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CONGRESSIONAL TESTIMONY

Hearing on Prescription Drug Pricing and Negotiation for the Medicare Prescription Drug Benefit

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My name is Edmund F. Haislmaier. I am Research Fellow at The Heritage Foundation. The views I express in this testimony are my own, and should not be construed as representing any official position of The Heritage Foundation.

Chairman Baucus, Senator Grassley, and members of the committee:

Thank you for inviting me to testify today on government negotiation in the Medicare prescription drug program.

In order to determine whether the government has a role in, or would be successful at, negotiating prices in Medicare one must first consider how price negotiations work, then examine how drug negotiations could be conducted for Medicare, and lastly assess the likely outcomes and implications.

The Elements of Negotiation

Negotiation is a bargaining process and an aspect of everyday life. Family members negotiate over dinner options. Employees and employers negotiate levels of compensation. Buyers and sellers often negotiate the prices of goods and services such as cars or houses. Even members of Congress negotiate over legislation.

But negotiation is not a haphazard or arbitrary exercise. While it is true that people sometimes negotiate foolishly or with unrealistic expectations, the negotiation process itself is always and everywhere governed by a set of simple, understandable, but inflexible, rules.

Rule 1. Each party to a negotiation has a final price, called a reservation price or "walk away" price, beyond which that party will not negotiate.

Rule 2. A party's reservation price is, by definition, the point at which the party thinks it would be better off with no deal.

Rule 3. If a deal cannot be reached, then each party will, by definition, pursue some other alternative. Therefore, a party's reservation price is equal to the cost (self-perceived) of pursuing its "best alternative to a negotiated agreement" (BATNA).

Rule 4. Negotiation consists of coming to agreement on a price somewhere between the respective reservation prices of the two parties. Thus, successful negotiations cannot occur if the two parties range of acceptable prices don't overlap.

These basic rules governing any negotiation have a number of clear implications. First and foremost, is that the most important consideration in any negotiation is each parties' "best alternative" to consummating a deal. For each party the "best alternative to a negotiated agreement" can be determined as follows:

1. List the actions it might conceivably take if no agreement is reached.

2. Estimate the costs of each conceivable alternative option.

3. Select the one option that seems best.

While this is a rational set of steps, people do not always behave with perfect rationality. But this framework can be used, by the parties themselves, or by an outsider, to calculate what is the likely best alternative for each party. Furthermore, to the extent that actual negotiating behavior differs from anticipated behavior based on such an assessment, it can reveal flaws or vulnerabilities in one or the other, or both, parties negotiating strategy.

In some cases, a party might miscalculate the costs of one or more possible alternatives – either underestimating or overestimating them – which skews its decision as to which alternative is best. For example, someone might rush to buy a condominium in an escalating real estate market, only to discover six months later that the market has flattened and prices are falling. If the cost of the condo dropped by more than the additional rent the buyer would have paid if he waited six months, then we can say that the buyer overestimated the costs associated with waiting to buy. Waiting to buy might have been his best alternative, or his best alternative might have been buying a similar property in another neighborhood where demand wasn't as likely to shift.

In other cases a party may miscalculate for emotional reasons. Consider the homeowner who has to sell his house to take a job in another city, but is emotionally stuck on getting a high price to cover the cost of what he wants to buy when he relocates. His emotions may lead him to disregard the additional expense of renting in the new location while his previous home sits unsold. Thus, he fails to see that selling his home quickly at a lower price and buying a smaller house in his new locale is really his best alternative.

Working through these steps also enables us to assess how the equation might change if there is a change to an external variable that affects the calculation of which alternative is best. For example, last year's run up in gas prices led many car buyers to rethink the trade-offs between vehicle size and operating costs. Suddenly, a smaller more fuel-efficient car became a best alternative to the roomier, but low-mileage vehicles many buyers originally wanted. Indeed, market observers were even able to quantify the phenomenon. They noted that the average price paid for a new SUV dropped by almost exactly the same amount as the increase in the one-year average cost of operating an SUV due to higher gas prices.

Thus, the change in the external variable of gas prices led to a recalculation among buyers of their best alternative and a shift in demand. That shift weakened the negotiating position of SUV makers and strengthened the negotiating position of fuel-efficient carmakers by changing their best alternative scenarios. Selling SUVs for less became a better alternative than waiting for buyers willing to pay the old asking price.

Conversely, sellers of smaller cars stuck to their asking prices since if a buyer walked away from the table, they could expect another one to soon walk in the door.

In the case of prescription drugs, the most important external variable is the reaction by those consuming the drugs (patients) to the strategy and choices of those negotiating on their behalf. This holds true whether those negotiations are conducted, as presently, by private plans or are conducted by the government. As will be seen in my later remarks, patient reactions inevitably shape and limit the negotiating freedom of those who negotiate on their behalf. This means that, the "buy side" negotiators must always be mindful of how patients will react to their decisions, lest their actions produce a consumer response that undermines their negotiating strategy. Indeed, they must also be sensitive to the possibility that the "sell side" negotiators could spark or encourage such a consumer reaction as a way of altering the negotiation parameters in the sellers' favor.

Is Bigger Always Better?

One of the variables most commonly thought of as affecting negotiating position, or "leverage," is the relative size, or "scale," of the parties to a negotiation. People presume that if a manufacturer has little or no competition it can simply dictate prices, since buyers have no reasonable alternatives. Conversely, people also presume that large volume buyers have an inherent negotiating advantage over sellers. This thinking further leads many to conclude that the only effective counterweight to a producer monopoly or oligopoly is to somehow organize a very large buying group.

This thinking is certainly present in the debate over pharmaceutical purchasing. But before moving to that topic, let us pause to consider what is missing from such an analysis. The missing piece is the failure to account for other variables in the negotiating equation.

Let us take Wal-Mart as an example. Clearly, Wal-Mart regularly uses it size – an enormous customer base – as leverage to extract price concessions from its suppliers. But what if Wal-Mart encounters the phenomenon of price-inelastic demand for a product in limited supply? Say, for example, something like the Cabbage Patch Doll craze in the Eighties. Why should the manufacturer give Wal-Mart a discount? Supply can't meet demand and buyers will seek out the product regardless of where it is sold. Indeed, other stores will be happy to carry the product at the manufacturer's price, if for no other reason then to attract customers away from Wal-Mart. In such a situation, one can imagine the negotiations going the other way. Wal-Mart might end up not only abandoning any effort to get a price discount, but offer inducements of its own, such as stocking more of the manufacturer's other products, in exchange for being the only distributor of the desired product, in an attempt to protect its customer base.

At this point it would appear that the monopoly producer clearly has the upper hand – even over the largest potential purchaser. But we need to also consider some of the other variables involved, such as time. The inelastic demand for that "must have" product is only a temporary phenomenon. Eventually, the manufacturer will produce enough

supply to meet the initial, overwhelming demand. What happens then? If the manufacturer still wants to sell more of the product it will have to start making price concessions. Also, fads and fashions change quickly, and the manufacturer shouldn't expect that the phenomenon of sudden, inelastic demand would be repeated with each new product. Maybe it's in the manufacturer's interest to give a bit in its negotiations with Wal-Mart in exchange for a better, long-term relationship once it's current negotiating advantage has dissipated.

This example does not invalidate the common perceptions about the role of scale in negotiation, or the efficacy of pitting bulk purchasers against monopoly suppliers. But it does show that there is a great deal more complexity and nuance involved than most would imagine at first glance. It also shows how much scope exists for even the biggest of purchasers and the most monopolistic of sellers to miscalculate their own "best alternative" and significantly disadvantage themselves in a negotiation. Size may be important, but it's far from everything.

Negotiating Pharmaceutical Prices.

From the buyer's perspective another term for "best alternative" is substitutability. In other words, how practical is it to substitute one product for another if agreement can't be reached on the price of the preferred product.

While in some case non-pharmaceutical therapies, such as diet or surgery, can be substituted for drugs for certain patients with certain conditions, in most cases with respect to prescription drugs substitutability refers to replacing one pharmaceutical product with another. In that regard, the pharmaceutical market can be divide into four broad categories, based on the relative substitutability of drugs.

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 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.**

   These products are safely substitutable for many patients, but 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) but one has a dosing regime of three times a day, and the other is a once a day dose.

While to the patient the main difference may be one of convenience, to the physician the difference in bioavailability between two dosing regimes can sometimes be important to the success of the treatment, given the condition being treated and the particulars of the individual patient.

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 is when an innovator company uses a patented drug delivery technology to create a new version of an existing drug.

In these 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. But if the outcome for the patient is likely to be much better, then the total cost of treatment is also likely to be less, even though the new drug costs more than its generic competitors. In such cases it would make sense for the buyer to agree to pay a higher unit price, since the benefit will be greater and the total cost will be lower.

3) **Therapeutically similar products.**

These drugs have different active ingredients, but treat the same condition in a similar manner. For example, the various drugs that regulate cholesterol levels. With therapeutically similar products, all the drugs in a class may be on-patent, or some may be on-patent while others are off-patent generics. When doctors can safely substitute one of drugs for another for a particular patient (a practice known as 'therapeutic substitution'), then relative price differences can become a consideration in the decision. (Technically, substituting drugs with the same compound but different bioavailability is also therapeutic substitution.)

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 'co-morbidities'), the medically appropriate thing is for the doctor to prescribe the best drug for each patient from among the different ones available in that therapeutic class. Also, different drugs in a therapeutic class may have different side effects and individual patients will differ in their abilities to tolerate 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 to otherwise harm the patient.

If therapeutic substitution is medically appropriate, then the relative prices among drugs within a therapeutic class can be a legitimate consideration. But 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 the 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 thus their manufacturers could theoretically charge monopoly prices.

Conversely, the less 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 thus, the less competitive pressure on manufacturers to offer discounts will arise.

4) **Unique innovator products.**

These are products which are not only on-patent, but for which there is 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 back in the 1980s. In other cases, the new drug may offer such a significant advance in either treatment effectiveness or 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 prices. But, again, such monopoly pricing power lasts only until such time as either the patent on the new drug expires or, as is more often the case, another company introduces another new drug that is similar to the first one, and therapeutic substitution for some patients becomes a possibility.

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 price concessions from manufacturers. It was this insight that lead to the rapid growth during the past two decades of new companies specializing in reducing pharmaceutical costs, called 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. But while volume purchasing encourages manufacturer discounting, it is not, in and of itself, sufficient to extract large discounts. Manufactures will only offer substantial discounts if the buyer combines the ‘carrot’ of volume purchasing with the ‘stick’ of being able to substitute one supplier’s goods with those of another.

However, compared to other businesses that purchase goods in large volume, such as a bakery that buys flour in bulk, a PBM faces five obstacles to effectively wielding the ‘stick’ of substitutability to extract large discounts from drug makers:

1) The patient, not the PBM, is the end user of the product.

2) The ultimate purchaser is the patient or the patient's insurer, not the PBM.

3) The PBM doesn't fully control product demand. Ultimately, demand is a function of the specific drugs prescribed by doctors for patients enrolled in the PBM.

4) The PBM cannot legally make substitution decisions on its own authority. Only a physician may legally prescribe one drug instead of another.

5) Drugs aren't commodities. They have different degrees of substitutability.

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

1) System efficiencies.

The first set of strategies center 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,' or 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 is that by providing a pharmacy with a larger share of customers, the pharmacy will be able to achieve its own economies of scale, with some of the savings passed back to the PBM and its customers.

2) Substitution incentives.

While costs can be reduced somewhat through system efficiencies, much greater savings can be achieved by substituting lower priced drugs for more expensive ones. 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 can't legally make such substitutions on its own authority. It needs agreement from the patient or the doctor, who 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 the specific drugs are then ranked by preference. The considerations in determining a drug's

rank within its class are its effectiveness and cost. Thus, a drug that should be effective for a substantial subset of the population being treated (a criteria called 'clinical appropriateness'), and 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 including physicians, pharmacists and others with particular clinical expertise. This helps the PBM 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 in prescribing and purchasing drugs. Those incentives typically include charging the patient lower copays for a generic drug than for an on-patent drug, and lower copays for a preferred, on-patent drug versus another, non-preferred, on-patent drug. The PBM will also have pharmacists call doctors to get physician approval for substituting one drug for another.

3) Manufacturer discounts and rebates.

While the use of formularies and related incentives can, as a standalone strategy, generate substantial savings, they also give PBMs another lever 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 to induce drug makers to offer the PBM further discounts or rebates as a way to get their drugs better placement on the formulary.

However, because many drugs are not perfectly substitutable, a PMB must be careful in 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 mainly driven by cost considerations, then they will seek another avenue for purchasing drugs. This natural market check on PBMs again reinforces the incentives on them to seek savings only within the context of clinical appropriateness.

4) Health care quality assurance systems.

To provide further value for their customers, PBMs have also developed strategies to

reduce health care cost through better prescribing and dispensing practices. In this regard, it is important to remember that price is only one half of the cost equation. The other half is volume. Thus, fewer, but more expensive, drugs used more effectively can result in a lower total cost than more, but less expensive, drugs used less effectively.

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 the relevant data about a given patient's drug consumption. When a patient sees different doctors for different ailments, each doctor only knows what the patient tells him about any other drugs he is taking. Similarly, without a PBM involved, a retail pharmacist only knows about the particular prescriptions a particular patient has had filled at his pharmacy.

But 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 about the potential drug-drug interaction and suggest alternatives for the doctor to prescribe instead. Another common flag is to check whether the prescription is appropriate for the patient's age, or whether the dosing 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 of PBMs practicing DUR is within the context of the PBM managing the drug component of a comprehensive health insurance plan that pays for the patient's total care.

Other, related, quality strategies include patient and physician education programs, disease management programs, and patient compliance programs. For patients with chronic conditions, such as diabetes, disease management and education programs can increase the effectiveness of their drug regimens and avoid costly of doctor visits and hospitalizations. The same results can also be achieved through patient compliance programs that help ensure 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, it may target the physician for one of its education programs, since 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 emphasis that which favors their company's products, PBMs use physician education programs to give doctors a more comprehensive picture of information on clinical best practices in prescribing.

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 spending on pharmaceuticals, but also 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 the decentralized, private market in health care. In essence, the private market 'invented' PBMs not only as a way to increase health system efficiency but also 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 economist call 'learned intermediaries' (PBMs) interact with other sets of learned intermediaries (drug makers and doctors) and the result 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 overemphasis cost considerations to the detriment of benefit considerations. However, to the extent that a PBM functions as part of a comprehensive health plan 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 also 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.

Could the Government do Better?

One year into the Medicare Part D program, private drug plans appear to have extended their successful record to the senior market. Individual prices for many drugs have declined, the program's costs (which are the product of price times volume) are coming in well below initial projections, premiums are significantly lower than expected, and high rates of patient satisfaction with the program are being reported.

The question on the table, then, is whether the government could reasonably expect to get a still better deal by negotiating directly with pharmaceutical companies?

To answer that question it is necessary to consider the other tools the government, but not PBMs, could use to obtain drugs at even lower prices. Governments essentially have four other sets of tools, not available to private entities, for extracting discounts from drug makers. Those tools are the government's unique powers to: 1) Impose increased substitution of drugs; 2) Restrict market access; 3) Limit manufacturers pricing freedom, and; 4) Extract price concessions by non-market means.

1) Impose increased substitution

Encouraging the substitution of cheaper drugs is an important lever 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 effectively limited by the market power being exerted over PBMs by their customers.

In 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 pay the costs. PBMs are also tempted to act that way, but unlike the government they 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 manufactures 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 at the expense of quality patient care. Under a single formulary, doctors are more likely to be forced to prescribe drugs that are cheaper, but may not be as effective for the patient, as other drugs. This is the situation with single, government set, formularies in other programs such as the Veterans Administration (VA) health system and foreign national health systems.

Indeed, it may also come at the price of higher program costs. Forcing patients to accept lower priced, but less effective drugs can actually result in increased total drug spending as the volume of drugs prescribed increases.

Furthermore, even if a government imposed, restrictive formulary does lower total drug expenditures it may still backfire on the government as the savings it achieves in drug spending are more than offset by added costs for hospitalization and physician visits due to the prescribed course of drug treatment being sub-optimal.

The same effects occur when the government uses a related tool; the imposition of a single fee schedule for covered drugs. In this case the government simply tells manufactures what it will to pay for drugs and refuses to cover those for which the manufacturer won't accept the government set price. However, such as system must be enforced, or otherwise 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 own money to buy it. Similarly, if the government decided to only pay 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 doesn't control a captive market, will lack the necessary stick with which to enforce lower *real* prices.

In sum, Medicare *could* extract deeper discounts from drug makers than PBMs, but only if it is willing to limit, or deny, patients coverage for a manufacture's drugs if the manufacturer won't 'play ball.' Thus, the government's power to extract additional discounts is entirely a function of its willingness to limit market access to drugs, for both patients and drug makers.

But a government that pursues such a strategy also risks creating a patient backlash against access restrictions. If enough patients exert enough political pressure on their elected representatives, then the government will be forced to abandon some or all of its access restrictions. In such a situation, the government could actually end up worse of and spending more on the program than it would have had it left the negotiations over price and access to a competitive private market better able to calibrate patient willingness to accept access restrictions in exchange for lower prices.

2) Restrict broad market access

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

While a private plan can refuse to cover a drug as a way to extract price concessions from the manufacturer, that option is limited by the plan's need to satisfy customers who want the drug covered. However, a government program faces no such pressure from consumers. Patients denied access to drugs under a government program can't 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 extract price concessions by threatening to deny manufacturers access to a major market segment. In such a situation the distinction between threatening to not cover a drug and actually refusing to cover the drug is largely irrelevant, since without a genuine willingness to deny coverage any such threat would be meaningless.

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. All it will really do is ensure that manufactures 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– direct control over manufacturers pricing freedom.

3) Limit 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 giving it, legally enforceable, exclusive marketing rights. Once a drug's patent expires, anyone can copy and sell it after proving to the FDA that their copy is identical to the original. Then, as generics enter the market, the innovator company's pricing power with respect to a drug vanishes, literally, overnight.

But 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. But it carries a high price for any government that wields it, and the price would be particularly steep for the U.S. Such a move would seriously undermine confidence in the basic fairness and consistency of intellectual property protections granted by the government. Without those assurances, not only drug makers, but other companies as well, will avoid investing in developing new products since they risk having their investments effectively expropriated by the government. Innovation throughout the industry, and even throughout the economy, would diminish or cease, and the flow of new products to consumers would dry up.

If the U.S. Government adopted such a strategy, America would be particularly hard hit. The U.S. 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 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, music, etc. would be forced to discount the value of their intellectual property, since what the government was willing to do to one industry it might be willing to do to others. Furthermore, the U.S. would be unable to argue that other countries should respect the intellectual property of U.S. citizens or corporations. Given that the U.S. probably has a greater share of its economy and export sales dependent on intellectual property than any other nation, the U.S. economy would disproportionately suffer the economic effects of such a move.

4) Extract 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 lie with the non-market powers governments exercise. Those are powers over aspects of the manufacturer's business that are not

directly related to the manufacturer's products, and include tax policy, financial market access and a host of other regulatory regimes. Governments can impose adverse policies in any of these areas on companies that refuse to accept it's pricing dictates.

But as with intellectual property, any such actions would likely 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 for political reasons tax penalties or financial market access restrictions on companies in one industry, will naturally lead companies in other industries to question the fairness and consistence of the government's policies in those areas with respect to their own businesses.

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 various examples of once reasonably prosperous nations that impoverished themselves by their government's arbitrary economic policies.

Conclusion

In the final analysis, the government's power to negotiate lower drug prices is entirely a function of two things. The first is its ability to deny access to a larger number of beneficiaries. The second is its ability to limit property rights.

Absent provisions requiring the exercise one or the other, or both, of those unique governmental powers, it is completely unrealistic to expect any meaningful result from legislation authorizing direct government negotiation with pharmaceutical companies.

But if Congress chooses to pursue those options, I must warn you that they carry very high price tags. I can also assure you that the price will be political as well as monetary. The economic distortions resulting from restricting market access for drugs in Medicare could not only lead to increased overall Medicare spending but would likely spark a political backlash on a scale not seen since senior citizens forced Congress to repeal the 1987 Medicare Catastrophic Coverage Act.

In the case of compulsory licensing, or other similar threats to intellectual property rights, the economic consequences would be much more severe, though the political backlash would likely be slower in coming. Nevertheless, the backlash will occur when those seeking treatments for their, or a loved one's, illness figure out that Congress has destroyed the incentives for researchers to develop the cures they seek. The precedent will be the pressure from AIDS activists that lead Congress to reform the FDA drug approval process and speed to market life-saving drugs for HIV.

In the end, both the government and the drug makers "best alternative" to direct negotiation may prove to be the same thing -- the current system enacted in the Medicare Modernization Act of 2003.

Thank you, Mr. Chairman. That concludes my prepared remarks. I will be glad to answer any questions you or the other Senators may have.

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