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Eliminating drug price differentials across government programmes in the USA

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Abstract: Federal agencies in the USA pay significantly different prices for the same prescription drugs because each agency uses a different approach to derive the payment rate. Because we do not identify any economic rationale or socially accepted moral reasoning that would justify the current level of price variation, we suggest that the federal government should pay a uniform price for each drug. Laws and regulations that give certain federal agencies the ability to earn rebates, use formularies, or permit other special arrangements would need to be eliminated in order to have a single payment rate. This could make some government agencies worse off than others; however, a uniform payment rate would not need to affect beneficiaries' current financial contributions, access to drugs, benefits or overall public expenditures. At the same time, having a single rate would permit the government to adopt a more effective approach to purchasing drugs and send a consistent message to pharmaceutical companies concerning which types of drugs the government wants them to develop for government beneficiaries. How this single price would be derived and how it would compare with the lowest or highest prices currently achieved by government agencies would depend on a variety of policy issues including the government's desire to encourage pharmaceutical research and development and the need to control health care spending.

Price differentials across government programmes

In 2005, the Congressional Budget Office (CBO) compared the average prices paid by different government programmes relative to the average wholesale

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price (AWP) for a selection of top selling single-source branded drugs (Congressional Budget Office, 2005). The CBO analysis revealed wide price variation across federal programmes. The Department of Defense (DoD) and Veterans' Affairs (VA) paid approximately 40% of the AWP. The Medicaid programme paid, on average, over 25% more than the VA. Medicare was not included in the 2005 CBO analysis because there was no outpatient Medicare prescription drug insurance program in operation at that point.

Provisions within the Medicare Modernisation Act require that the actual acquisition prices (including all discounts) of drugs by Part D plans remain proprietary and inaccessible to academic or government analysts such as the Congressional Research Service. However, one analysis of the drug prices obtained by Part D plans, conducted by the House Government Affairs and Oversight Committee, showed that the drug prices paid by Part D plans are even higher than Medicaid and, therefore, much higher than VA and DoD (House Oversight Committee, 2007). Furthermore, a recent court decision found that Medicare Part B programmes were overpaying pharmacies and physicians for drugs administered in their offices (United States District Court and District of Massachusetts).

In this study, we examine the possible reasons for such a wide variation in drug prices across government programs. In addressing this question we consider economic, institutional/legal and ethical arguments and their interrelations. We review the arguments for price discrimination as a means for achieving efficiency in the market for patented drugs and question whether price discrimination, in the economic sense, is at all applicable to the current setting of different government buyers. We then describe the institutional/legal arrangements that confer different programs different levels of bargaining power and explore whether there is an ethical basis for such arrangements as a reflection of societal value judgements about differential deservedness of the different government-subsidised populations. We conclude that there is little economic or ethical basis for the observed price differentials and propose that a more consolidated approach to government purchasing of pharmaceuticals is the necessary first step towards rationalising drug expenditure, improving health outcomes and incentivising good value innovation. We do not explore the practical aspects of implementing such a proposal, which are better considered by policy makers in the context of the ongoing health insurance reforms. Instead, we highlight the weak basis of the arguments used so far to prevent such a debate from taking place.

Whilst, in this study, we focus on Medicare Part D, VA and Medicaid, the same considerations and principles apply to other federal programmes such as Medicare Part B, the Public Health Service, DoD and federal prisons. The same arguments for a uniform price also could apply to state and local governments in the US because they too purchase drugs for multiple programmes and agencies such as community health centres, prisons, mental and other state hospitals and

Medicaid beneficiaries. Finally, there may be applications in other countries that may also pay different prices for drugs within their country.

Economic basis for price differentials

Purchasing power

Economic theory predicts and empirical evidence substantiates that large buyers are able to obtain price discounts because their size confers increased bargaining power (Galbraith, 1952).[1] This principle is thought to hold true even when the seller has been granted additional market power by government through such mechanisms as patent protection for drugs. Because the federal and state governments are the largest purchasers of drugs, representing 40% of the total US pharmaceutical market, in theory they could obtain the largest possible discount (Poisal *et al.*, 2007). Similarly, because the Medicare programme alone currently accounts for over one-fifth of the national spending on drugs, it should also be able to command substantial discounts (Poisal *et al.*, 2007). However, because of current legislation, neither government as a whole nor the biggest public purchaser, Medicare, receives volume discounts because of the way drug programs are structured.[2] A recent analysis of Part D data demonstrated that Medicaid, which spends half as much as Medicare on pharmaceuticals, achieved over three times the rebates as private plans administering Part D on behalf of Medicare (House Oversight Committee, 2007). According to the same report, private plans failed to get any rebates for 18 out of the top 100 drugs driving Part D spending.

By combining all its purchasing power into one price, the federal government could obtain a price even lower than the current VA/DoD price. However, it may decide to pay a higher rate in order to subsidise research and development in the pharmaceutical industry. Later in this study, we discuss this and other reasons why the federal government may choose not to purchase drugs at the lowest possible rate. However, policy considerations about the final rate are separable from the general question of whether the government should be using its purchasing power differently for different government programmes.

Price discrimination

In economics, when two or more 'similar products with the same marginal cost are sold by a firm at different prices' there is price discrimination (Armstrong, 2006;

1 Whether size alone (as opposed to ability to shift market share) in a monopoly context is enough to secure price discounts has also been questioned (see for example Ellison and Snyder, Countervailing power in wholesale pharmaceuticals (2001), Working paper). In any case, large size results in lower and not higher prices, overall.

2 Legislation establishing Part D prevents Medicare from negotiating drug prices with manufacturers. See: Some Successful Models Ignored As Congress Works on Drug Bill, *New York Times*, September 2003.

Pigou, 1920). According to economic theory, price discrimination requires that (1) some consumers within the market are willing to pay more than others for the same product, (2) firms can identify and charge these consumer groups different prices for the same product and (3) there is no arbitrage, that is, the product cannot be resold from the lower to the higher price submarkets for immediate, free-of-risk profit.

Drug companies can price discriminate when they are granted patent protection for single-source branded drugs since they command sufficient power to be able to set differential prices for different consumer groups (second condition above). At the same time, legal provisions (Prescription Drug Marketing Act) and the organisation of distribution channels and money flows between different players (retrospective rebates rather than upfront discounts), make arbitrage both illegal and practically impossible in the US market (third condition). Under such circumstances, drug companies can maximise profits by price discriminating (Frank, 2001; Reinhardt *et al.*, 2004). There are debates over the pros and cons of price discrimination. It can result in a 'maldistribution of resources' opposed to both on grounds of fairness and efficiency (Robinson, 1933). At the same time, however, it could allow the poorest individuals access to the service.

We begin by noting that the economic literature remains largely inconclusive about the benefits of price discrimination since these depend on the specific circumstances. 'Evaluating the overall gains and losses from discriminatory discounts becomes an extremely complex problem…for which no clear conclusions can be drawn without data much richer than those available' (Scherer, 1997). There are, however, cases where price discrimination can potentially benefit overall social welfare, including: improved market access, economies of scale and learning, enhanced competition, and better incentives for research and development.

Improved market access

One possible advantage of price discrimination is that higher income individuals (or groups) can subsidize prices for less affluent individuals (or groups), hence improving access for the latter. If a drug company can use price discrimination to open up new markets and thus increase market output, then society as a whole may be better off (Schmalensee, 1981).[3] This argument has been used in the context of the international market for pharmaceuticals where drug companies can price discriminate between industrialised and low-income countries, for example, for HIV/AIDS drugs. This allows low-income countries access to drugs they would most likely not have been able to afford under a uniform global price.

3 In his discussion of J. Robinson's work on third degree monopolistic price discrimination, Schmalensee shows that the distributional inefficiencies of price discrimination can be offset only by an increase in total output through improved market access for 'weak' markets. Increased output is a necessary but not sufficient condition for net welfare gain.

While this is possibly a valid argument in the international setting, it is, unclear how price discrimination across the various federal agencies results in expanded market access for some federal beneficiaries. Transferring the 'improved market access' argument to the US government setting would suggest that the VA and DoD, constitute the most price sensitive groups, the equivalent of the 'weak' markets in low income countries. Similarly, Medicare and Medicaid, currently paying more, are in the position of the 'stronger' markets.

While it may be that access to drugs would be even further restricted for poorer countries if higher income countries were to insist on a uniform global price, it is unlikely that VA and DoD would be unable to afford necessary drugs if Medicare and Medicaid were to pay lower prices. Furthermore, there is currently no transfer mechanism for higher prices paid to drug companies by Medicaid and Medicare to translate into lower prices for the VA or DoD. Indeed, price increases following the introduction of Part D in 2006 led to higher company revenues and not lower prices for the VA and DoD markets (Frank and Newhouse, 2007).

Economies of scale and learning

Price discrimination can positively affect welfare if total output increases. This is in comparison with a situation of no price discrimination. One way that this could happen is if there are economies of scale for the good or service in question. This is because unit costs decrease as a function of accumulated experience or reduced incremental production costs (Hausman and MacKie-Mason, 1988). Once a pharmaceutical product has been developed, scale and learning economies are unlikely to result in lowering average marginal costs as output increases thanks to discrimination opening up new markets. In this sense, although economies of scale do exist in the research and development components of pharmaceutical research – for example, in navigating complex clinical trial requirements for large firms, or by tapping into larger companies' expertise through licensing agreements for smaller companies – once a product has been launched, such economies of scale do not (at least not directly) affect the, already very low, marginal cost of production. For example, factors such as regulatory barriers, patent issues and the cost of setting up and maintaining distribution networks (in addition to the threat of arbitrage) make poorer countries less attractive markets even when rich ones pick up the cost of Research and Development (R&D) through much higher than marginal cost prices.

Enhanced competition

Economic analyses of price discrimination traditionally focus on industries operating in a monopoly setting. However, the market for branded pharmaceuticals is closer to an oligopoly because single-source branded drugs often face competition from therapeutic substitutes or other treatment modalities. In this setting, the effects of price discrimination on total welfare, according to economic theory, are more

sensitive to assumptions about the shape of the demand curves of the different market segments. In certain cases, price discrimination can lead to welfare gain through intensified competition.

For this to occur, competing firms must differ in their assessment of a particular government agency's price sensitivity for the same type of drug. As an example, the manufacturer of a branded anti-hypertensive drug might raise its VA price while the manufacturer of a competing anti-hypertensive drug might reduce its VA price, based on differing assessments of the government's price sensitivity. This 'best response asymmetry' is usually driven by consumers' strong brand preferences (rather than price). According to economic theory, different assessments of brand loyalty would trigger competition between the therapeutic substitutes and lead to price reductions across the board (Holmes, 1989; Corts, 1998; Armstrong, 2006). However, in our case, federal (or state) agencies are the consumers and they are forbidden by law from exercising brand loyalty, making this scenario less applicable in the government context.

Better incentives for R&D

Price discrimination can support future R&D investment if it allows for higher aggregate spending on drugs by the federal government (Hausman and MacKie-Mason, 1988; Danzon, 1997). We return to the 'R&D incentives' argument towards the end of this study.

For price discrimination to make economic sense, observed price differentials need to reflect underlying demand elasticities (first condition). Does this theoretical framework, developed for individual consumers making choices based on their willingness to pay, also apply in the government context? A relevant question is whose demand curves should be considered when drug companies are selling to government programmes – beneficiaries or government agencies?

To the extent that price sensitivity is an inverse function of income, government agencies that benefit the poor should have higher elasticities of demand. However, in the context of the health care market, demand elasticities are distorted by public and private insurance, imperfect agency on behalf of the physician and information asymmetry, and further compounded by the high cost to patients (or clinicians) of accessing information on the relative value of treatments. Co-pays are relatively small, particularly in the case of Medicaid, and premiums rare. For example, given the initial deductible in most plans, and an up to 100% coinsurance if a drug becomes excluded from a formulary, Medicare beneficiaries are likely to have higher elasticities of demand than Medicaid ones.[4] In most cases, the federal beneficiaries are (at least in part) insulated from the price differentials paid by the various government agencies.

4 Other factors, such as, life expectancy or disease severity may have an opposite effect. Finally, there is the 'Wal-Mart effect', whereby beneficiaries can buy selected generics at $4 – this can affect their elasticity of demand for generics within Part D programs, as it is sometimes cheaper to go outside of Part D.

The first condition of price discrimination could still apply if individuals chose to use certain government agencies based on their own sensitivity to price and value. Government agencies utilise different measures to control prices and utilisation such as formularies, preferred drugs' lists, prescription guidelines and mandated rebates. To the extent that some beneficiaries can choose between various government agencies to receive their drugs, the choice may reflect individual preferences. In these special cases, price discrimination would be justified by underlying differences in price sensitivity of beneficiaries. However, most beneficiaries are not eligible for drug benefits under multiple federal programmes.

In conclusion, neither volume-based discounts nor price discrimination are good rationales for the observed drug price differentials. It seems that legislative and organisational structures that evolved differently over the years, led to distinct purchasing approaches, providing the government with very different types of bargaining power and creating different incentives for the industry. These institutional arrangements dominate economics, distorting the government market for pharmaceuticals with important economic and ethical implications.

Legal frameworks and institutional arrangements

One reason for existing price differentials across government agencies is the Congressional structure and governing rules and regulations. Congressional decisions determine the cost control and price negotiation mechanisms the different federal agencies can use such as statutory rebates or the use of closed formularies. Below we briefly describe certain aspects of the three major government programmes, VA, Medicaid and Medicare Part D that might need to be revised if a single price were enacted (Government Accountability Office, 2007; Jacobson, 2007). The CBO report mentioned earlier describes the approaches used by other government agencies. Many of these agencies use approaches that are variants of the VA, Medicaid and Medicare approaches and would also require revisions. Government finances the bulk of pharmaceutical expenditure in all three programs, apart from beneficiaries' contributions in the form of premiums and co-insurance (Part D) and (nominal) co-pays (Medicaid and VA).

The Veteran's health Administration (VA), receives discretionary funding by the federal government in the form of earmarked annual appropriations set by Congress, and can choose from a range of drug prices, including federal supply schedule (FSS) prices, set by statute to be no higher than those charged to manufacturers' most favoured private customers or Big Four prices.[5]

5 FSS is run by VA that negotiates prices with manufacturers and aims to provide federal entities that purchase drugs directly from manufacturers with prices comparable to those achieved by private purchasers. Federal entities eligible to use FFS include VA, DoD, Public Health Service (including the Indian Health Service), the Bureau of Prisons and others. Big Four are: VA, DoD, PHS (including the Indian Health Service) and the Coast Guard. Big Four prices are 24% of the non-federal average manufacturer price.

Furthermore, VA can enter in direct negotiations with manufacturers, nationally or locally, to reduce prices below the FSS or Big Four levels. In the latter case, price-volume agreements or preferred status on the VA formulary and shifting market share serve as bargaining tools. In addition, VA serves as an important physician-training centre, which may also contribute to manufacturers' willingness to concede price discounts to get into its formularies.

Medicaid is a joint federal/state program with federal government covering more than half of the total cost as entitlement spending.[6] Medicaid agencies use several mechanisms to determine the prices they pay. First they establish a payment rate based on the AWP or wholesale acquisition price. They may also negotiate supplemental rebates at the state level through pharmacy benefit managers (PBMs) and/or, since 2004, through multi-state purchasing pools. In 1990, the Congress passed the Omnibus Budget Reconciliation Act (Omnibus Budget Reconciliation Act of 1990 OBRA-90), which allows Medicaid programmes to receive rebates based on the lower of 15.1% of the average manufacturer price (AMP)[7] or the best price achieved by private payers. The trade-off for this rebate is that Medicaid programmes cannot have a formulary and have to include all products of those firms that agree to participate in this rebate program (Pollard and Coster, 1991).

Medicare Part D, funded from general revenue via annual appropriations that automatically adjust to match expenditure (and by additional individual contributions when the beneficiary is in the donut hole), uses private plans called pharmaceutical drug plans (PDPs) or Medicare advantage drug plans (MA-PDs) to provide its drug benefit. The private plans negotiate directly with manufacturers or contract with PBMs representing multiple plans. Private plans and PBMs can negotiate volume discounts or use market shifting agreements and preferred drugs lists to get a better deal.

So, while VA negotiates prices and reimburses manufacturers directly acting both as an insurer and a pharmacist, Medicaid and Part D plans negotiate rebates with manufacturers but then reimburse pharmacies for the drugs their beneficiaries purchase. For the federal government to move towards a single price, through, for example, direct negotiations with manufacturers regarding the purchase price or the overall rebate, differences in financing streams and cost-sharing levels, programme design and distribution channels would need to change. However, before discussing these issues it is important to investigate if there are ethical reasons that would support the different prices.

6 This is in contrast to VA spending which is discretionary: while Medicaid beneficiaries are by law entitled to receiving the benefit, veterans eligible for VA are not. For a discussion on reforming VA's funding status see 'The House Committee on VA: the future of funding of VA', http://veterans.house.gov/hearings/hearing.aspx?NewsID=130

7 AMP is the average price paid to manufacturers for drugs distributed via retail or mail order pharmacies. It is not publicly available and is set by manufacturers; in that sense is as fictitious a number as AWP.

The ethics of drug price differentials

For the current structure of drug price differentials across government programs to be ethically defensible, at least two sets of considerations need to be satisfied. Firstly, morally relevant reasons for providing more public assistance to the military and veterans than to the poor, and to the poor than to the elderly, as is currently the case, need to be adduced. Secondly, assuming such reasons are persuasively put forward, granting each program independent drug purchasing authority and distinct organisational and institutional arrangements must be the only or best way to ensure these differential benefits.

What counts as a morally relevant reason for differential benefits and burdens in a health care system depend on multiple features of that system, including most notably questions of substantive and procedural fairness. Numerous substantive criteria have been put forward for making judgments about fairness in the context of health care setting, including considerations of health utility and cost-effectiveness (Gold, 1996; Waters, 2000; Ubel, 2001; Gold *et al*., 2007), unjust inequalities and systematic disadvantage (Powers and Faden, 2000), need (Atkinson, 1983; Mooney, 1987; Veatch, 1999; Brock, 2002), contribution (Beauchamp and Childress, 1994) and fair equality of opportunity (Daniels, 2008). All of these considerations deal, in one way or another, with the issue of whether treating the military, poor and elderly differentially in drug policy is ethically justifiable, an issue which is beyond the scope of this study.

Particularly in the absence of agreement in moral and political theory about whether there are sufficient, morally relevant reasons to determine if differentiating between military service, poverty and old age in drug pricing policy is ethical, societal consensus on the issue may play an appropriately determinative role. From the standpoint of procedural fairness, considerations of democratic legitimacy and societal values themselves can count as morally relevant reasons in defence of value trade offs within and across different sectors of social policy. Federal spending on health care, relative to other federal spending such as transport or defence, reflects a social valuation of health. This same social valuation also plays a role within sectors of government spending.

Thus, one reason for drug price variations is that society may choose to convey differential bargaining powers to different government programmes based on societal determinations expressed through legitimate legislative and regulatory processes that, from an ethical standpoint, beneficiaries of certain programmes deserve (e.g. active military, veterans) or need (the poor) more comprehensive, less financially burdensome assistance than beneficiaries of other programmes. There is little evidence in the historical record, however, that the current method of drug pricing in different government programmes was created explicitly to reflect American society's moral valuation of what different groups should receive by way of drug benefit or incur in terms of cost. At best, it could be argued that the resulting system of subsidies *implicitly* reveals societal

preferences toward specific groups, but this is a thin reed on which to claim a societal determination that the military and veterans should receive more assistance than the poor, and the poor more assistance than the elderly.

Assume, however, that it is determined that as a normative matter different groups should receive differential benefits. The second consideration still remains – whether the only or best way to ensure such differential benefits is to grant each programme independent drug purchasing authority and distinct organisational and institutional arrangements as described earlier.

There is little basis for reaching this conclusion, however. Granting different programmes independent authority under different rules to negotiate with pharmaceutical companies adds unnecessary complexity to government purchasing without necessarily facilitating differential benefits at the beneficiary or programme level. A single price paid to manufacturers for the same drug across government programmes can be coupled with additional institutional and policy arrangements regarding programme-specific government subsidies or co-pays. This will, in turn, allow for differential burden of support through taxes at the programme level and differential benefits in terms of individual financial contributions at the beneficiary level. In fact, a single price will make such arrangements both administratively less burdensome and more explicit to taxpayers and beneficiaries alike.

Furthermore, a unified approach to purchasing pharmaceuticals across government programmes will make it easier to ensure what the beneficiaries receive tracks programme-specific drug pricing and explain the differential burden to taxpayers who ultimately fund the bulk of the benefit package. Insofar as there is currently an extant lexical ordering of societal preferences across beneficiary groups, this ordering is not necessarily reflected at the individual beneficiary level in terms of cost sharing. For example, despite the apparent 25% price premium taxpayers' pay for the same drug when purchased by Medicaid compared to VA, Medicaid beneficiaries and veterans pay similar nominal co-pays.[8] If the societal intent is to provide (at least some) VA beneficiaries with better benefits than Medicaid beneficiaries, why do VA beneficiaries have formularies and thus more restricted access whilst Medicaid beneficiaries do not? Another example of the disconnect between pricing and social policies regarding magnitude of benefits is the recent move of dual eligibles from Medicaid to Medicare under Part D. This has resulted in government paying higher prices for drugs for Medicaid beneficiaries without any improved benefits experienced by those dual eligibles (Frank and Newhouse, 2007).

Under the provisions of the Medicare Modernisation Act, Medicare beneficiaries have to make larger financial contributions, which can have significant access implications. While there is no premium for VA and Medicaid recipients and their co-pays tend to be comparably small, Part D beneficiaries pay on average approximately $384 on premiums. After a $275 deductible, Medicare

8 Low income, compensable service-related disabilities, prisoner of war and decorated status are some of the attributes of VA beneficiaries qualifying them for exemption from paying any co-pays.

beneficiaries pay 25% of the prescription cost up to $2235, at which point they fall into the 'doughnut hole' where they bear the full cost of drugs they purchase up to $5450 when their co-insurance rate drops to 5% (Kaiser Family Foundation, November 2007; Center for Medicare Advocacy, 2008). The elderly receive a less generous, more burdensome to them drug benefit than the Veterans or the poor. At the same time the Medicare programme pays higher prices for drugs compared to Medicaid and VA, which means that taxpayers' dollars do not go as far when spent on drugs for the elderly (Anderson *et al*., 2004). However, if societal preferences are for the elderly to have a less generous drug benefit than the other groups, then the per capita drug benefit price to the taxpayer for the elderly should be lower and not higher.

Clearly the currently fragmented system does not serve any disposition on society's part to differentially subsidise different beneficiary groups; at times, as is the case with Medicare, it achieves the opposite. Furthermore, the current situation makes any attempt by the government to articulate the ethical basis of its coverage policies or inform such policies by broader societal values, unlikely. Therefore, instead of impeding the expression of societal preferences for differential support to different population groups, a single government price would foster a rational and transparent approach.

Arguments against a single government price

Political concerns

Structural and organisational obstacles

Given their weak grounding on economic theory or ethics, drug price differentials across government purchasers are more the products of historical accidents and subsequent political compromises. This evolution has in turn generated and is currently sustaining distinct political constituencies and lobbying parties. There are now significant bureaucracies built around each programme, with different Congressional committees carrying responsibility for VA, DoD, community health centres, Medicare or Medicaid.

Change is thus likely to be opposed not only by drug manufacturers concerned about the ability of the government to negotiate lower prices and PBMs administering Part D plans,[9] but also government agencies worried about the implications of a rise in spending in their own programme, even if overall government spending remains unchanged. Consolidation may result in some of the bureaucratic and administrative structures becoming redundant, another ground for opposing reform. Perhaps one of the greatest barriers is the myriad of Congressional committees that could lose jurisdiction over drug spending.

9 The health industry spent $15 million on lobbying congress in the first half or 2009 alone. OpenSecrets.org – accessed 2009.

These political and bureaucratic constraints may be the primary reason for the continuation of differential drug prices.

Aversion to administered prices

There is a general concern that if government determines drug prices, this could create price distortions with possible adverse implications for the health of drug companies. But, with appropriate access to information on comparative effectiveness of alternative technologies, it is possible for the government to increase the value of billions of taxpayers' expenditures on pharmaceuticals. However, this is subject to the institutional arrangements for prioritising, generating and using comparative effectiveness research. Access to information is necessary (but not sufficient) for government to make informed purchasing decisions, especially in the current climate where decision makers are explicitly prohibited (by statute) from using this information to make coverage decisions (Chalkidou *et al.*, 2009).

Economic concerns

The threat of cost shifting or price distortions in the private sector

Cost shifting exists when a firm raises its prices to one buyer *because* it lowers the price to another buyer (Morrisey December, 1996). Two conditions must hold: (a) the firm has enough market power to cost shift (i.e. there is little or no competition) and (b) the firm has not been fully exercising this power (Morrisey, 2003). Patent protection suggests that the first condition is met. Sole source drugs with no therapeutic substitutes have considerable market power to set the price without significant market constraints (Frank and Newhouse, 2008). For the second condition to apply, drug companies must be currently offering some government agencies lower prices than they could obtain if they were fully to use their market power. In other words, the drug companies are currently not charging the full amount they could to certain government agencies.

While higher prices to private insurers have been causally attributed to provider rate reductions by Medicare and Medicaid, the extent to which such effects of administered prices on private sector rates fit the conventional economic definition of cost-shifting has been questioned (Ginsburg, 2003). Irrespective of whether cost shifting goes against a firm's self interest, what matters to policy makers is whether such behaviours have been observed in the healthcare setting, under what circumstances and what their financial impact has been. We examine the empirical evidence of cost shifting or distortionary effects caused by administered prices, in the 'natural experiment' that was the introduction of the most favoured customer clause for Medicaid reimbursement of pharmaceuticals (Omnibus Budget Reconciliation Act of 1990 OBRA-90). It has been argued that this policy was directly responsible for higher drug prices for private purchasers, a conclusion often cited as a key reason why government should avoid,

in the future, using its bargaining power to get lower prices (Scott-Morton, 1997; Kyle and Ridley, 2007; Hogberg, 2007).

In the early 90s the General Accounting Office carried out two analyses, neither of which supported the cost-shifting hypothesis (Government Accountability Office, 1991, 1993).[10] In 1996, a CBO report attributed the reduction in the number of large price discounts to private purchasers observed after 1991 to Omnibus Budget Reconciliation Act (OBRA's) inclusion of a provision that guaranteed Medicaid the 'best price' obtained in the private sector. However, without data from the period that preceded the legislation, no causal relationship could be credibly established. The analysis also showed that best price discounts health maintenance organizations (HMOs) and hospital groups received from manufacturers were in fact higher in 1994 compared to 1991 for 30% of the drugs reviewed (Congressional Budget Office, 1996).[11]

Two highly cited studies published in 1997 and 2005 claimed that the Medicaid best price provision resulted in higher costs for the private sector (Scott-Morton, 1997; Duggan and Scott-Morton, 2005). The 1997 study concluded that the Medicaid best price provision resulted in a 4% increase across drugstore (but not hospital) non-Medicaid prices for multi-source branded drugs, while it had no significant effect on single-source branded drug prices. The study has severe data limitations and reaches a rather counterintuitive conclusion that the more intense the competition (multi-source drugs) the larger the cost-shifting effect.[12] More importantly, the impact of OBRA on prices, even if causality is accepted, is, at best,

10 The 1991 report was inconclusive due to data limitations including lack of pre-1991 data, and the 1993 one revealed a mixed picture. Overall, the rate of growth in drug prices more than doubled for outpatient drugs (purchased mainly by health maintenance organizations) after 1991 while prices dropped for inpatient drugs (purchased by GPOs on behalf of hospitals). As inpatient drugs were excluded from Medicaid rebate this trend was consistent with cost shifting; however, this was contradicted by a later analysis of a similar dataset by F. Scott-Morton, The strategic response by pharmaceutical firms to the Medicaid most-favoured-customer rules. *Rand Journal of Economics* (1997), **28**(2): 269–290.

11 The CBO analysts focused on new drugs launched after 1991 as they questioned whether cost-shifting affecting prices of drugs already in the market could occur. The higher best price rebates after 1991 for one third of the drugs assessed were mostly attributed to a faster increase of AMP compared to best price.

12 Data limitations include the lack of companies' individual invoice level data that are considered proprietary, using average instead of best prices (the latter are also proprietary), lack of Medicaid share data (key explanatory variable) for half of the observations and no information on cash rebates and bundling pricing agreements with private payers which reduce the final non-Medicaid prices. The theoretical assumption behind the counterintuitive conclusion is that, higher competition results in greater price dispersion and thus a higher probability that a firm would be bound by the 'best price' clause and have to raise its lowest price. This contradicts the 2005 analysis by Duggan and Scott-Morton. Furthermore, low price dispersion coupled with low average price could also result in a firm increasing all prices to raise its average and take advantage of the percentage of the average price provision. In fact, as the same author shows in later empirical work price dispersion is a rather poor predictor of price increases: F. Scott Morton, The interaction between a most-favored-customer clause and price dispersion: an empirical examination of the Medicaid rebate rules of 1990. *Journal of Economics & Management Strategy* (1997), **6**(1): 151–174

modest: a 4% price increase for a small subgroup of drugs studied. Averaged across all branded drugs, the observed rise in price would be much lower than 4%.

The 2005 study showed that drugs popular with Medicaid tended to be, on average, more expensive, which the authors attributed to OBRA.[13] However, the observed trend was not statistically significant at the conventional 5% level. Based on the empirical analyses, the Medicaid best customer clause may have led to a very small increase in non-Medicaid prices. Given the methodological and data limitations and the modest effect size, this finding cannot be used to discourage current thinking on a consolidated government approach to purchasing drugs.[14]

Since January 2006, over 6 million Medicaid beneficiaries were moved to the Medicare programme under Part D (Tritz, 2005).[15] Prices paid by private health plans under Part D are proprietary and cannot be accessed; however, firms' 10-K[16] forms show increases in company revenues immediately after the switch (Berenson, 2006; Frank and Newhouse, 2007). According to a 'cost shifting' argument some of these extra revenues should be channeled back to privately insured employees or other public payers such as VA in the form of reduced drug prices. The limited available evidence suggests the opposite: higher drug prices currently paid by the elderly translate into greater profits for manufacturers.

Dynamic efficiency and the 'innovation premium'

A consolidated government approach to purchasing drugs equates, for some, to a monopsony situation where the government uses its considerable buying power to negotiate a single (lower) drug price, which could, in turn, reduce

13 After controlling for endogeneity that is the possibility that Medicare market share not only influences but can also be influenced by drug prices, they fail to demonstrate significant correlation between Medicaid favourite drug status and higher prices for private sector payers. The authors also investigate the effect of the inflation limit rule according to which firms provide Medicaid with an additional rebate if their AMP grows faster than inflation. This constraint was identified as a key reason for the lack of cost shifting in the case of single source branded drug prices by Scott-Morton in 1997. In this study it is found to be the cause for increasing rates for new drug introductions in drugs popular with Medicaid customers, albeit statistical significance (at the 10% level) is only achieved after subgroup analysis by drug's age and firm's revenues and for some drug subgroups only. An alternative explanation for this increased rate of introduction of new drugs in areas of high Medicaid need, not discussed by the authors, could be that the Medicaid reimbursement arrangements created a dynamically efficient environment strongly supportive of R&D.

14 Alternative analyses suggest that the application of bargaining tools by one segment of the market do not cause higher (and in fact may result in lower) prices for other sub-markets. See for example: J. R. Borrell, Drug price differentials caused by formularies and price caps. *International Journal of the Economics of Business* (2003), **10**(1): 35–48; S. Mujubdar and D. Pal, Do price ceilings abroad increase US drug prices? *Economics Letters* (2005), **87**: 9–13.

15 These 'dual eligibles' represented 13% of Medicaid beneficiaries and accounted for more than half of total Medicaid spending on prescription drugs.

16 The annual report on Form 10-K provides a comprehensive overview of the company's business and financial condition and includes audited financial statements. See http://www.sec.gov/answers/form10k.htm

industry profitability and future R&D investment. This does not have to be the case. First, it is unclear that the government would choose to lower aggregate payments for drugs. The reform could be introduced in a 'budget neutral' fashion as was the case with the Medicare prospective payment system (PPS). There is a broad recognition that drugs play an important role in improving health and that considerable investment is necessary for developing new drugs.

Second, it is unclear how the pharmaceutical industry would respond to less revenue from the federal government. A reduction in revenues could trigger either increased R&D spending to recoup losses, or reduced R&D investment if manufacturers failed to raise external capital. In addition, there is little empirical evidence suggesting that increased revenues from higher prices translate into more R&D expenditure. R&D spending by drug companies as a percentage of net sales has been reasonably constant for the past 20 years despite the higher profits of pharmaceutical companies (Pharmaceutical Research and Manufacturers of America, 2004; Cohen, 2005).

The current financial incentives may not be designed to encourage drug companies to invest in blockbuster drugs. According to Food and Drug Administration data, the number of new drugs continues to fall despite increasing profits (New Molecular Entities slump continues: FDA clears 18 novel drugs in 2006, same as 2005).[17] Only 14 percent of pharmaceutical revenues is invested into R&D, according to industry-reported data, accounting for less than half of what is spent on marketing (Reinhardt, 2001; Gagnon and Lexchin, 2008).[18] Perhaps a new pricing system that rewards good value innovation could be designed if the government paid a single price instead of multiple prices that provide mixed signals.

Not all innovation necessarily adds value and not all R&D is necessarily worthwhile from society's perspective (Dasgupta and Stiglitz, 1980; Tandon, 1983; Skinner *et al*., 2006; Dorsey *et al*., 2009; Light, 2009). Uncontrolled monopoly prices, particularly in the context of price discrimination, coupled with insurance-subsidised demand, can lead to excessive incentives for innovation (Garber *et al*., 2006). In fact, the lower the co-insurance rate, the greater the need for some sort of upper bound to price, possibly through negotiating mechanisms, in order to achieve socially beneficial dynamic efficiency.

Finally, prices are not the sole or necessarily the most appropriate means for encouraging innovation. Government already supports drug innovation through intellectual property laws and patent protection, tax breaks for commercial

17 In 2006, FDA approved 18 NMEs and 10 biologics and vaccines. One of the 18 NMEs was an OTC sunscreen, so only 17 new prescription NMEs were approved in 2006 – matching the 20-year low of only 17 approvals in 2002.

18 Data exclusivity clauses in intellectual property agreements, 'evergreening' policies and litigation brought against generic entry after a patent has expired reduce the chances of even imperfect competition in the pharmaceuticals market; see 'Lobbying Stalls Generic Drug Legislation' Associated Press, Washington DC, November 2007.

R&D, financing of infrastructure and training of scientists. Most importantly government invests considerable funds in research, particularly at the early and, thus, riskier preclinical stages. For example, the US National Institutes for Health spent over $28 billion in 2007 on medical research.

Above we describe a classical path dependency process, which has led to a lock-in-effect, with the major players resistant to change. The bureaucracy and fragmentation of the administrative system with multiple jurisdictions and congressional committees; an ideological aversion to administered prices or a what might perceived as a move towards a 'single payer system'; the threat of cost-shifting to the private sector and the possible effects of reduced company revenues on innovation are key obstacles to change and underpin the current opposition to the presidential healthcare reform efforts in the USA.

Towards a single government price for drugs

In industries with large fixed costs, as is the case with the pharmaceutical industry, marginal cost pricing is inefficient. The cost for manufacturing an extra pill (marginal cost) is negligible compared to the investment that goes into developing a new drug (fixed cost). In this context, economists have developed Ramsey prices as a second best solution (Ramsey, 1927). Because they exceed, on average, marginal costs, Ramsey prices could be used to cover the fixed costs of pharmaceutical R&D. Ramsey prices differ across different buyers since they are inversely related to buyers' price elasticities, which have to be known for Ramsey pricing to work. However, under limited competition due to patent protection and the ability to charge differential prices not necessarily reflecting true price elasticities, profit-maximising mark-ups set by monopolists will deviate from optimal Ramsey prices. Therefore, a private firm's incentive to maximise profit needs to be counterbalanced by the buyer's, in this case the government's, willingness-to-pay for a certain product. For Ramsey pricing to work, government as a single buyer, needs to be able to signal society's (taxpayers') demand curve. To do this, two steps are necessary:

Step 1: Uniform approach to government purchasing

In order for government to adopt a rational approach to buying pharmaceuticals, it first needs to consolidate the highly fragmented and inefficient current purchasing mechanisms across its different agencies. This would require significant legislative efforts and restructuring of the extant institutional structures. To the extent that such structures are justified neither by economic theory nor by a moral case, this is a worthwhile undertaking. In the current climate, major restructuring of Congressional committees and revision of the jurisdictions and responsibilities may not be a viable option. What is needed may be to focus on a single government programme. Medicare Part D is by far the most fragmented and less transparent in terms of prices, government programme. Perhaps, keeping the option of government negotiating prices, on the table,

during the ongoing reform efforts, is a start towards improving the coherence and rationality of government pharmaceutical purchasing policies.[19]

A single government price does not necessarily mean that the government should pay at lowest possible level. To start with, government could choose a budget neutral solution, for which there is, precedence when introducing payment reforms. For example in the original design of the PPS for hospitals, when Medicare changed from cost-based to prospective payment, the decision was made to have the change be 'budget neutral' in the short run. Under this scenario, some government programmes would pay more for drugs and others would pay less, which would require reallocation of dollars across government programmes.

Alternatively, Medicare could be allowed to negotiate prices for at least the most expensive and fairly inflationary single-source drugs, where monopolists have the most power to price-set, or, through increasing price transparency for Part D, government could claw back and pass on to beneficiaries excessive margins of PDPs. Our analysis so far demonstrates that the economics or deservedness arguments often used to prevent policy makers from even discussing a single price option or empowering government programmes, especially Part D, to negotiate prices, are not necessarily valid. The practicalities of implementing a single price goes beyond the scope of this draft and has been discussed elsewhere (e.g. see Frank and Newhouse, 2007).

Taking control of the drugs budget through a single purchasing mechanism is a necessary first step which can then empower government in adopting an evidence-based approach to investing in pharmaceuticals and future innovation, subject to budgetary constraints and an objective valuation of the health benefits of new technologies.

Step 2: Comparative effectiveness

In an environment where buyers can exert their choices as to where to invest their healthcare dollars, tools such as cost-effectiveness analysis can help decide the relative worth of different products (given the available resource) and inform government's decisions as to the maximum price it should be willing to pay for a certain product. To do this, buyers need reliable unbiased information on the comparative clinical and cost effectiveness of different technologies, including drugs (Reinhardt, 2001; Garber, 2004; Newhouse, 2004; Lopert and Moon, 2007). Such information can support rational decision-making by government and lead to more efficient spending of taxpayers' money, improved health outcomes and reduced uncertainty for naturally risk averse private investors.

Comparative effectiveness research can ensure that consolidated government purchasing arrangements do not become synonymous with a cost-minimizing

19 Negotiation of Medicare Drug Prices Back 'For Now', *The Wall Street Journal*, http://blogs.wsj.com/washwire/2009/07/31/negotiation-of-medicare-drug-prices-back-for-now/

monopsony, hence protecting both innovators and patients. In the context of a transparent and independent deliberative processes set up to interpret comparative effectiveness research findings, government can exert its consolidated purchasing power and signal a demand curve on behalf of taxpayers in a much more rational and accountable fashion than profit maximising monopolies, as is the case today. To the extent that comparative effectiveness incorporates costs, having a single price will simplify both the analysis and the decision making process. Empowering the demand side through better information of comparative effectiveness is a common trend across countries (Chalkidou *et al.*, 2009). For example, in the UK, the Office of Fair Trading recommended a value-based approach to the pricing of branded pharmaceuticals, based on evidence of better performance compared to available alternatives. The recent pricing reforms in the UK include provisions for flexible pricing and risk sharing between government and Pharma, conditional upon additional evidence being assessed (Garber and McClellan, 2007; Department of Health, 2009). In Australia, the government has been 'purchasing outcomes' through its Pharmaceutical Benefit Scheme, based on evidence of comparative clinical and cost-effectiveness, since the early 90s.

Conclusion

A single price and a uniform government purchasing policy have numerous advantages. A single price will eliminate congressional, administrative and bureaucratic redundancy, improve efficiency and reduce some barriers to conducting comparative effectiveness studies. It will allow for greater price transparency. It will make it possible to compare prices across government programmes (Medicare vs VA), between the public and private sectors and between the US and other countries. Most studies suggest that the US government is paying much higher prices for drugs than governments in other industrialized countries. A single price would make these comparisons easier. A single price would send explicit and consistent signals to drug companies concerning the type of innovation valued by society (taxpayers) through a clear and uniform set of financial incentives. Finally it would allow policy makers to explicitly decide about the structure of government-provided drug benefits for different populations based on society's normative valuations of what ought to be provided to each group and what it is possible to do.

In the Congressional debates over health care reform, a practical application of the issue of uniform drug pricing policies, became apparent. Before the passage of the Medicare Modernization Act, Medicare beneficiaries also were eligible for Medicaid ('dual eligibles') received their drug benefit through the Medicaid program. As noted earlier the Medicaid program paid lower prices than the Part D plans pay for Medicare beneficiaries. Once the Medicare Modernization Act became effective, the beneficiaries began receiving their drug

benefits through Medicare. The CBO reported that the higher prices paid to drug companies because of this switch of responsibility was approximately $60 billion over a ten year period. This additional payment goes directly to the drug companies and is paid for by the American tax-payer. Price differentials across government agencies can have substantial budgetary implications.[20]

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