Executive Insights

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The New Normal for Biopharma as Price Growth Finally Slows

The growing cost of pharmaceuticals has been a global issue for decades. In recent years, it has been exacerbated by the biopharmaceutical industry's push toward more sophisticated, higher-priced specialty therapeutics to treat and cure disease. This is particularly evident in the United States, where the biopharmaceutical industry is in the midst of a turbulent period driven by political uncertainty and widespread recognition of flaws in the current healthcare model.

Typically, prices for innovative drugs in the U.S. are set by manufacturers on the basis of cost-avoidance analyses, market prices for comparable drugs, therapeutic unmet need and target patient epidemiology/treatment dynamics. Beyond these factors, however, setting a price point for a novel drug is often dictated by one key question: What are patients and health insurers willing to pay? While these processes parallel how prices in other industries are set, drug prices in the U.S. have been the subject of intense public and political controversy for decades. An emerging issue in this discussion is that in addition to setting premium initial price points, biopharma has consistently relied on large annual price increases for novel therapeutics, to the point where a significant portion of a drug's lifetime value is derived from these increases.

After regulatory approval of a drug and widespread acceptance of its initial price point, biopharma companies in top specialty disease areas have increased list prices on average by 10-20% annually (Figure 1). However, with sharply increasing scrutiny from politicians and payers (both public and private), and emerging pressure from health systems (increasingly taking on cost risk directly) and end purchasers such as self-insured large employers, biopharma companies are facing price growth expectations that are very different from the conventional approach in the past. For example, some drug innovators have recently instituted a "10% pledge," whereby all future annual price increases on pharmaceutical assets will be limited to a maximum of 10%.

These developments invite us to investigate the consequences of different price growth dynamics in the industry, to develop insight into the corresponding impact on biopharma companies' ability to drive value and returns for their shareholders. To explore how reduced price growth would affect the lifetime value of innovative therapeutics, we undertook an analysis of different price growth scenarios to determine the proportion of a novel drug's lifetime value directly attributable to annual price increases.

Data were collected from a sample of "top 20" drugs to model a representative blockbuster therapeutic with post-ramp U.S. revenue of approximately $2.5 billion. Using the anti-TNF

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therapeutic area (TA) as a tether, which has historically relied on 12-15% annual price increases, the **Historical Growth** case examined the lifetime value — measured as non-risk-adjusted net present value — of a specialty pharmaceutical with annual 15% price increases. Relying on industry and L.E.K. Consulting benchmarks for revenue, cost and valuation, the non-risk adjusted NPV of a **Historical Growth** case drug was determined to be about $2.6 billion. An alternative **Future, Limited Growth** scenario modeled the aggregate impact of reduced annual price increases of 9%, in which asset NPV and other financial metrics, including peak year revenue, peak year price and cumulative revenue, were all significantly impacted (see Figure 2).

With the increasing influence of U.S. healthcare value research organizations such as the Institute for Clinical and Economic Review, along with growing utilization of value frameworks and tools (ASCO Value Framework, RxScorecard and DrugAbacus, among others), pharmaceutical companies are being challenged to justify not only launch-year prices, but also any subsequent price increases. The "10% pledge," despite some recent positive reception, may not be sustainable for biopharma companies over the long term. Now more than ever, biopharma companies must view these alternative, lower-price growth scenarios as the new reality.

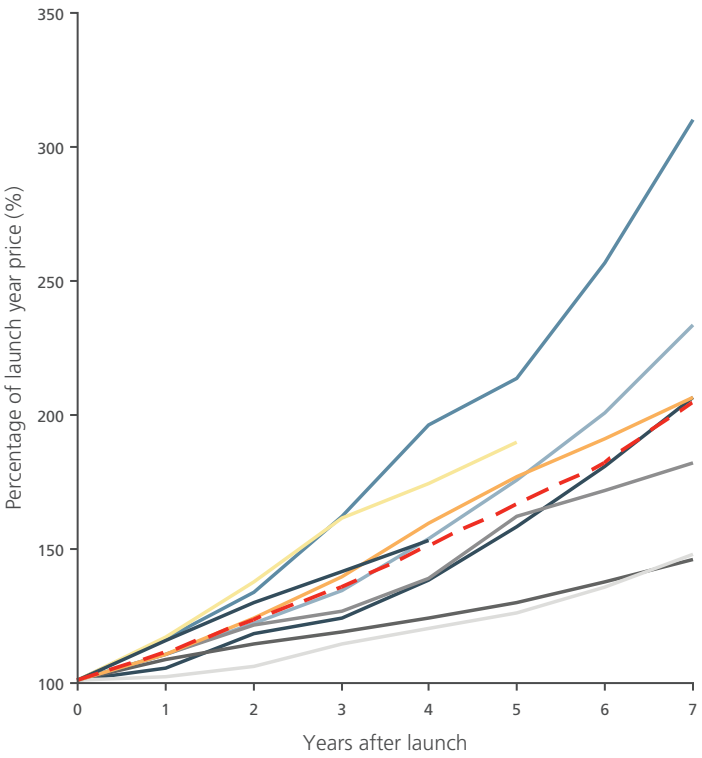
Widespread attention in the U.S. and recent legislative initiatives have fueled the push for drug pricing restrictions and transparency. The FDA has recently echoed this sentiment by issuing its own plans to address high drug prices through a more efficient generic approval process intended to increase competition. These aggregate dynamics oblige biopharma executives to:

- Re-evaluate how they forecast revenues for individual innovative assets
- Evolve how they plan portfolios
- Think differently about value demonstration and payer/health system relationships over time for their innovative programs

In an environment where double-digit annual price increases are no longer tolerated, financial performance for many drugs will be significantly eroded.

There are currently no universally recognized frameworks or tools for assessing asset value over time, though the importance of these assessments will be magnified in the coming months and years. While increased pushback on drug prices and price increases is unlikely to happen overnight, the current economic and political environments require fresh, creative strategies from an industry that has long relied on a minimally regulated pricing system.

Figure 1
Annual price growth relative to launch year price of top 2016 specialty drugs



Source: PriceRx, L.E.K. Consulting analysis

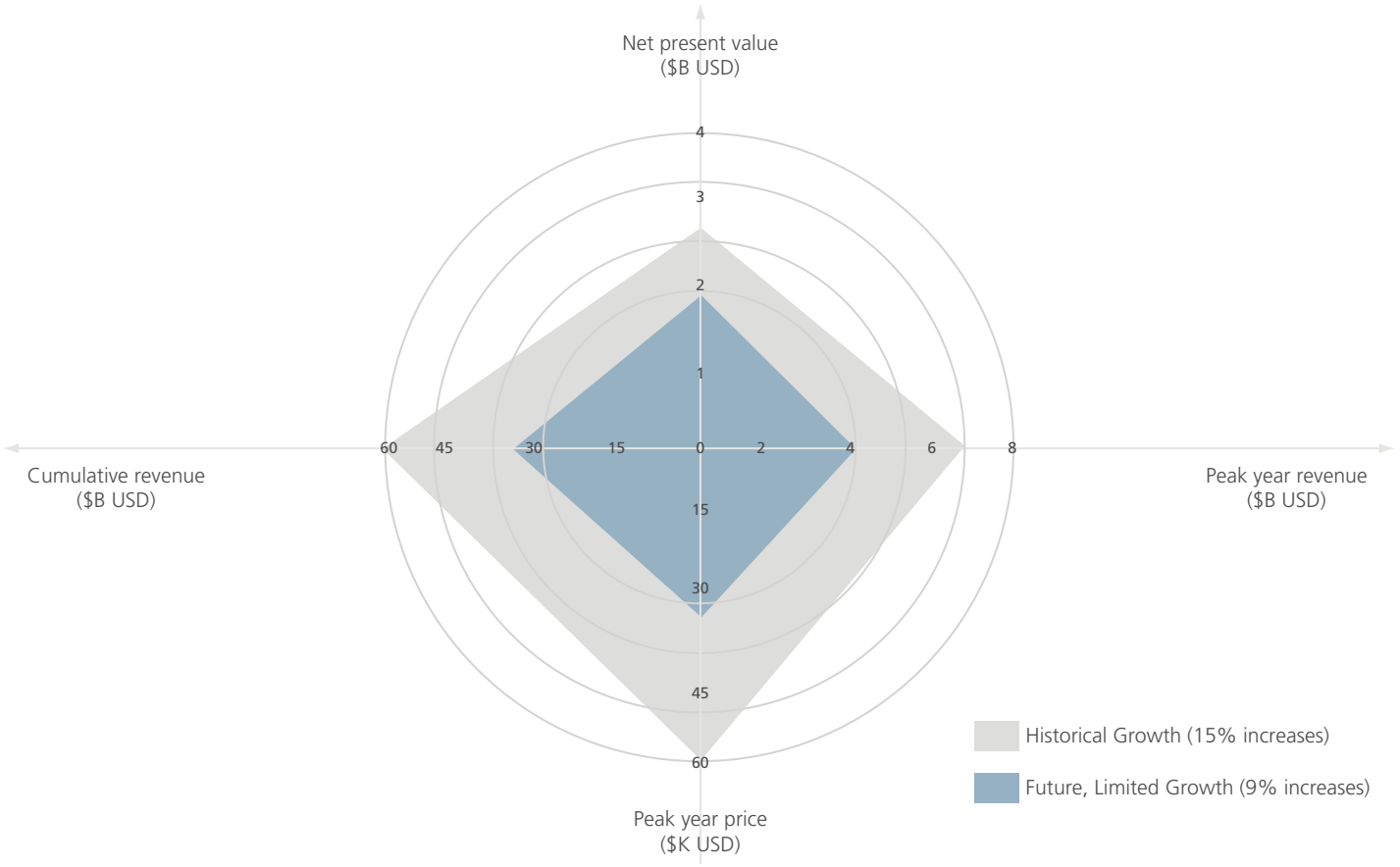
Figure 1 shows the historical percentage price increases over launch price of the top specialty drugs in 2016 by years after drug launch. The red dashed line indicates average price growth by years after launch. On average, historical list prices for top specialty drugs have increased to approximately 200% of their launch price within seven years of launch.

Impact

The possibility of a commercial environment where double-digit year-over-year price increases for innovative therapeutics are no longer acceptable implies several imminent realities:

- First, the nature of pharmaceutical product development may meaningfully shift, reflecting reduced lifetime value. Commercially successful, innovative drug launches are needed to cover the costs of development for failed drugs within company portfolios, which will impact how the biopharmaceutical industry chooses to prioritize, develop and launch new products, potentially reducing risk tolerance. These dynamics may also drive biopharmaceutical innovators

Figure 2
Financial performance metrics for a representative blockbuster



Source: L.E.K. Consulting research, benchmarking and analysis

Figure 2 shows a holistic view of a representative blockbuster drug's financial performance across net present value, cumulative revenue, peak year revenue and peak year price. The Future, Limited price growth scenario illustrates the significant decreases in financial value of an asset as a consequence of reducing price growth from 15%, the historical average for top specialty drugs, to 9%.

to disproportionately pursue diseases that offer the potential for greater value capture over time through incremental evidence generation and/or product performance success fees.

- Significant reductions expected in annual drug revenues will dramatically impact pharmaceutical life-cycle management (LCM) budgets, potentially driving away hundreds of millions of dollars in sales and marketing (S&M) and R&D spend per year. As a result, large promotional efforts — such as direct-to-consumer and LCM initiatives for label or product-line extensions within R&D — may be sharply curtailed.
- While therapeutic area and modality diversification for biopharmaceutical companies has been a key avenue of growth historically, reduced price growth and increased P&L compression are likely to drive up costs and reduce ROI for organizations looking to diversify beyond their core moving forward

Implications

In view of these emerging dynamics, it is imperative that biopharma companies start to view long-term product strategy through a new lens. The impact of alternative drug price growth scenarios will have implications for both asset- and portfolio-level strategic planning. Specifically, biopharma executives should consider incorporating new considerations around 1) portfolio

strategy, 2) ongoing asset value demonstration, and 3) marketing and R&D budget reduction management (see Figure 4).

Among the first-order changes we may see from biopharma will be changes in portfolio strategy. The inherent risks of biopharma ventures are well-documented; notably, revenues from commercially successful drugs help offset the development costs of drugs that aren't ultimately approved. A diminished ability to offset these costs may lead biopharma companies to adopt a more risk-averse drug development strategy, avoiding potentially high-impact ventures that may be deemed too risky. Accordingly, there are likely to be important shifts in therapeutic area, disease/indication and mechanism/class selections toward more-established, lower-risk development opportunities.

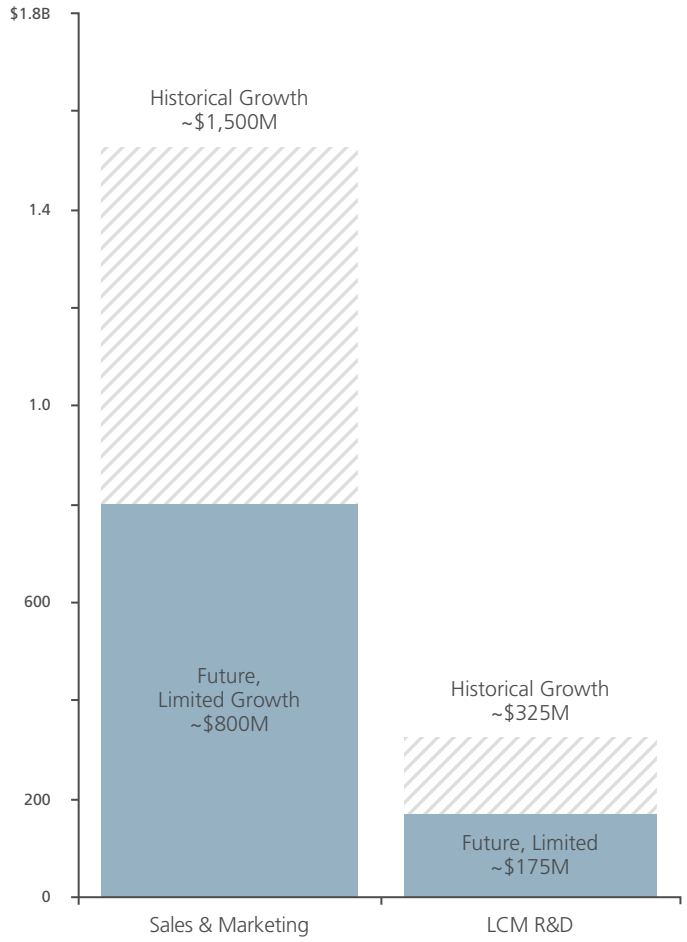
The significant cut to annual revenue due to reduced price growth may lead to approximately $700 million in annual sales and marketing spend reductions and $150 million in R&D reductions for representative blockbusters, with proportionally large impacts on lower-sales products.

Relatedly, biopharmaceutical manufacturers may increasingly pursue diseases with clear/measurable clinical markers tied to a patient's treatment outcome over time (e.g., cardio-metabolic diseases with established surrogate endpoints), which can be incorporated into pay-for-performance success fees, and reconsider TA/modality diversification beyond the core given expanded P&L pressure on "build" opportunities.

Biopharma companies will likely be required to better support their case for high initial price points. Some clinical trial designs are already beginning to acknowledge that trial data may be subject to ongoing economic analyses based on value frameworks and intermediate endpoints. Investment into preapproval, value-based analyses for innovative therapeutics may well become a prerequisite to secure preferential pricing.

In response, the biopharmaceutical industry may begin to prepare for increased payer reliance on value demonstration data, by developing a more integrated ongoing value demonstration strategy for assets. A relatively recent example of this strategy involves PCSK9 drugs for patients with atherosclerotic cardiovascular disease (e.g., evolocumab), for which post-approval cost-effectiveness assessments strengthened biopharma's negotiating position with payers (despite facing other market headwinds). Without incremental real-world cost-effectiveness evidence as part of an integrated product-level evidence generation plan over an asset's life cycle, payers are increasingly likely to push back or refuse to support price increases for innovative therapeutics.

Figure 3
Price growth impact on peak year S&M and LCM R&D for a representative blockbuster



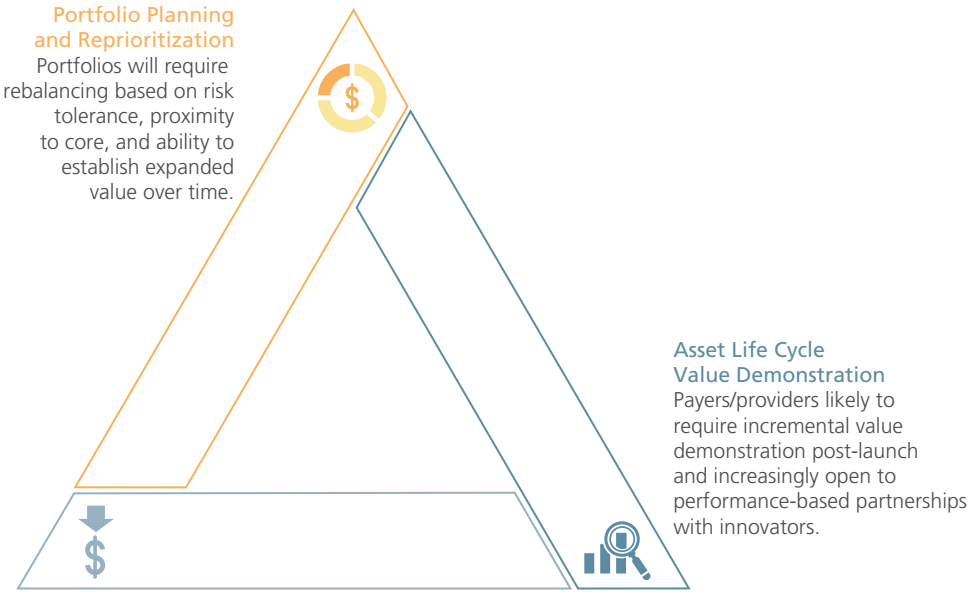
Source: L.E.K. Consulting research, benchmarking and analysis

Figure 3 illustrates how S&M and LCM-related R&D budgets could be expected to decrease significantly in the Future, Limited price growth scenario for innovative drugs.

Biopharma companies may also benefit from utilizing this information to educate an often-neglected public audience on the true value of innovative therapeutics, potentially helping alleviate some of the public's negative sentiment toward drug pricing holistically.

In light of the shifting pricing reality, the biopharma industry must take a more sophisticated view of the payer landscape. CMS will continue to pace-set, as it has more broadly with a push toward accountable care organizations and other value-based care initiatives. Medicare Advantage (MA) lines of business are

Figure 4
Implications of reduced drug price growth



Source: L.E.K. analysis

Figure 4 provides a high-level overview of implications in the biopharma industry as a consequence of reduced year-over-year price growth. The diminished value of innovative therapeutics is expected to impact how the industry assesses ROI and approaches portfolio planning. Concurrently, there is an increasing need to demonstrate differential value from trials, including aligning "real-world" data analyses with economic endpoints, and to develop value-based partnerships with payers/providers.

major hoped-for growth drivers for the national payers. This level of focus, plus a comfort with intensive care management and openness to innovative models, makes this market ripe for payer-manufacturer partnerships aimed at managing total cost of care (and price/value share dynamics) through more nuanced, value-focused drug regimens.

In the under-age-65 market, commercial and managed Medicaid payers are increasingly responsive to cost pressure from self-insured employers and cash-strapped state governments, respectively. Addressing the needs of these ultimate end purchasers represents an emerging opportunity for biopharma in an era of cost scrutiny. And across all covered populations, progressive health systems (e.g., Kaiser Permanente, Intermountain Healthcare) and increasing numbers of ACOs and provider-sponsored plans may represent ideal pilot partners for manufacturers seeking counterparties with both risk and patient care concerns.

The U.S. healthcare system appears to be reaching a tipping point where annual 10-20%+ price increases on innovative therapeutics are no longer sustainable. In order to preemptively address changing economic and political attitudes, an asset's value creation and demonstration strategy over time must become more central to asset- and portfolio-level strategic planning for biopharmaceutical innovators. Industry leaders should be rethinking how they establish, articulate and forecast the lifetime value of their products, enabling the U.S. pharmaceutical industry to maintain its ability to develop and provide lifesaving innovations to patients across the globe.

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