



May 7, 2019

The Honorable Lindsey Graham
Chairman
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Dianne Feinstein
Ranking Member
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Graham and Ranking Member Feinstein:

As the Senate Committee on the Judiciary holds a hearing on “Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and 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. Current FDA regulations and processes delay access to treatments and technologies, thus limiting price lowering competition in multiple therapeutic categories. HLC supports strengthening FDA processes and operations in order to enable more pharmaceutical products to get to the marketplace sooner, thus creating a more competitive environment. Addressing barriers to and encouraging the entry of new 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 with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary R. Greal". The signature is fluid and cursive, with the first name "Mary" and last name "Greal" clearly visible.

Mary R. Greal
President