



March 13, 2019

The Honorable Anna G. Eshoo  
Chairwoman  
Subcommittee on Health  
Committee on Energy and Commerce  
U.S. House of Representatives  
Washington, D.C. 20515

The Honorable Michael C. Burgess, M.D.  
Ranking Member  
Subcommittee on Health  
Committee on Energy and Commerce  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Chairwoman Eshoo and Ranking Member Burgess:

As the Subcommittee holds a hearing on lowering the cost of prescription drugs and reducing barriers to market competition, the Healthcare Leadership Council (HLC) welcomes the opportunity to share its thoughts with you.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, home care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

### **Competition and Innovation**

The U.S. healthcare system has seen an increase in the cost of prescription drugs which has adversely affected patients, providers, payers, and other healthcare stakeholders. Increases in drug prices are often due to the lack of competition in the prescription drug marketplace. As a diverse coalition of healthcare stakeholders across the U.S. healthcare system, we believe innovation is essential to increasing market competition to deliver affordable, cutting-edge drug therapies to the public. HLC believes policies that encourage competitive markets and support innovation will lower drug costs and improve access to treatment. HLC supports a continuation of streamlining the Food and Drug Administration's (FDA) responsibilities and processes, which would include decreasing the backlog of generic drug approvals at the FDA and broadening FDA authority to accelerate review and approval for new generic drugs. Addressing barriers to and encouraging the entry of new generic drugs into the market will create more competition and help to lower drug prices.

### **Promoting Value-Based Care**

HLC supports a shift towards a value-based system that pays based on value versus volume. In a value-based system, payment for medications is tied to patient outcomes and achieving

clinical targets. A value-based payment system creates a disincentive for inappropriate prescribing practices and overutilization, protecting both patient and federal healthcare dollars. However, the adoption of value-based systems, including for prescription drugs, has been stifled by laws designed to discourage inappropriate behavior in a fee-for-service payment model. The most notable barriers in our current healthcare system, the physician self-referral law (“Stark Law”) and the Anti-Kickback Statute, require modernization as our healthcare system shifts from volume-based care to increasing the value of care. Modernization of federal fraud and abuse laws will enable pro-patient, value-focused collaboration among payers, providers, and manufacturers.

Another regulatory barrier is the Medicaid Best Price rule requiring drug manufacturers to offer the Medicaid program the lowest price negotiated with any other buyer. This requirement can deter companies from entering into value-based contracts. To utilize value-based contracting, manufacturers must be able to work with providers and health plans to assess the efficacy of a certain drug in a clinical setting and then set prices based on the results. Under current regulations, if a manufacturer sets a substantially discounted price for a drug while waiting for an evaluation of patient outcomes, that artificially lowered price would have to be offered to the Medicaid program. This creates a disincentive for pharmaceutical companies to accept increased risk in value-based contracting and thus, decreases patient access to innovative drug therapies.

Innovation, competition, and a collaborative environment for payers, providers, manufacturers, and patients are conduits for lowering prescription drug costs for all Americans. Thank you for examining this important issue and please feel free to reach out to Tina Grande, Senior Vice President for Policy, at (202) 449-3433 or [tgrande@hlc.org](mailto:tgrande@hlc.org) with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary R. Greal". The signature is fluid and cursive, written in a professional style.

Mary R. Greal  
President