

The US drug pricing debate 2017

Managing risks to results through uncertain times

The trajectory of health care spending in the US is generating much dialog and consternation across a variety of stakeholders, including governments, industry, media, academic think tanks and the general public. Prescription drug prices, despite comprising only 10% of overall spending, are a major focal point of this dialog. While drug prices have been steadily increasing for some time, much of the recent focus has been caused by the objectionable acts of a select few – acts that have generated hearings on Capitol Hill with specific industry players, calls for self-regulation of drug prices by industry leaders, U.S. Department of Justice reviews of industry and pharmacy benefit manager (PBM) practices, and discussions of policy changes like allowing the government to negotiate drug prices with companies.

The drug pricing environment

Drug companies have enjoyed a free-pricing environment in the US, which is different from every other major developed country in the world. In the US, companies are able to set drug prices and raise drug prices without oversight or regulation by the government. Market forces, via payer, health system, hospital and PBM contracting, create the checks and balances for this system. In recent years, drug price increases have been under scrutiny due to three main factors:

1. Manufacturers, facing a large number of brand products moving to generics, raised prices prior to the revenue cliffs to protect earnings.
2. Products with little or no competition have sustained overall commercial through unrestrained price increases, as payers/hospitals have limited alternatives.
3. While recent value-based reimbursement initiatives have put hospital spending in check, drug spending is seen as one of the last frontiers of “uncontrolled” growth that still needs to be addressed.

The launch of transformative specialty brands and invoice price increases drove higher spending on drugs, which were partially offset by rebates and the use of lower-cost generics.

The gap between the “gross” spending on medicines and the “net” realized revenue by manufacturers has increased and will likely widen.

Pricing pressure

Rebates are expected to increase and offset the declining selling, general and administrative expenses.

Diabetes and respiratory along with other therapeutic areas with high spending will likely witness the maximum pricing pressure.

Increase in US net prices have led an increase in net income for few companies making them prone to the impact of pricing pressure.

In response, the public, policymakers and the media have called for reform. The pharmaceutical industry has been cast as a rogue villain taking advantage of the current status quo. Diverse stakeholders from Democrats to President Trump have vowed significant action to make changes. How this change happens – whether through federal policy, state policy or industry self-regulation – remains a core question.

Potential changes related to drug pricing

There are many policy options on the table to address drug pricing in the US:

- ▶ Forced transparency related to drug price increases and list-to-net contracting specifics
- ▶ Re-importation of drugs from Canada
- ▶ Drug price negotiation by Medicare as a large block purchaser
- ▶ Special rules for drug price increases for public payers, like Medicaid
- ▶ Increase the government's exercise of its march-in rights to grant additional licenses to the product if federal funds were utilized in its development
- ▶ Test additional payment models to determine if efficiencies can be developed in the Part B and Part D Medicare drug programs
- ▶ Extend Medicaid rebates to prescription drugs purchased under Medicare
- ▶ Reference pricing
- ▶ Expediting FDA approval of generics

These policies are being considered at the federal and state level.

In addition, industry members are themselves attempting to self-regulate as a way to avoid drastic actions by policymakers. Examples come from Allergan, Novo Nordisk and AbbVie, who have each made "price pledges" capping percentage price increases across their portfolios. These moves have been met with mixed responses by other industry members, but largely applauded by policymakers. Whether they are far-reaching enough to dampen the call to action remains to be seen.

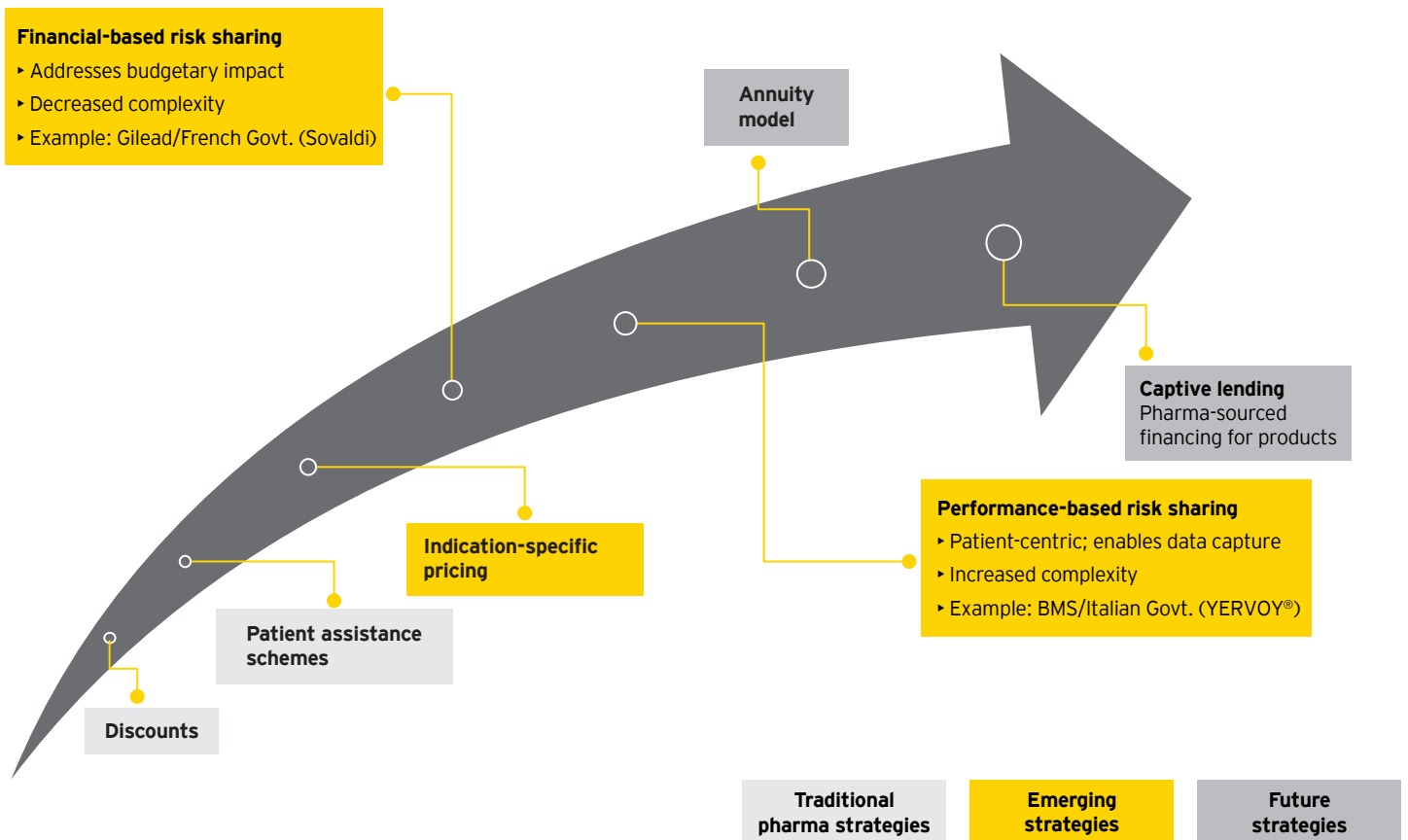
As part of the pricing debate, there is a new reality for the life sciences industry: a drug's price increasingly must reflect the value that the product delivers. While value is a flexible concept, with different connotations for each stakeholder in the health care ecosystem (payers, providers, policymakers, patients), it is largely seen as a function of clinical benefit/cost. Value-based pricing as a conceptual framework places increasing burden on biopharma companies to justify a product's price within both the context of its impact and relatively to other products on the market. This comparative perspective on pricing/value is not codified in the US the same way it is in other markets. For example, in the UK, the national Health Technology Assessment Programme (part of the National Institute for Health Research) strictly applies cost-effectiveness analysis to determine whether new drugs will gain coverage within the system. Price is a key variable driving perceptions of relative affordability and value.



Future and innovative pricing models

While in the near term it is unclear how much pressure government will exert on drug prices, longer term it is expected that the price/value relationship will expand. In addition to pricing decisions at launch, price evolution over time will be increasingly impacted by the degree to which a product's effectiveness/impact is demonstrated in the real world. Practically speaking, post-launch monitoring of a drug's effectiveness to inform potential adjustments in price will be increasingly standardized. Once a drug

goes to market, continued observations will occur to allow payers to adjust access based on outcomes. Payers will glean insights using advanced analytics offerings that collect and examine data from real-world monitoring platforms or in collaboration with manufacturers. Real-world data taken from pre- and post-launch perspectives on the value of a drug are necessary to align with value-based pricing demands.



In the not-too-distant future, the data supporting the analysis of impact/value is important because innovative pricing models will consider comprehensive sets of outcomes and expanded continuums of care to more closely determine the total cost of a drug or treatment plan. New pricing models will also mean managing patient populations while evaluating value, instead of tracking single patients. By fully capturing a product's effectiveness within a patient's entire treatment pathway and understanding outcomes within the contexts of patient populations, the value of

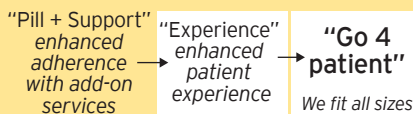
an optimized treatment protocol can be realized. In addition, by integrating analytics within new pricing models, a broad overview of a drug's value can be demonstrated to inform pricing decisions.

New commercial models are developing in response to these market pressures. While the future state is not certain, most stakeholders see three main pillars as driving the future state. These include integrating offerings, outcomes-based contracting and delivering value to multiple stakeholders.

New commercial model

Evolution into integrated health care providers

Providing an integrated offering across patient pathway including product and services serving health care ecosystem



Such some-scale experiments would turn into sustainable business model:

Sanofi taking a 360° approach to treating diabetes

Merck created a venture unit "Global Health Innovation Fund" that would allow Merck to look beyond the pill and give them optionality around the future

Janssen through its entrepreneurial arm, Janssen Healthcare Innovation is placing high bets on patient-centric innovation e.g., Care4Today®

Forging more outcome-based contracting models in an integrated health care delivery system

Such ad-hoc experiments will evolve into long-term patient-centric partnerships:

Pay-for-performance deal with payers:

Novartis – Aetna/Cigna for heart drug, Entresto

Improving patient outcomes

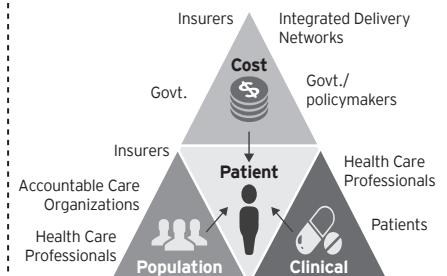
Fresenius Medical Care – Aetna collaborative care models for renal disease patients resulted in overall improvement in clinical measures (hospitalizations, mortality rate, etc.)

Enhancing operational efficiency

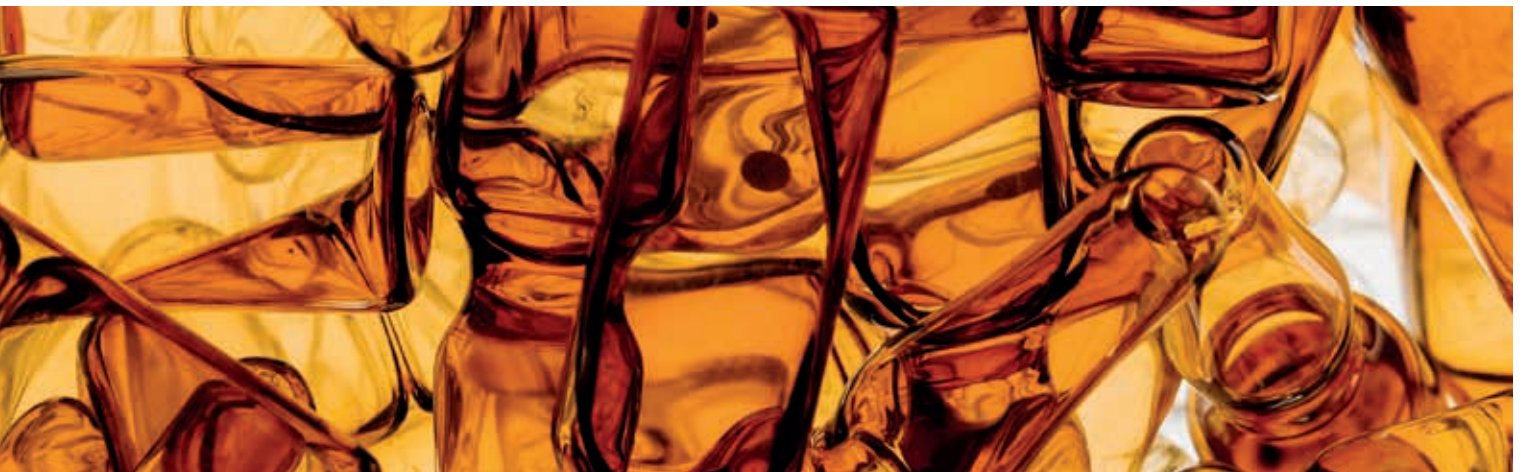
Lilly – Quintiles: redefine its clinical trial designs and incorporate patients' inputs

Communicating "proven value" of products/services tailored to much broader array of evolving customer groups

Tailoring business models/strategies around competitive orientation:



Three competitive orientations of various stakeholders



Value-based pricing

Furthermore, risk-sharing and value-based agreements are changing the way value is determined. The evolving health care landscape is shifting risk from payers onto hospitals, Accountable Care Organizations (ACOs) and other provider sites. This places more decision-making power onto the provider and creates an opportunity to examine the link between products, care delivery and value. These shifting roles will require increased transparency of pricing protocols, which will enable greater pricing predictability and allow for better allocation of resources across stakeholder groups.

Value-based pricing is accelerating as patients share a greater portion of health care costs and have a greater stake in value-based decision-making. Advanced platforms that sift through data collected from the patient-provider network can establish patterns that translate services and outcomes into value-based insights.

Now more than ever, innovation is needed to build trust and collaboration between the pharmaceutical industry, payer and provider stakeholders. By involving stakeholders in pre- and post-launch discussions, developing innovative pricing models that support comprehensive paradigms of treatment, and

taking advantage of risk-sharing and value-based agreements, life sciences companies can better prove the value of a drug. Companies that understand and prepare for this paradigm shift are likely to minimize the risk and maximize the opportunity associated with some of these changes.

Managing risks to results

One thing is clear: change is inevitable and uncertainty will prevail, at least in the short term. Self-imposed or externally imposed, drug prices will remain under pressure, with increased scrutiny on outcome measurement and value. With top-line growth challenged, driving sustained profitability and shareholder returns will require a focused re-evaluation of the cost and profitability drivers across the value stream. Converting this uncertainty into an opportunity requires a focused approach toward risk management. In taking this approach, companies can identify and manage variability in the outcome against their initiatives, plans and expectations.

Examples of key drivers with associated risks and key considerations are listed on next page.

Conclusion

“A bend in the road is not the end of the road ... unless you fail to make the turn”.

— Helen Keller

These short-term disruptions are a bend in the road, and as companies navigate the bend, a key focus on the right risks will keep biopharma companies on course to success. Companies that consider changes to pricing models in terms of the many dimensions of risk and uncertainty they need to manage are more likely to leverage the turbulent times successfully to their advantage.



Cost or profitability driver	Strategic risks	Strategic considerations
Demonstrate value: shift focus from price to outcome	▶ Is the value from the drug “affordable”?	▶ Prioritization of drugs that have both clinical and economic value in the short term
	▶ Do you have access to the right data?	▶ Partnerships with other health stakeholders for access to data that matters
	▶ Are your commercial decisions founded on big data insights?	▶ Advanced analytic capabilities that allow companies to segment payers, optimize marketing and embed patient-centric views into product development plans
	▶ Are you leveraging risk-sharing business models?	▶ Development of close monitoring mechanisms to manage risk and maximize ROI
	▶ Does your product strategy provide you competitive advantage?	▶ “Around the pill” solutions to address the care continuum
R&D productivity	▶ Are you able to continually monitor R&D investment decisions based on ROI?	▶ Approaches that enable failing faster and cheaper ▶ Milestones and “gating” mechanisms to reduce waste ▶ Real-world data to drive predictive algorithms
	▶ Are you managing risks in shared R&D investments?	▶ Close monitoring mechanisms to manage risk and maximize ROI
	▶ Are your statements of purpose (SOPs) for research and clinical development designed and operating effectively?	▶ Optimized controls around data quality, handling, recordkeeping and archiving for both pre-clinical and clinical research ▶ Optimized controls around patient recruitment and drug dispensation process assessment; clinical trial outsourcing process, including assessment of CRO organizations; process for data collection and preparation for drug filings ▶ SOPs around FDA GxP compliance and similar standards
Operations management: top-line pressure resulting in margin pressure and driving the need for efficiencies across the value chain	▶ Is your manufacturing footprint based on a detailed analysis of make versus buy?	▶ A segmented approach either to create a competitive advantage through focus on sustainable operational efficiencies and quality or, where a strong, established, contract manufacturing organization network exists, to outsource based on price, quality and service-level reliability assessments
	▶ Have you made the right technological investments toward longer-term competitive advantage?	▶ Shifting toward autonomous value chains with centralization of integrated planning towers for demand, supply, production scheduling and logistics ▶ Leveraging big data to monitor and tune supply chain product flows ▶ Robotic process automation and artificial intelligence to deliver touchless planning and execution
Indirect cost optimization	▶ Is there a defined cost-optimization initiative with milestones and measurements?	▶ Strong project management office with approach, tools and focused deliverables to track progress ▶ Driver-based analysis to isolate key cost drivers with associated cost optimization action plans ▶ Increased use of third parties that can provide scale benefits, enabled with third-party analytics and performance monitoring ▶ Zero-based functional budgeting to build expectations from the ground up
	▶ Have you recently assessed the opportunity for end-to-end process optimization?	▶ End-to-end process optimization across finance, IT, HR and other indirect functions, enabled by technology ▶ Shared service opportunities on platform of standardized and streamlined processes
	▶ Are you leveraging innovative technologies?	▶ Robotic process automation to reduce cost, increase reliability and sustain process ▶ Advanced analytics with a visualization layer that enables users to make real-time, informed decisions

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As populations age and chronic diseases become commonplace, health care will take an ever larger share of GDP. Scientific progress, augmented intelligence and a more empowered patient are driving changes in the delivery of health care to a personalized experience that demands health outcomes as the core metric. This is causing a power shift among traditional stakeholder groups, with new entrants (often not driven by profit) disrupting incumbents. Innovation, productivity and access to patients remain the industry's biggest challenges. These trends challenge the capital strategy of every link in the life sciences value chain, from R&D and product supply to product launch and patient-centric operating models.

Our Global Life Sciences Sector brings together a worldwide network of 11,000 sector-focused professionals to anticipate trends, identify their implications and help our clients create competitive advantage. We can help you navigate your way forward and achieve sustainable success in the new health-outcomes-driven ecosystem.

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