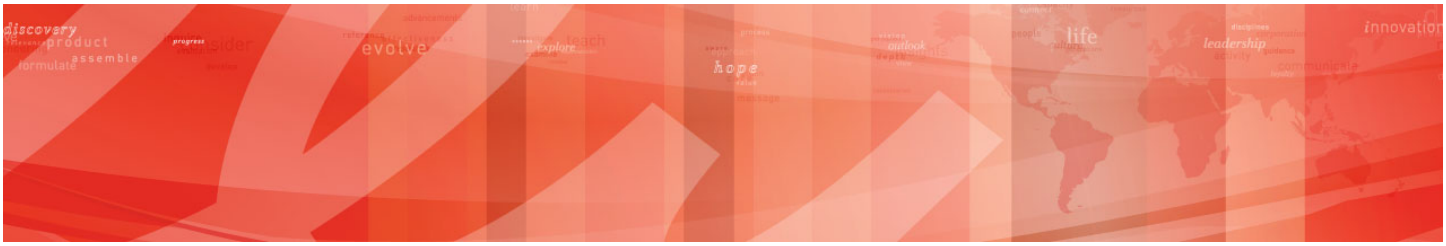

A Holistic Approach for Prescription Drug Prices

The U.S. needs a more constructive and inclusive approach to the challenge of affording high-quality medicines. This starts by developing insurance benefit designs that encourage patient access to medically necessary care, makes value the key criteria in pricing medicines, and promotes a more competitive prescription drug market for consumers.

These ideas are well-aligned with the country's recent focus on moving towards a patient-centered health system. They proceed from the real-world experience of patients, insurers, employers, and drug manufacturers navigating the complexities of drug development and of America's health care system. And most importantly, they focus on removing obstacles to a well-functioning marketplace for medicines so that patients can access the treatments they need.

Put the needs of patients first

To start, we need to take a serious look at how insurance benefit designs might pose challenges for patients, particularly those with serious health conditions. Patients should not pay more than their insurance plan pays for their medicines.

Like many large employers, Lilly believes in the power of the consumer in health care and was among the first large employers to offer and ultimately mandate high-deductible health plans because we believe our employees should have the power to make choices between lower cost and premium alternatives. However, we recognize that these coverage options can expose patients to large "out-of-pocket" obligations before their deductibles are met.

That being said, there are a number of steps that employers can take to provide employees with greater protection and value with their high-deductible plans:

- Employers can lessen the patient's financial burden from high deductible insurance plans by evaluating the size and timing of employer contributions to employees' Health Savings Accounts (HSAs) and Health Reimbursement Arrangements (HRAs). For example, rather than spreading employer contributions throughout the year, Lilly created an affordable and competitive benefit design by paying in full on the first day of the insurance plan's year in January, thus reducing patients' out-of-pocket costs upfront which mitigates the impact of employees delaying treatments because of cost.
- Another way to reduce patients' financial burden is to exempt preventive medicines entirely from the deductible.
- Finally, we believe that patients should appropriately benefit from the full cost-savings given to insurers and pharmacy benefit managers through negotiated rebates.

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Make value the preeminent criteria in pricing medicines

To assure that breakthroughs in medical science continue, pricing for new medicines should reflect the value they are likely to deliver to the health care system and society. Through the use of "value-based contracts", which Lilly is piloting with several large health insurers, we are exploring new approaches to contracting that hold us all more accountable for delivering effective and targeted treatments in the real world of patient care. By aligning payment with patients' health outcomes, biopharmaceutical companies are focused on demonstrating value, and health plans have the predictability and data to ensure patients get the right treatments at the right time. Best of all, if value-based contracts were in widespread use, patients would benefit from being the focus of a true race to the top in quality of care.

Value-based contracts remain the exception and not the norm when determining the ultimate cost of prescription drugs because antiquated policies dating from the pre-Medicare era prevent drug companies from discussing new products with insurers before they obtain regulatory approval. Such outdated provisions keep health plans in the dark about the possible costs and benefits of new products for specific patient populations.

Removing these hurdles, while continuing to scale-up comprehensive health-data systems, would provide a true test of value-based contracting and bolster larger convictions about the effectiveness of the free market in supplying affordable health-care choices.

Focus on removing obstacles towards drug development and review

Introducing more breakthrough treatments targeting similar diseases will mean greater competition, lower prices and a higher likelihood that there will be an effective answer for patients who seek better treatments or cures.

Where the development of new medicines is concerned, the rate-limiting factor is very often the complexity of clinical research: the approval, conduct, and analysis of trials that often involve hundreds or thousands of patients worldwide. There are several ways to address this:

- Biopharmaceutical companies need to make sure that patients who qualify are found for individual trials and have the support they need to fully participate.
- Companies conducting clinical trials need to develop research protocols jointly and share in the pool of patients willing to take part in such research.
- We must tap so-called "meta-data" on previous clinical-trial patients to draw connections previously obscured or missed, as well as real-world data on the outcomes of existing treatments.

These and other ideas have broad support among stakeholders. In fact, the FDA appears to be encouraging much of what has been described in proposals submitted to Congress for renewal of the Prescription Drug User Fee Act (known as PDUFA VI).

Individuals, companies, and even government agencies seeking to drive change and point to a better way have considerable power to do so. So, for innovation-minded regulators and biopharmaceutical companies, the time to act is now.