

Presidential Advisory: American Heart Association Principles on the - Accessibility and Affordability of Drugs and Biologics – Summary -

Background -

In 2015, net U.S. spending on pharmaceuticals reached \$309.5 billion, an 8.5% increase from the year before, and is expected to reach between \$370 and \$400 billion by 2020.¹ These current and projected levels have raised serious concerns by policy makers, providers, payers, and patient groups that they are unsustainable and threaten the affordability of, and accessibility to much needed therapies for patients. Two trends related to drugs/biologics and generic drugs/biosimilars are converging to create a situation that requires serious consideration by all healthcare stakeholders. First, the market entry prices of innovator pharmaceutical products, or brand drugs and biologics, are at levels that some assessments consider unaffordable to the healthcare system.⁴ The approval of two PCSK9 inhibitors for hypercholesterolemia, alirocumab and evolocumab, and another drug for heart failure, sacubitril/valsartan, have focused attention on the price of specialty therapies for cardiovascular disease. Second, prices for some established generic drugs, such as digoxin and captopril, have seen sharp, and rapid increases. For example, between 2013 and 2014, the prices for digoxin and captopril increased 894% and 129% respectively.⁶

The increase in prices for “innovator” or brand drugs and biologics are seen by many as symptomatic of underlying problems in the marketplace – complex and expensive approval process with high levels of fail rates and a patent system that incents the use of loopholes to extend market exclusivity - as well as a lack of clarity of the costs factored into a drug’s cost, added costs from actors across the supply chain, and the US’s lack of government oversight or regulation of prescription drug pricing. In the generic market, analysts point to lack of competition and long approval times for new products.

Potential Solutions

A range of solutions have been proposed to address the problem. Overall, a dialogue has begun about assessing “value,” as a way to match payment and resource allocation decisions to a product’s alignment with patient, societal, and system priorities. One grouping of proposals, such as indication-based pricing and value-based arrangements, attempts to align measured value with the prices of the drugs. Other proposed solutions, including adaptive clinical trial design and adaptive licensing, address the key drivers of cost within clinical trials by incorporating new evidence along the development and approval continuum. New payment arrangements that promote value-based treatment decisions comprise another category of proposed solutions. Allowing the federal government to negotiate drug prices, requiring transparency of the price setting process, and caps on consumer’s out of pocket spending on drugs, have also been proposed.

AHA Considerations

Research shows that when passed onto patients, high prices reduce medication adherence and can lead to negative health outcomes. A 2012 literature review found that increased cost sharing by patients decreased medication adherence in 85% of the studies reviewed, and adversely impacted health outcomes in 76% of the studies. According to a 2015 Kaiser Family Foundation Health Tracking Poll, 24% of respondents who were currently taking a prescription medication reported that they or a family member had not filled a prescription due to cost.

The lack of medication affordability, therefore, threatens to have detrimental effects on individual
Policy Research: Linking scientists, clinicians and policymakers to help improve cardiovascular health and decrease heart disease and stroke mortality.

patient's health and limit the Association's achievement of its population impact goal. Additionally, disparities of care are potentially exacerbated by placing many drugs beyond the financial reach of low income and average wage families, and perpetuating a system of 'haves' and 'have nots.' The American Heart Association consistently has advocated for equity and affordability, and it is imperative that the Association continue this work as the voice of patients, and work towards ensuring equitable access for all.

Principles

Solutions must be found to address the unsustainable spending that is occurring for drugs and biologics, and to develop a process by which resources may be allocated to support medical innovation while ensuring appropriate access to, and availability of, treatments to patients who have or at risk of cardiovascular disease and stroke. In light of these considerations, the AHA has developed a set of principles to guide its advocacy and help frame the ongoing debate in support of patients in addressing rising drug costs and the associated adverse health impacts that consequently occur.

1. Therapeutic advances in cardiovascular and stroke treatment have greatly improved the lives of patients. All patients should have full access to the therapy most appropriate for their disease when used in accordance with current clinical and scientific evidence.
2. Affordable access to these medications is necessary to effectively prevent and treat cardiovascular disease and stroke. Innovative therapies are ineffective if patients cannot afford to buy them.
3. Society has a long-term interest in the discovery and development of new medicines. Policies to address the high-cost of new treatments should reward, not stifle discovery.
4. The regulatory climate must be responsive to drug development. Although consistent attention must be paid to maintaining the safety of approved therapeutics, inspection of, and revisions to, the regulatory processes may be necessary. These could include adjustments to testing requirements such as adaptive clinical trial design or creative approaches in approvals like adaptive licensing.
5. Value should be defined as the benefit accrued along the entire continuum of care rather than solely the cost and benefit associated with a discrete episode of care or hospital stay. The patient perspective must be incorporated into the determination of overall benefit.
6. Drugs and biologics must be understood as one component of a larger healthcare system, and one in which an individual's treatment may include pharmaceutical and non-pharmaceutical elements. Savings or costs attributed to one component must be considered as part of this larger ecosystem. Calls for solutions that address only one component, therefore, are less than ideal; a multi-pronged approach is preferred.
7. Transparency of the process by which prices are set and the contributing costs along the supply chain for medicines is necessary so that all payers may be informed purchasers.
8. Costs of treatment must be readily available for practitioners and patients so that they may make informed treatment decisions. Tools that translate information on pricing and value to make it actionable for decision-making must be developed so that providers and patients may work together in selecting care regimens that best align with patient and family preferences and goals.