AN AUDIENCE WITH…

Joseph DiMasi

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Potential US legislation relating to the prices of innovative drugs, which could have a major impact on the biopharma industry, is currently the subject of considerable debate. What are your thoughts on this?
The impact of legislation that would lift the ban on the government negotiating drug prices under Medicare Part D [which provides beneficiaries with assistance to pay for prescription drugs] in the United States depends very much on whether the federal government is empowered to develop a national formulary. The bill that passed the House requires the US Secretary of Health and Human Services to negotiate with drug companies over prices for Part D drugs, but it expressly prohibits a national formulary. The Senate bill, which did not pass, was weaker in that negotiations would not be mandatory. Without the ability to exclude drugs from a formulary, the government would have little leverage to extract price discounts from manufacturers. The Congressional Budget Office (CBO) examined this issue and concluded that without a national formulary, Medicare would realize little or no savings. I think that the CBO is right.

Is some room for price negotiation desirable?
Price negotiations have been a part of the Medicare Part D programme from the beginning. It is just that it does not happen directly with the federal government on behalf of all Medicare enrolees, which could be viewed as a form of price control given Medicare's size, the coercive power of the state and the leverage that could come from a national formulary if one existed. Instead, we see it in many private interactions between drug manufacturers and competitive Part D prescription drug plans. This is the type of system that was already in place for the private non-elderly insurance market. In general, I would prefer to have competitive drug-makers interacting with competitive drug plans than to have a *de facto* price control regime for a large segment of the total market, with inevitable repercussions for the rest of the market. So far, we have seen that the system in place has worked very well in terms of controlling costs. Programme costs have come in well below the original expectations.

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What do you think the impact of greater drug price controls in the United States might be?
Basic economics suggest that if you reduce the reward for an activity then you will get less of it. Price controls will diminish the incentives to invest in research and development (R&D). The more stringent they are, the greater the number of projects that will be seen as not financially worth pursuing. This has been demonstrated in a number of studies using different methodologies. For example, one study indicated that if the United States adopted price regulations at levels seen in other developed nations, R&D spending would decline by approximately one-quarter to one-third.

How have drug price controls in other countries affected the availability of innovative drugs and the amount of R&D conducted in those countries?
The location of R&D activities depends on numerous economic, political and regulatory factors, as well as pre-existing scientific networks. Unless a firm wants to make a political statement, price controls for a multinational firm should not be a determining factor. Price controls do, however, reduce development incentives. The availability of new drugs can be affected by the length of the price negotiation process, which can drag on well after regulatory authorities have already approved a drug for marketing.

Other proposed legislation linked with pricing issues for innovative drugs aims to create a pathway for 'follow-on' versions of biologic drugs. What are your thoughts on this?
US regulatory pathways for follow-on biologics, also known as biosimilars, are probably inevitable. However, it may take a while to get all of the thorny scientific, regulatory and legal issues worked out for the more complex biopharmaceuticals. What seems certain is that the end product will have little in common with the pathways for small-molecule generics. In general, there will probably have to be significantly more extensive non-clinical and clinical testing for biosimilars than has been the case for small molecules, and, to some extent, the pathways may vary by product class.

From an economic and intellectual property protection perspective, the issue of data exclusivity is particularly important. The proposed Waxman legislation in the House and the Clinton–Schumer legislation in the Senate on follow-on biologics does not provide for any data exclusivity. This is a serious disincentive for the development of biologics that would have little remaining, none, or uncertain patent protection at the time of original approval. However, more recently, Congressman Inslee and others have introduced legislation that would provide 14 years of data exclusivity, with an additional year for approval of a new indication with a significant clinical benefit. This remains an important unsettled area.