Have your cake or eat it: do decisions based on cost-effectiveness undermine incentives for research and development?

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Abstract

Background: Although cost-effectiveness analysis allows efficient decisions about the use of existing technologies (static efficiency) it has been argued that it will disincentivise the development of innovative technologies (dynamic efficiency). These concerns have also been raised about the report by the UK Office of Fair Trading which recommends that the price of pharmaceuticals should be based on the cost-effectiveness of the technology.

Aims: To establish whether decisions based on cost-effectiveness necessarily undermine incentives for the development of future health technologies.

Methods: The arguments put forward as to why cost-effectiveness decisions might undermine incentives for innovation are examined and are used to consider the implications of the type of value based pricing which has been proposed in the UK.

Results: The argument depends on whether the purpose of health care is to improve population health or to maximise welfare (consumer and producer surplus). If it is the former, then achieving static and dynamic efficiency requires a clear and predictable signal of value (cost-effectiveness) to the private sector. The private sector can then choose to invest in developments which it believes will provide a satisfactory return on investment, where intellectual property rights are protected by patent. From this perspective manufacturers should be allowed to appropriate some share of the surplus (monopoly rent) realised to incentivise investment in research and development, as they would with marginal pricing based on cost-effectiveness. However, they should not take it all (even with a welfare maximisation objective). The public sector subsidises research and development in many ways, therefore, even if society was unconcerned about who benefits from innovation (patients or the pharmaceutical industry) it would not be efficient to allow full appropriation. In other markets, where innovation is protected, society simply offers monopoly rent during patent protection but does not allow full appropriation by, for example, facilitating perfect price discrimination. Finally it may be appropriate for society to be concerned about who receives the benefits and that at least some of the benefits of innovation should accrue to patients in the form of improved health outcomes.

Conclusions: The argument that decisions about the use and price of a technology based on cost-effectiveness will undermine the incentives for research and development are misplaced if the objective is to improve population health given a fixed budget constraint.

1. Introduction

Many countries now base their decisions on whether to reimburse pharmaceuticals and medical technologies on cost-effectiveness analysis.[1-3] When performed appropriately cost-effectiveness analysis should allow efficient decisions about the use of existing technologies, thus resulting in static efficiency. However, it's implications for dynamic efficiency are less clear.Concerns have been raised in the US[4] and more recently in the UK following the Office of Fair Trade report on reforming the UK Pharmaceutical Price Regulation Scheme (PPRS), which recommended abandoning profit and general price controls in favour of basing a new drug's price on its health benefit.[4 5] If prices are to reflect the "value" of a new pharmaceutical to the Health Care System (HCS) a clear definition of value and a means of measuring it is required.

It has previously been argued that the decision rules of CEA undermine incentives for the development of innovative technologies, leading to a loss of dynamic efficiency.[4] However, these concerns are based on a misconception about the cost-effectiveness threshold. Building on the analysis in previous papers[6 7] we will show that the normative perspective taken determines the appropriate choice of threshold which should be used to set the prices of new pharmaceutical. The threshold determines the value of the pharmaceutical and if this does not provide enough return on the innovation to the pharmaceutical companies to ensure dynamic efficiency then other policy measures should be considered rather than artificially altering the price, for example length of patent protection.

This paper is organised as follows. Section 2 examines what is the value of a pharmaceutical innovation and how this can be encapsulated into the price paid. Section 3 considers the benefits of an innovation in the long run, focusing on the period when generic versions of a pharmaceutical become available after patent expiry. Section 4 examines how the benefits of an innovation should be split between the HCS and the pharmaceutical companies. Section 5 discusses some of the issues raised in the article, while section 6 draws some conclusions.

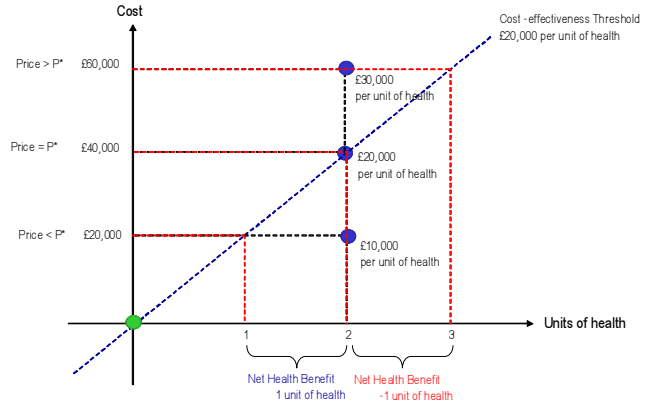
2. Value of a pharmaceutical innovation

Cost-effectiveness analysis is often seen as a means of maximising an exogenously set objective (for example, health) subject to an exogenously set budget constraint.[8] Decisions can be based on the net health benefit, the net monetary benefit or by comparing the incremental cost-effectiveness ratio (ICER) to a cost-effectiveness threshold which represents the cost per unit of health of the health care which will be displaced to fund a newly introduced intervention.[9-11] In such circumstances cost-effectiveness analysis does not, and cannot, make claims about social welfare or the optimality of the budget. Instead its role is to inform social decisions in health rather than prescribing social choice. It is this role that cost-effectiveness analysis has tended to play in practice, for example with the National Institute for Health and Clinical Excellence (NICE) in the UK. In such circumstances the agent can be regarded as a delegated authority which cannot be asked to improve social welfare, since social welfare cannot be

specified. Rather resources are allocated and explicit, and therefore necessarily narrowly defined, objectives (e.g., improve health) are determined by the principal. The implications of this process (i.e. the shadow prices of the constraints imposed) are a partial social expression of some unknown latent welfare function.

In such circumstances as described above a drug can be said to be of value to the health care service, for example the NHS, if the health expected to be gained from its use exceeds, or is at least equal to, the health forgone as other treatments are displaced by its additional cost, i.e. if it is cost-effective and provides positive, or at least non-negative, net health (or monetary) benefits.

Figure 1- Cost-effective and prices



k = Cost-effectiveness threshold
ΔH = Extra units of health generated by the new drug
ΔC = Extra costs generated by the new drug (we will assume that this is equal to the price only)

Net health benefit = $\Delta H - \Delta C / k$

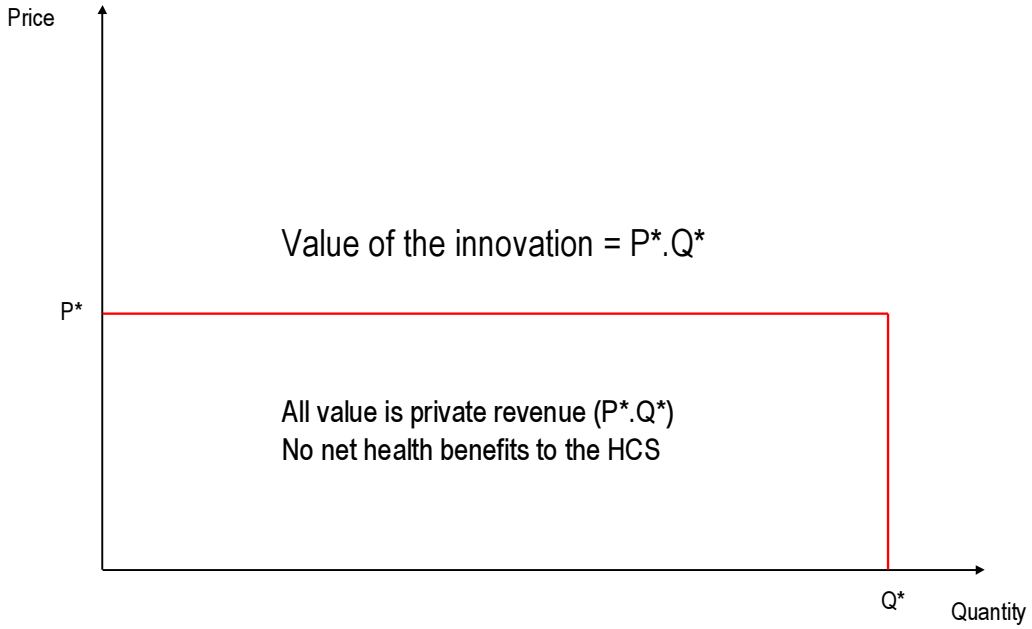
Incremental cost-effectiveness threshold = $\Delta C / \Delta H$

Figure 1 shows a new drug which provides two additional units of health benefit. For every extra £20,000 spent on the new drug, one unit of health is displaced elsewhere in the health system to fund it, i.e. the cost-effectiveness threshold is £20,000 per unit of health. If a price of P=£20,000 was set then there would be a net health benefit to the HCS of one unit of health as only one unit is displaced yet two units are gained. If a price of P=£60,000 was set then there would be a net health loss to the HCS of two units of health. At prices up to P* (P=£40,000), where the incremental cost-effectiveness ratio (ICER) of the drug is equal to the threshold, the drug would be regarded as a cost-effective use of HCS resources (as there is at least no net health loss).

Price, demand and cost-effectiveness

If a price is set (P*) such that the ICER for a patented drug (across its whole indication Q*) is just equal to the threshold, then the health benefits offered are just offset by the health displaced elsewhere (there are no net health benefits to the HCS). The value of the innovation is P*.Q* but the HCS does not share this value during patent protection (all of the benefit accrues to the producer of the drug).

Figure 2 Perfectly inelastic demand



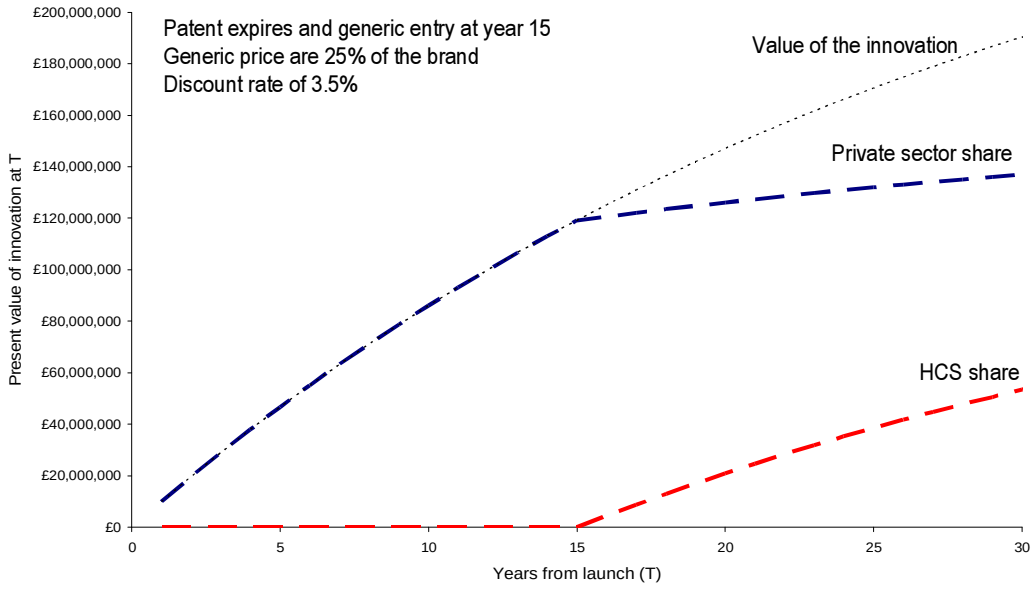
Estimates of cost-effectiveness, on average across the whole patient population, offers a perfectly elastic demand curve to the temporary monopolist upto Q* and then a perfectly inelastic demand curve. The profit maximising monopolist will therefore price at P* and capture the entire value of the innovation in the form of revenue (there is no consumer surplus, or net health benefit ($\Delta H - {}^{\Delta C}\!/_{k} = 0$). Rather then undermining patent protection and incentives for innovation it offers full appropriation of all the value by the producer. This is arguably a greater reward (or at least as great) than in other markets which protect innovation.

It has been suggested by others[4] that the cost-effectiveness threshold k does not represent the marginal social valuation of a unit of health (which we will refer to as v). This view is based on a broader view of the role of economic analysis in informing social choice. Such a role for CEA is more ambitious; providing a means of making statements about social welfare but also requiring the specification of an explicit social welfare function which will have more than mere health as its arguments . If such a view is taken and the health care system is still subject to an exogenously set budget constraint and v > k as has been suggested[4] then the healthcare system is not spending enough on health,. However, the price of the drug should not be based on v. If we used a threshold of v to set the price of the drug, where v>k, then the net health benefit to the system would be negative, less units of health would be produced than are displaced (i.e. we would set it such that $\Delta H - \Delta C/v = 0$ which would result in the true net health benefit to the HCS being $\Delta H - \Delta C/k < 0$). It would also be possible to consider a situation where there is no exogenous budget constraint, such that the budget becomes endogenous to the problem. In this case the costs can fall on consumption (i.e. if the budget is increased) or health (i.e. if other interventions are still displaced to fund the new intervention).

3. Future benefits of innovation

If cheaper generic versions of the drug become available following patent expiry then the HCS may ultimately benefit in the long run under certain conditions. The most important of these are: i) the generic market for the drug remains competitive and ii) the cost-effectiveness and prices of future patented drugs are compared to the cheaper generic versions when they become available.

Figure 3 Share of the value of innovation given inelastic demand and competitive generics market



The share of benefits between private sector and HCS depends on several factors; i) the period of patent protection (longer protection gives a greater share to the private sector), ii) the price reduction at generic entry (larger price reductions give a greater share to the HCS), and iii) the discount rate (the higher the discount rate the larger the share to the private sector as future benefits to the HCS due to generic entry are valued lower)

In figure 3 above, where T* is 30 years, the patent life is 15 years, generic prices are 25% of P* and future costs and benefits are discounted at 3.5%, the private sector appropriates 72% of the value of the innovation (based on a cost-effectiveness threshold of k). Even when the assumption that T* is finite is relaxed such that there is an unbounded time horizon (i.e. the innovation is forever relevant) the private sector retains 57% of the value.

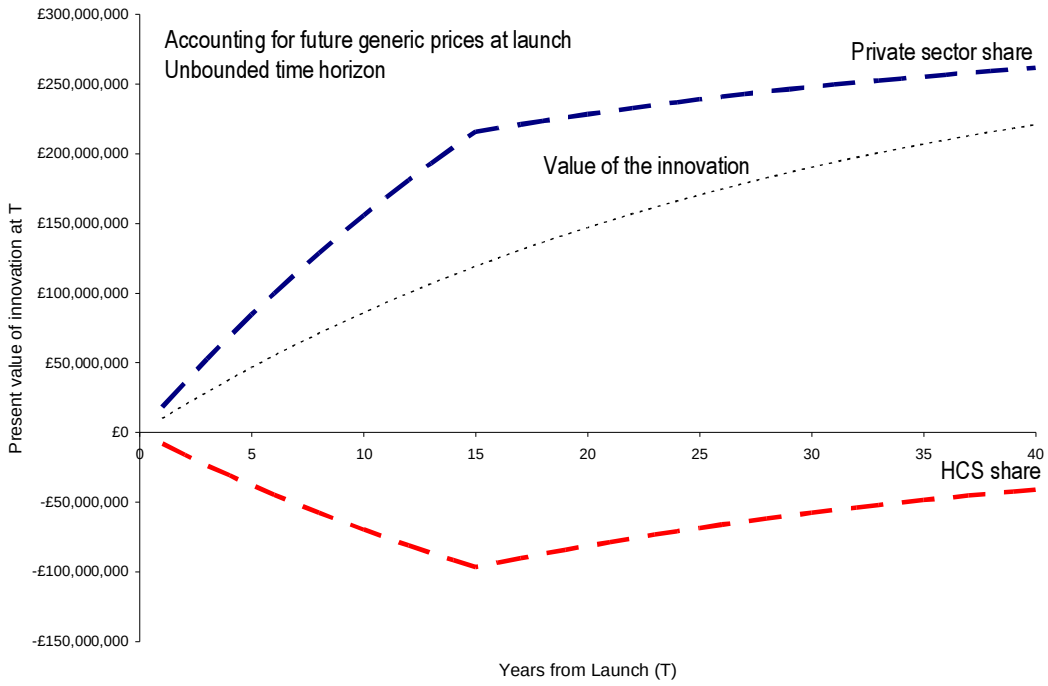
Figure 3 represents the best possible scenario for the HCS, for example it assumes that generics will be fully implemented following their introduction and that a competitive generics market will result in a price drop of 75%. However, this clearly may not be the case as inappropriate prescribing will result in the branded drugs still being used and there is no guarantee of a competitive generics market.[5 12]

Is this enough to ensure dynamic efficiency?
It has been argued that the expected reduction in price following patent expiry and generic entry should be taken into account in CEA when making decisions about branded drugs at launch, i.e., the HCS should be willing to accept price greater than P* during patent protection in anticipation of prices less than P* following patent expiry.[13] This is akin to saying we should accept negative health benefits in the short run as these will be just off set by positive net benefits in the longer run.

If we were to account for future generic prices, the private sector appropriates all the future benefits of innovation as well as all the benefits during patent protection and there are no overall health gains from pharmaceutical innovation- you can have your cake but never eat it. At best and only in the long run it is equivalent to extending patent protection indefinitely. In the short run (any $T<\infty$) it is worse - since more than the total value is appropriated, the HCS is damaged by the innovation and net benefits only approach zero at an unbounded time horizon. Such a situation is represented in figure 4.

Figure 4 represents a situation which we would not expect to see in any other markets. We would not expect consumers to pay more than a good is worth now as they know it will be cheaper in the future. Why should we expect the HCS to do just that?

Figure 4 Accounting for generic prices- Infinite patent protection or worse?



When should we account for future generic prices?

We have previously shown that to account for future generic prices now would result in the health care system losing out in the short run (Figure 4). However, there may be situations whereby future generic prices should be taken into account when evaluating cost-effectiveness. It must be noted that when we make a decision on whether to prescribe a drug it is not a now or never decision, for example we could choose to delay its introduction. It will be worth taking account of future generic prices only under restrictive conditions which would result in treatment being less cost-effective the longer the treatment is delayed. These conditions include the disease being chronic, progressive and with a degree of irreversibility such that the treatment costs more per unit of health benefit as we delay its introduction into the future.

4. How should the benefits of innovation be shared?

Even if social welfare is defined as the sum of producer and consumer surplus (i.e. society is indifferent to whom the benefits accrue to the HCS or the producer) there are good reasons why full appropriation of the value of the innovation by the producer would be inefficient. Society contributes to research and development and thus to innovation in pharmaceuticals in many ways such as: (i) indirectly through investment in general infrastructure; (ii) through publicly funded research; and (iii) through subsidies and tax

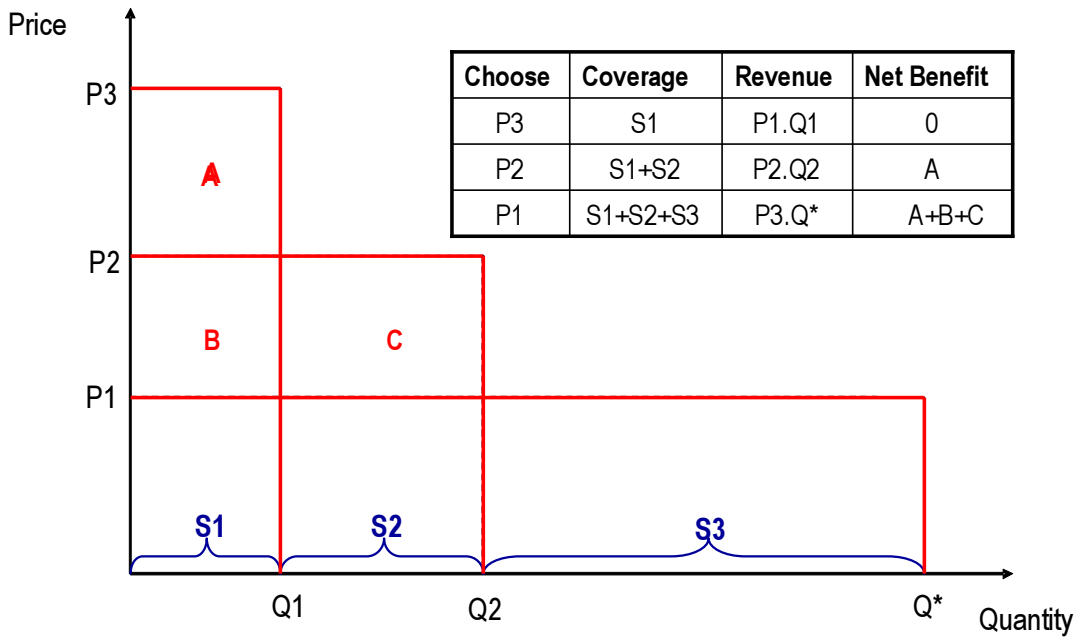
incentives for commercial research and development. Therefore, full appropriation of the value of the innovation by the private sector would not result in an efficient outcome, it would reward the private sector too much and encourage over investment in the development of new pharmaceuticals.

Society also legitimately cares who receives the benefits and it is reasonable that at least some of the benefits of innovation should accrue to consumers (patients in the case of pharmaceuticals) at some point, e.g. patent protection is temporary in all markets. The purpose of the HCS is to improve health (not maximise the sum of producer and consumer surplus) now and in the future. In doing so it is important to incentivise (only) those innovations which will be valuable to the HCS. But this does not mean the private sector should take all the benefits even during patent protection

Mirror other markets?
In other markets, where innovation is protected, society regards it as enough to offer a temporary monopoly during patent protection. CEA simply mirrors this situation offering a 'HCS demand curve' to the monopolist.

For most indications, cost-effectiveness will usually vary between identifiable groups of patients, e.g., due to different relative effects of the drug, differences baseline risks, costs or quality of life. The relationship between price and coverage based on CEA, or the 'HCS demand curve', is illustrated in Figure 5 below for three patient sub-groups (S1, S2, S3). The intervention is most cost effective for group S1 and least cost effective for S3. A menu of prices and the associated coverage is available to the manufacturer

Figure 5 – A menu of prices and coverage



Choose	Coverage	Revenue	Net Benefit
P3	S1	P1.Q1	0
P2	S1+S2	P2.Q2	A
P1	S1+S2+S3	P3.Q*	A+B+C

In this example, if the manufacturer wishes to maximise revenue they will choose P1 with full coverage of the indication (demand is price elastic). There will be no net monetary (or health) benefits for S3 but there will be positive net benefits (consumer surplus) of A+B+C for groups S1 and S2.

Just as in other markets which grant a temporary monopoly through patent protection, the manufacturer can choose any price they wish but mindful of the implications that very high prices will have for their sales, revenue and profit. The only difference here is that it is an assessment authority, on behalf of the HCS, rather than individual consumers that signal the demand curve based on a formal assessment of cost-effectiveness (arguably a more predictable situation than in other markets, which could result in benefits due to less risk associated with investments). Price and coverage based on CEA ensures that the private sector and the HCS may share the benefits of innovation in a similar way to that observed in other markets. It should be noted that other price and quantity deals are possible and these may be more or less beneficial to the HCS

With a simple inelastic demand curve we discussed the situation where v>k and v is used to set the price. In such a situation the HCS will always lose out, more units of health will be crowded out than generated by the new treatment. However, when a elastic demand curve is offered but an inappropriate valuation of health is used (i.e. v instead of k, where v>k) the HCS may still benefit in the short run as long as the quantity is set above that of the most cost-effective subgroup (i.e. above Q1), and v is not so large compared to k so that the benefits accrued in terms of units of health in all but the least cost-effective subgroup covered are not cancelled out by the higher price paid across the entire coverage.

5. Discussion

An inappropriate valuation of health

As discussed previously there is the possibility that the budget for healthcare might be set too low or too high such that the cost-effectiveness threshold would not represent the true social marginal value of a unit of health, such a situation has been suggested by Jena and Philipson.[4] We have discussed earlier how when v is greater than k, the HCS can not benefit in the short run when an inelastic demand curve is offered (as in figure 2) but may benefit in the short run when subgroups are taken account of and coverage more than the most cost-effective subgroup is offered.

Whether v is different from k is a matter for empirical research but even if it was, using v instead of k to set prices will not in itself lead to improved dynamic efficiency. This is actually a general equilibrium problem which is far beyond the scope of this paper. However, it is worth noting that if we used v instead of k, we are crowding out other interventions which are more productive per pound spent in terms of QALYs. We have already discussed the loss of consumer surplus, or health, as a result of this. However, we are also transferring producer surplus from one producer to another, despite the producer who is losing out producing QALYs more efficiently.

An appropriate return for pharmaceutical investment
For appropriate innovation the risk related rate of return in pharmaceuticals should be the same as that in other markets. However, assuming that capital markets are performing competitively then the risk related rate of return should be equal to that in other markets. However, this will not necessarily lead to the optimal level of investment as, for example, inappropriate patent periods could result in inefficient levels of investment. We argue that such a situation occurring has nothing to do with the price offered, which should always be based on k, instead other implements should be used to ensure an efficient level of investment in pharmaceuticals, most notably the length of patent and subsidies.

6. Conclusions
The use of CEA to inform decisions about the use of patented drugs are reflective of other markets with patent protection. They do not undermine the temporary monopoly but simply signal the demand curve on behalf of the HCS. In fact the danger is that CEA can be used to offer too much to the private sector, by failing to estimate CE for subgroups within an indication, incorporating the effect of future lower generic prices or by facilitating perfect price discrimination.

Those that argue that decisions based on CEA will undermine incentives for research and development are quite right. It will appropriately discourage investment in innovation that are unlikely to be sufficiently valuable to the HCS to command prices and coverage which will justify the investment required. It will also appropriately encourage and reward those innovations that do justify the investment. CEA simply signals demand and aligns incentives for innovation with value to the HCS.

The objections seem not to be about CEA itself but either to the notion of publicly funded health care (it should be individuals rather than the HCS that should signal demand for drugs) or that the HCS budget does not reflect some alternate social valuation of health. Of course it is possible that current levels (length and scope) of patent protection for pharmaceuticals are inadequate, such that there is a socially non optimal level of investment. If so, the case needs to be made for reform of patent law rather than blaming decisions rules in CEA for doing their job - signalling demand and indicating which types of innovations will be most valuable to the HCS.

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