A new pricing system to reduce price growth and stimulate drug innovation

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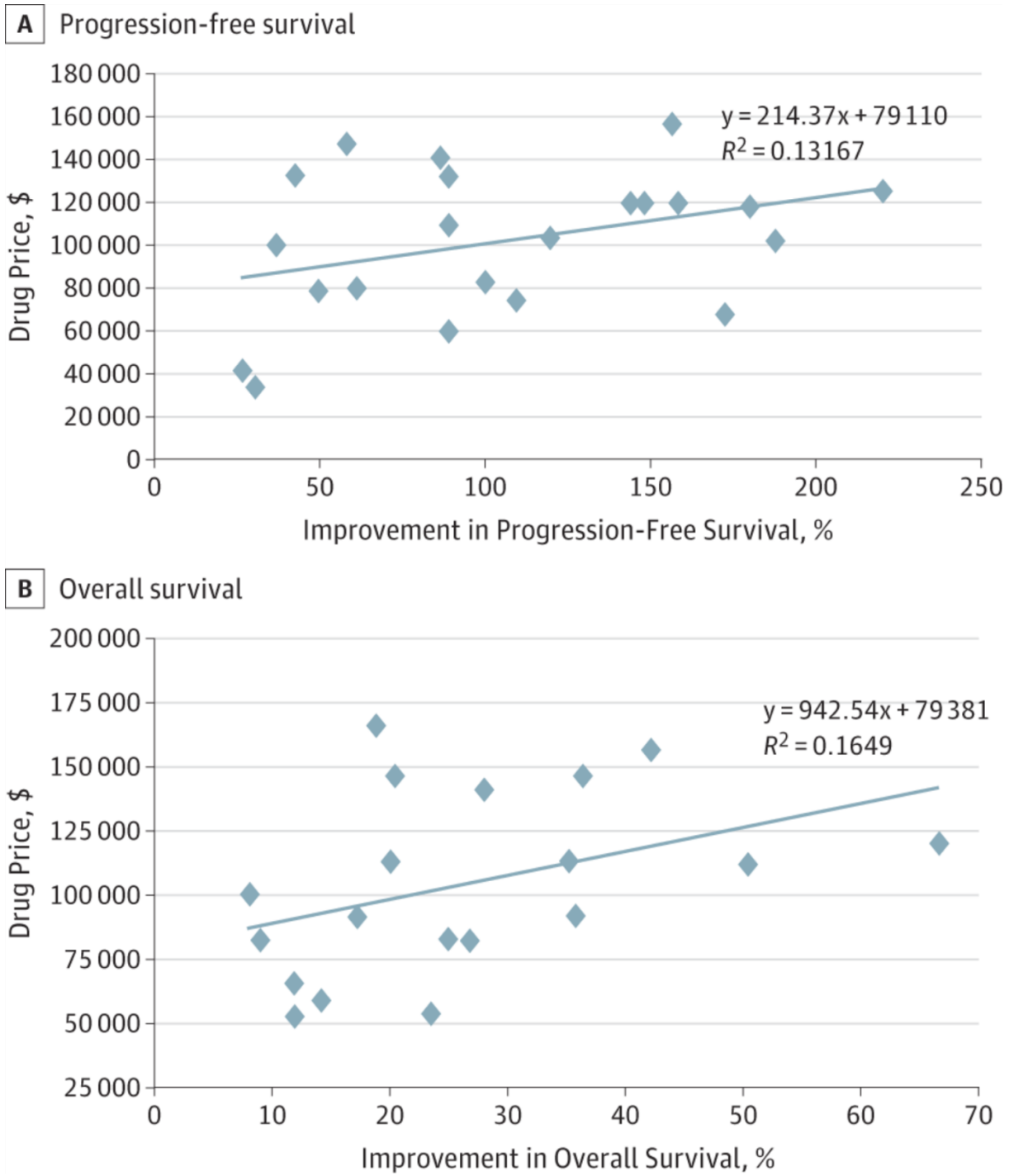
Acceleration in the price growth of new drugs

- One of the most significant phenomena in recent years concerning the pharmaceutical industry and, at the same time, payers in healthcare systems, is the sharp acceleration in the growth of new drug prices Impact on healthcare spending
- The industry justifies these increases with R&D costs.
- Without debating whether this is credible (some studies show much lower costs than those claimed by the pharmaceutical industry), it is necessary to contain the increases for the sustainability of the health system. But not only that: we need to incentivize R&D for really innovative drugs, and not only marginally better ones.
- In fact, many R&D resources are spent to introduce drugs with few additional benefits compared to the first in class.

Acceleration in the price growth of new drugs (cont.)

- Finally, many drugs get high prices without any evidence of solid efficacy with small additional benefits (e.g. in terms of OS -Overall Survival- you have oncology drugs with few weeks of additional survival). Several studies showed the poor correlation between treatment costs and survival. (Oncology is the wider market of new expensive drugs).
- A quite recent study has analyzed the 51 drugs approved in the USA by the FDA for solid tumors in the period 2000-2015. No relationship was found between the price of the drugs and their value, measured according to two scales (ASCO-VF and ESMO-MCBS) (they are scales that attribute scores to some important characteristics of oncology drugs, such as increased survival and disease-free progression, quality of life of patients). (Vivot et al, 2017).



(Mailankody and Prasad, 2015).

Current solutions

There are numerous mechanisms to contain pharmaceutical spending:

- Impact budget models, through which a reduction in the price requested by manufacturers is justified, and in fact by now the price demands are very high, knowing that prices will be approved a little bit lower, but still high.
- Confidential discounts. In this way the ex-factory price remains quite homogeneous among the different countries, but you get a lower net price.
- Managed Entry Agreements (MEAs). Whether they are financial agreements, like cost-sharing, or outcome based, like payment by result, these systems allow to obtain in practice a reduction in the average cost per patient.

Current solutions (cont.)

- Application of internal restrictions by local payers (e.g. hospitals), based on tenders, special negotiations with pharmaceutical companies and also internal prescription rules based on the age of patients, comorbidities, etc.
- **Cost-effectiveness analysis (CEA):** QALY (Quality Adjusted Life Year) is the health outcome measure; new drug is reimbursed if the ICER is below a certain ICER (Incremental Cost-Effectiveness Ratio). The value of threshold is decided by the heath authority and might varies across countries.

$$ICER = \frac{\Delta Cost}{\Delta Effectiveness} = \frac{Cost_{New} - Cost_{Comparator}}{Effectiveness_{New} - Effectiveness_{Comparator}}$$

Current solutions (cont.)

Limitations to CEA

- By rewarding even small incremental benefits, it fuels price growth. Each drug slightly better than the previous one will have a price increase, and so on for all new drugs that are added.
- Companies have an incentive to produce modest innovations because they will still be well remunerated.

To slow down these progressive price increases, we propose to introduce a minimum value of efficacy required to obtain a price increase (a minimum level of QALYs gained).

The model

- New drug about to be launched in the market where a comparator exists and produces effectiveness equal to E_0 for a price p_0.
- Eligible population N equal to one
- Effectiveness of new drug is E_N and p_N is the price proposed.
- New active principles listed if their ICER (Incremental Cost Effectiveness Ratio) is below a specific threshold, whose value varies across countries.

The model (cont.)

- Define λ the maximum value that the regulator pays for an extra unit of effectiveness, listing is granted if :

$$T_{ICER} = \frac{\Delta\, p}{\Delta\, E} \leq \lambda$$

$$\Delta\, p = p_n - p_0$$

$$\Delta\, E = E_n - E_0$$

- Maximum price:

$$p_n^{MAX} = p_0 + \lambda * \Delta E$$

The model (cont.)

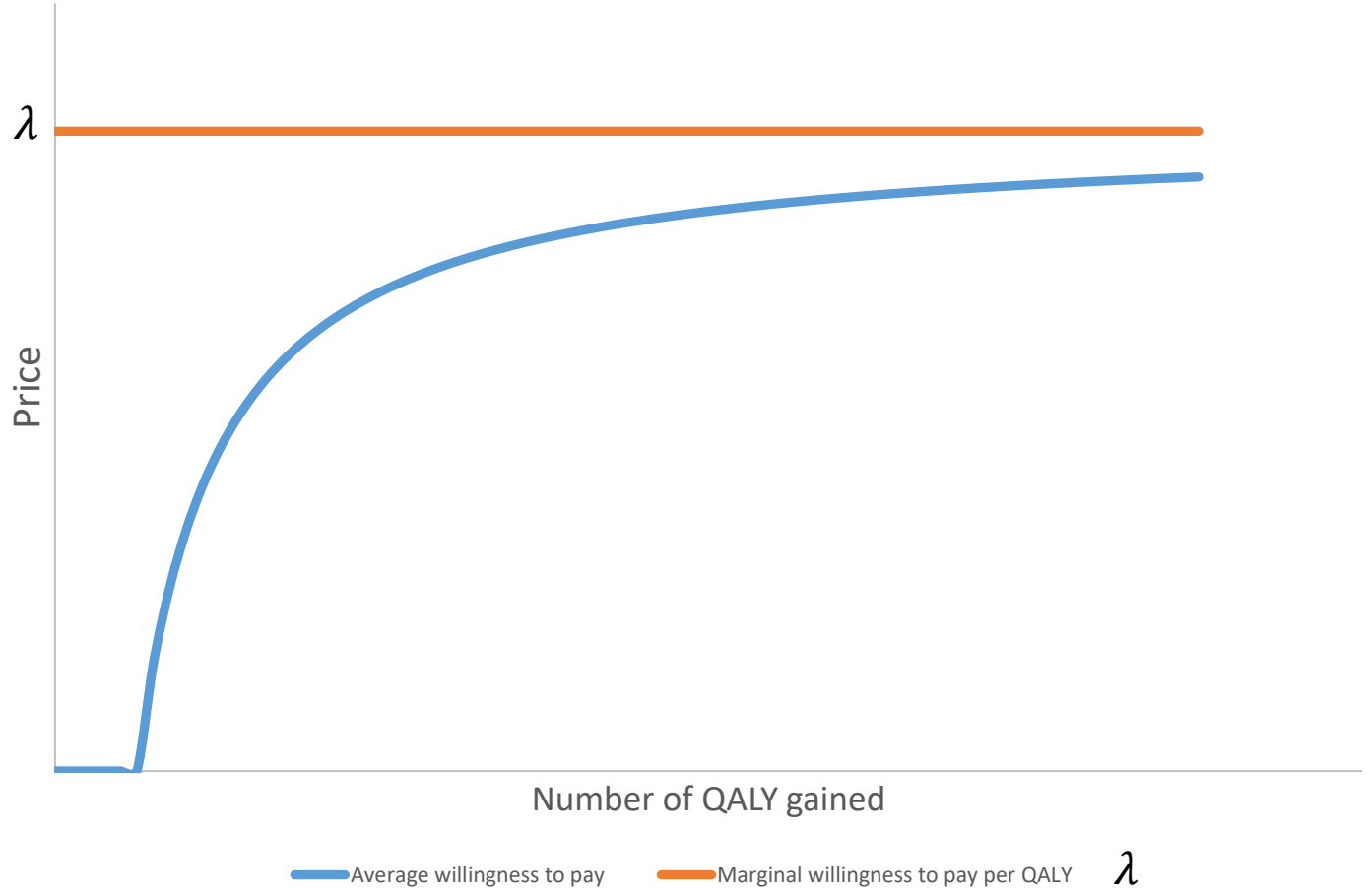
We propose that regulators pay for increases in the number of QALY gained only above a specific threshold q

$$p_n = p_0 \ \text{if}\ \Delta E < q$$
$$p_n = p_0 \ + \lambda * (\Delta E - q)\ \text{if}\ \Delta E > q$$

Which implies

$$T_{ICER} = \begin{cases} 0 \ if \quad \Delta E < q \\ \leq \lambda\left(1 - \frac{q}{\Delta E}\right) if \quad \Delta E < q \end{cases}$$

The threshold is inversely related to the QALY gained and it approaches λ for a number of QALY gained sufficiently high. Figure 1 presents the average and the marginal price paid for each QALY gained.



With the normal ICER applied:						
	costs	QALYs	diff. Cost	diff. Efficacy	classic ICER	incremental price (%)
docetaxel	30.049	0,58				
nivolumab	107.631	1,23	77.582	0,65	119.357	258%

With new ICER applied			0,25	q limit		
	costs	QALYs	diff. Cost	diff. Efficacy > 0.25 QALYS (3 months)	new ICER	
docetaxel	30.049	0,58				
nivolumab	107.631	0,98	77.582	0,40	193.955	
	NEW costs (maximu price)	QALYs	diff. Cost	diff. Efficacy		
docetaxel	30.049	0,58				
nivolumab	42.049	0,98	12.000	0,40	30.000	
considering that has been approvrd with ICER > 30.000, we can apply a price based on the old ICER = 119357						
	NEW costs (maximu price)	QALYs	diff. Cost	diff. Efficacy	classic ICER	incremental price (%)
docetaxel	30.049	0,58				
nivolumab	77.582	0,98	47.533	0,40	118.833	158%

The model (cont.)

- Only drugs above a certain level will have a higher price than the competitor, the others will have the same price even if better, but not enough better so the price curve will tend to grow more slowly.
- The incentive for companies to innovate in R&D grows because they will invest only or predominantly in projects with high efficacy content. This will also lead to more competition among companies that will focus on substantial changes in drugs and are on very similar drugs, almost me-too as is often the case today (e.g. in oncology, rheumatology, etc.).

Discussion

- Incremental vs. "drastic" innovations: would the model limit the contribution made by incremental innovations?
- As with the threshold value of ICER, the choice of the minimum value of QALY is a policy decision.
- For Italy and many other countries, this model is obviously far from being applicable as the CEA mechanism is not the the mechanism for pricing and reimbursement.
- This new criterion might differ if it is applied to a new, first-in-class drug, or to a new drug that belongs to an existing class. For example, it can be assumed that the investment in R&D for the first and second PDL-1 inhibitor is higher than the investment in R&D for the following PDL-1 inhibitors. The first-in-class drugs would therefore see a less stringent application of the new criterion, in order to reward them with higher prices.

Conclusions

This new pricing system would curb the race to indiscriminate price increases for new drugs and would provide incentives for pharmaceutical companies to direct their R&D efforts towards more innovative drugs.

A simulation of the new formula shows the functional relationship between marginal price growth and marginal growth in QALYs gained. More, it produces incentives for the companies whose drugs produce a significant increase in the number of QALY gained and should produce incentives to invest in “significant” improvements in the QALY gained rather than marginal ones, which may often be strategical to get a larger share of the market.