the government under the following terms:

- It must be offered at a price that "represents the same discount off a drug's list price that the manufacturer offers its most-favored nonfederal customer under comparable terms and conditions."[20]
- It must be offered "at a discount of at least 24 percent off [the] nonfederal average manufacturer price (NFAMP). An excess inflation rebate is also required, equal to the percentage by which the price increase for [the] drug has exceeded the consumer price index (CPI) in the prior period."[21]
- The manufacturer must make *all* of its drugs available through the FSS in order for *any* of its drugs to be eligible for reimbursement under the VA and Defense Department health systems; the Public Health Service (including the Indian Health Service); the Coast Guard; and the various state Medicaid programs.[22]

To date, drug makers have been willing to bow to this pressure and accept the discounted FSS price because (1) it represents a small share of their market (about 2 percent–3 percent); (2) it gives new doctors training in the VA system exposure to their drugs; (3) the VA operates a "closed" health system, so there is little risk that drugs sold to the VA at a discount will be resold on the private market and undercut manufacturers' broader pricing strategies; and (4) drug makers want to maintain access to the Medicaid market—which represents about 11 percent of domestic sales—where they must also offer discounts, but not discounts as deep as those for the FSS.

However, extending these policies to a much larger market (such as Medicare) would inevitably force manufacturers to revise their pricing strategies. That is what the U.S. General Accounting Office (GAO) concluded after evaluating a similar proposal to allow state and local governments to buy drugs at FSS prices:

> The size of the market eligible to buy drugs at FSS prices if the schedule is opened to state and local governments would be a key factor in determining what would happen to drug prices. The size of the market involved would affect both [the] VA's ability to negotiate and manufacturers' pricing strategies. The larger the market, the greater the incentive would be for manufacturers to raise FSS prices to limit

18. Senator Barbara Mikulski, *Congressional Record*, November 24, 2003, p. S15685.

19. For a more extensive discussion, see Patricia M. Danzon, *Price Comparisons for Pharmaceuticals: A Review of U.S. and Cross-National Studies* (Washington, D.C.: AEI Press, 1999).

20. 48 C.F.R. Sec. 538.270, as cited in U.S. General Accounting Office, *Drug Prices: Effects of Opening Federal Supply Schedule for Pharmaceuticals Are Uncertain*, GAO/HEHS–97–60, June 1997, p. 6.

21. Danzon, *Price Comparisons for Pharmaceuticals*, p. 16. For the specific provisions, see 38 U.S.C. Sec. 8126.

22. 38 U.S.C. Sec. 8126.

> the impact on their business of giving low prices to more purchasers.[23]

The GAO cited as evidence the experience under Medicaid's "best price" policy. Under the Medicaid rebate program enacted by Congress in 1990, for a drug to be eligible for Medicaid coverage, the manufacturer must pay state Medicaid programs rebates that result in Medicaid's getting either a flat 15 percent discount or the "best price" paid for the drug by a private entity. The GAO concluded that:

> After the rebate program's enactment, the prices many large private purchasers paid for outpatient drugs increased substantially. In particular, prices paid by health maintenance organizations rose, on average, more than twice as fast as [they rose] the year before the program. Moreover, the lowest outpatient drug prices in the market increased faster than the drugs' average prices as drug manufacturers significantly reduced the price discounts they offered private purchasers. On the basis of its analysis of these price changes for outpatient drugs, the Congressional Budget Office concluded that because of the size of the market represented by Medicaid, "pharmaceutical manufacturers are much less willing to give large private purchasers steep discounts off the wholesale price when they also have to give Medicaid access to the same low price."[24]

It is important to note that all of the government's leverage for obtaining lower prices in the VA health system and Medicaid is derived directly from its willingness to "punish" patients if manufacturers do not comply with its demands. Excluding a drug maker from a market if it does not make price concessions will certainly hurt the manufacturer, but it will harm the patients who need the drug even more.

Furthermore, while governments can use their control over market access to extort below-average prices in limited circumstances, not even a government can contravene the laws of economics and mathematics to ensure that *everyone pays "below average" prices*—an idea that, on its face, is a logical absurdity. All it really will do is ensure that manufacturers are eventually forced to eliminate pricing differences (mainly by eliminating price discounts) until all purchasers are charged the same price.

Thus, not even control over market access is sufficient for a government to force down *real* prices across the board. To achieve that, a national government must be willing to wield its biggest stick of all—direct control over manufacturers' pricing freedom.

3. Controlling Intellectual Property and Limiting Manufacturers' Pricing Freedom

The most severe tool a national government can deploy is control over the drug maker's intellectual property. The manufacturer can set its own price for a drug only because the government has granted it a patent, thereby giving it legally enforceable and exclusive marketing rights. Once a drug's patent expires, anyone can copy and sell it after proving to the Food and Drug Administration that their copy is identical to the original. As generics then enter the market, the innovator company's pricing power with respect to a drug vanishes—literally—overnight.

If the government can grant such limited monopolies, it can also extend, reduce, restrict, or eliminate them entirely. Thus, if a government wants to coerce a manufacturer to lower prices across the board, it can do so by threatening to limit or revoke its patent rights. In the most extreme form (called "compulsory licensing"), the government takes away the innovator company's patent protection and allows one or more other companies to make and sell the drug at a price that is acceptable to the government.

The imposition, or even threat, of compulsory licensing is the ultimate weapon that a national government can wield against drug makers. However, it carries a high price for any government

23. U.S. General Accounting Office, *Drug Prices: Effects of Opening Federal Supply Schedule for Pharmaceuticals Are Uncertain*, p. 9.
24. *Ibid.*, pp. 12–13.

that wields it, and the price would be particularly steep for the United States.

Such a move would seriously undermine confidence in the basic fairness and consistency of intellectual property protections granted by the government. Without those assurances, drug makers—and other companies as well—will avoid investing in the development of new products because they risk having their investments effectively expropriated by the government. The result could be such a severe crisis of confidence that innovation would become prohibitively risky, and the flow of new products to consumers could dry up.

If the U.S. government adopted such a strategy, America would be hit particularly hard. The United States is already, by a large measure, the global leader in pharmaceutical and biotech research, thanks to a combination of reliable patent laws and the freedom of companies to engage in market pricing. As such, America benefits from hundreds of billions of dollars' worth of investment in the pharmaceutical and biotech industries and hundreds of thousands of well-paying, highly skilled jobs in those industries. All of that would be jeopardized if the U.S. government began to make its intellectual property policies inconsistent and arbitrary by adjusting them to accommodate short-term political pressures.

Nor would the effects be confined to a single industry or to a single country. Other industries that rely heavily on intellectual property protections—such as electronics, software, aerospace, medical devices, film, and music—would be forced to discount the value of their intellectual property: What the government was willing to do to one industry, it might be willing to do to others.

Furthermore, the United States would be unable to argue that other countries should respect the intellectual property of U.S. citizens or corporations.[25] Given that the United States probably has a greater share of its economy and export sales supported by intellectual property than any other nation, the U.S. economy would disproportionately suffer the economic effects of such a move.

4. Extracting Price Concessions by Non-Market Means

The final set of tools that governments (but not private companies) can use to extract price concessions from manufacturers lies with the non-market powers that governments exercise. These are powers over aspects of the manufacturer's business that are not directly related to the manufacturer's products: tax policy, financial market access, and a host of other regulatory regimes. In any of these areas, governments can impose adverse policies on companies that refuse to accept their pricing dictates.

As with intellectual property, any such actions would be likely to have other adverse effects on the economy. In some cases, the effects might be localized, while in other cases, the effects might be economy-wide. For example, imposing tax penalties or financial market-access restrictions on companies in one industry for political reasons will naturally lead companies in other industries to question the fairness and consistency of the government's policies in those areas.

The introduction of any policy that makes the rewards of economic activity uncertain will serve to diminish economic activity in general. It is precisely the uncertainty and perceived arbitrariness of government policies in many other countries that keep their economies stagnant and millions of their citizens poor. Indeed, economic historians can point to a number of examples of once reasonably prosperous nations that impoverished themselves because their governments adopted arbitrary economic policies.[26]

25. For example, U.S. trade negotiators were put at a serious disadvantage in their negotiations with other countries over intellectual property rights when, during the 2001 anthrax crisis, the press reported that Health and Human Services Secretary Tommy Thomson threatened Bayer, the maker of the antibiotic Cipro, with compulsory licensing if Bayer would not sell Cipro to the government at a steep discount.

26. For example, Zimbabwe, once a net exporter of food and prosperous by African standards, is now impoverished and threatened by famine as a result of the arbitrary economic policies imposed by the country's government.

A current example is the provision in S. 2053 that denies the corporate tax deduction for advertising and marketing expenses to drug companies that try to limit the importation of their drugs from other countries in which they are priced lower.[27] Of course, imposing such a policy change could, in fact, result in the loss of advertising revenue in the publishing and broadcasting industries if drug companies refused to accede to the government's demands.

More likely, such a policy change would give drug makers a new incentive to take a harder line against price discounting in other countries because each of those countries constitutes a much smaller share of their global market than does the United States. If other countries responded with moves to compulsorily license drugs, the situation could quickly escalate into a trade war and undermine decades of work by the United States to construct a reliable framework of international intellectual property law that benefits all U.S. companies.

Finally, other industries would be concerned about the precedent such an action would set if the government used corporate tax policy as a weapon against disfavored companies or industries. These industries would become more cautious in their economic investments as a result.

Conclusion

The current debate over "non-interference" is essentially a debate over the superiority of competitive market forces relative to government price fixing. As Gail Wilensky, former Administrator of the Health Care Financing Administration (HCFA)—the agency now known as the Centers for Medicare and Medicaid Services (CMS)—recently noted, when the government functions as a monopsony purchaser, it does not "negotiate" prices; it "sets" them.[28]

But government's power to dictate drug prices derives from its powers to restrict market access for drugs and to limit or revoke intellectual property rights. Ultimately, governments can control market access for drugs only if they are willing to "punish" patients by denying them coverage for drugs for which manufacturers refuse to grant price concessions.

Similarly, a government can force price concessions by withdrawing intellectual property rights if it is willing to "punish" its own citizens and its own economy with less innovation and less economic growth. Indeed, the decline or disappearance of pharmaceutical and biotechnology companies in countries that control drug prices by threatening compulsory licensing has recently led a number of those countries to start rethinking the wisdom of such policies.

While there is much to criticize about the design of the new Medicare prescription drug benefit, the basic structure of coverage provided by competing private plans—free of government interference—is actually a commendable feature of the legislation. In drafting those provisions, the bill's authors recognized that consumer choice and market competition are the only reliable ways to ensure that seniors receive access to quality pharmaceutical care at reasonable prices.

However, any attempt by the government to circumvent those market mechanisms out of a desire to pay even lower prices would inevitably subordinate the interests of patients to the interests of government budgeting. Such an attempt not only would have an unfavorable impact on pharmaceutical investments, research and development, but also, of necessity, would diminish the quality of health care received by America's seniors.

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27. S. 2053, Sec. 5.

28. Gail Wilensky, "How to Curb Spending on Drugs," *The Washington Post*, February 15, 2004, p. B7.