Production Plus Profit Pricing (P-quad) for biologic drugs after expiration of FDA exclusivity

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August 17, 2021

It's still time to throw in the towel on biosimilars

Two years ago, we argued that policymakers should abandon hope that biosimilar competition will reduce the prices of biologics after their period of market exclusivity has lapsed. The primary reason was that for a biosimilar to come to market, it costs too much money, takes too long, and is too risky – realities that together create an insuperable impediment to effective market competition. Simply put, a functioning market relies on the ability of competitors to enter the market quickly, cheaply, and assuredly and take away market share by undercutting on price. These characteristics are often present in the market for small molecule chemical drugs and explain why generic entry can be so successful at ringing out excess profits captured by branded drugs after the end of their exclusivity period.

Since that time our core thesis is unchanged. Based on our analysis of data from Milliman consulting, 85% of biologic drugs that were past the end of their market exclusivity period by 2020 still face no biosimilar competition in the US market. That result is only marginally less disappointing, at 72%, if you reweight the calculation by the 2019 revenues earned by these products. Moreover, even among the biologics that do face competition, the number of biosimilar competitors going head to head with each remains low and hoped for savings have been slow to materialize. The combined revenue-weighted average 'blend' price of Herceptin today is 26% higher than its inflation adjusted 2007 average sales price and 80% higher than its 2007 price to the Veteran's Administration, even though in 2007 it had no competitors and today it has five biosimilar competitors.

The 2019 proposal – Price and profit regulation of innovator biologics post exclusivity

Given the structural impediments in the market to successful biosimilar entry and competition, we proposed an alternative policy aimed at achieving policymakers' intended objectives. Those are, unambiguously, that the price of drugs should fall to competitive levels once market exclusivity has lapsed. Having a period of monopoly pricing followed by a period of competitive pricing would be not only consistent with the pricing structure that policymakers have viewed as delivering optimal incentives for pharmaceutical innovation, it also aligns with the 'social contract' espoused by the bio-pharmaceutical industry itself.

Recently we named our proposal: Production Plus Profit Pricing, or 'P-quad' (pronounced like Ahab's sailing vessel in Melville's famous sea novel). Our approach would have the original innovators either continuing to supply their product to society in perpetuity or sell all the business elements needed to do so to a party that would. They would charge prices that would be based on their regularly filed reports that would enumerate their costs of production and distribution, incorporate capital expenses and depreciation, and include a statutorily guaranteed profit that would be considerable, such as 10% or 20%. We proposed such a sizable profit margin to ensure that the manufacturer finds continued production and distribution of their product to be attractive, or alternatively will be able to find a viable buyer for the business of making and distributing the

product. The manufacturer would not be allowed to simply discontinue production and distribution without transferring full ownership and capabilities to another firm. The generous profit margin in our view guarantees there will be interested buyers.

Potential savings from the P-quad policy:

Independent consultants from Milliman (whom we contracted with to conduct these analyses) have now estimated potential five-year savings (2021-2025) from P-quad pricing. They did so by first estimating the savings that current biosimilar policy will generate, which in their models totaled $95B overall and $45B in Federal program savings. This estimate is consistent with that published by IQVIA in October 2020 where projected savings from biosimilar entry would fall between $69B and $140B over the years 2020 to 2024.

The Milliman consultants then evaluated the savings impact of P-quad pricing, relying on an estimate that we calculated of what biologic P-quad prices would be based on production cost and then translated to net price discounts. Milliman selected a 65% discount from net prices for its modeling, which was the lower end of a range of discounts our calculations supported; the upper end those discounts exceeded 90%. Milliman found that between 2021 and 2024 P-quad pricing could potentially generate $265B in incremental savings overall, including $95B in incremental Federal savings. The savings derived in almost equal share from further reductions in prices of biologics that do or will face biosimilar competition ($130B in additional savings), and from drugs that do not and are not expected to face biosimilar competition ($135B in additional savings).

Borrowing from other policies to implement P-quad pricing:

Start date for P-quad pricing:

We proposed that innovator biologic drugs should be priced using P-quad starting 12 years after initial marketing approval of the product. This timing is consistent with the FDA exclusivity period for biologic drugs set forth by the BPCIA, but policymakers could consider lengthening the exclusivity period for drugs that were for such small populations that they did not earn a minimum level of revenues. We could anticipate holding off on P-quad pricing implementation for instance until a biologic drug had captured at least $1B in cumulative worldwide sales. We do not favor exclusivity extensions for new indications of minor modifications to the product or its delivery – those changes should improve returns during the period of existing exclusivity if they are of value.

Company reporting of costs:

Tracking costs of production and distribution (along with capital depreciation) on a per unit basis is integral to pharmaceutical companies' planning and reporting of their 'cost of goods sold' on their financial statements. P-quad reporting would only apply to well established drug franchises for which companies will have already logged a dozen years or more of history. That is important for two reasons – what process improvements and efficiencies they could wring out will have been vigorously pursued for years and likely reached a plateau, and knowledge of the product cost structure will be mature. Cost reporting as a basis for reimbursement is already established in federal health care policy. A well-known example is the prospective payment "DRG" system, which pays US hospitals an average cost for the care of patients with specific diagnoses, but that cost is based on averaging across hospitals.

A more relevant policy is the one that allows pharmaceutical companies to charge for their investigational new drugs (INDs) based on the costs they incur producing it: manufacturers submit documentation of the costs of production they seek to recover, as well as a statement from an independent certified public accountant verifying the disclosure. This mechanism is well suited to determining P-quad pricing, as it could incorporate the reality that some drugs, such as complex antibody treatments, are far more expensive to manufacture than are simpler biologics such as insulins. This heterogeneity would not stand in the way of regulators

evaluating cost reports from multiple different companies as a means of evaluating them against one another and uncovering outliers that could then be audited.

Pulling the P-quad price through the US market

Once the P-quad price has been determined, policymakers have a variety of options available to ensure it becomes the market benchmark. We favor setting the Wholesale Acquisition Cost (WAC) at the P-quad price, which create a means of passing through the savings from lower prices to patients in the form of lower out of pocket costs and premiums. Language from The Elijah Cummings Lower Drug Prices Now Act (or H.R.3) offers a roadmap for how the government might ensure companies set their prices at this level, by imposing sizable penalties if they do not. As prices would be at a desirable level, we believe there should not be additional discounts under the Medicaid Drug Rebate Program, to 340B hospitals, or to Big Four purchasers. Indirect means of achieving P-quad prices are less desirable, such as policymakers requiring all payers to adopt a maximum allowable cost (MAC) for dispensing or reimbursement, with any shortfall to the pharmacy being charged back to the manufacturer. Medicaid type rebates might be used to achieve P-quad prices after the fact; but that approach would not ensure that savings flow to patients in the same manner that lower WAC prices effectively ensure.

Transition to P-quad approach for existing biosimilar franchises

Several options exist for fairly moving forward with existing biosimilar manufacturers. Policymakers could do nothing beyond simply implementing P-quad for the originator company and let biosimilar makers compete for market share. This stance could be justified under the economic markets assumption that biosimilar makers anticipated the possibility that a competitive market would drive prices and profits down to economic cost levels. A modification of this approach would be to guarantee the existing biosimilar makers the same price as the P-quad based reference product, which could generate a small windfall for the biosimilar makers whose more modern production methods likely entail lower costs. Competition would continue based on non-price attributes such as quality, logistics and service. A third option would be to calculate a P-quad price based on the average reported costs of all products in the class. This would generate continued savings, avoid legacy windfalls from higher than needed cost ceilings, and encourage cost efficiencies. BPCIA biosimilar entrants with lower cost structures may continue to choose to enter under all options.

Other advantages of P-quad:

The P-quad approach sidesteps many of the complexities that have arisen over the past decade as policymakers have struggled with biosimilar policy. Patent thickets, used effectively by many innovator biologic companies to block competitors, could not be used to slow the transition to P-quad pricing for the innovator. The expensive and extensive clinical trials that are needed to test biosimilars prior to marketing approval will no longer be needed. To date those trials have involved more than 38,000 human subjects. Quality and efficacy concerns regarding biosimilars would no longer be an obstacle to achieving savings, and neither would the perverse incentives and rebate traps that currently lead to prescribing of more expensive drugs. Additional resources and services that biosimilar manufacturers say are needed at the FDA will no longer be. These include more pre-development meetings, additional guidance on interchangeability, and the creation of a regulatory science initiative within the agency.

Discussion

Biologic drug prices post-exclusivity should fall to economic cost levels. They are not doing so under current biosimilar policy, but they would under Production Plus Profit Pricing ("P-quad"). P-quad would generate hundreds in billions in savings, reduce uncertainty about biologic drug efficacy and safety, and maintain the innovation reward system that has worked so effectively to incentivize the invention of new and at times life-saving therapies.