



February 16, 2018

The Honorable Scott Gottlieb, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Gottlieb:

On behalf of the Healthcare Leadership Council (HLC), I write in support of the Food and Drug Administration's (FDA) 2018 policy priority areas. HLC members, through our broad National Dialogue for Healthcare Innovation (NDHI) platform support the FDA's efforts to reduce regulatory burdens on drug manufacturers, medical device companies and biopharmaceutical companies to encourage competition within the healthcare marketplace. Eliminating regulatory obstacles, such as restrictions on sharing scientific and healthcare economic information among various agents, can improve healthcare delivery which benefits the patient.

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 health 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, pharmacies, post-acute care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

The Healthcare Leadership Council supports the FDA's commitment to using innovation and competition as conduits to improve healthcare, increase access to information and advance public health goals. Increasing access to healthcare economic information will help health plans and providers measure and compare the economic consequences of a drug or healthcare intervention. Greater access to information can further innovation and broaden access to lower cost drugs for consumers. In addition, HLC strongly supports the FDA's "gold standard" for product review. We believe a consistent, clear and cutting-edge regulatory process can decrease fixed costs associated with improving product safety and efficacy. As the FDA notes, the U.S. system of "market-based pricing" needs to continue to provide strong incentives for companies to develop potentially high risk and costly drugs to advance medical treatments. HLC supports measures to ensure companies will not take advantage of FDA rules to limit generic competition of prescription drugs. Lastly, HLC lauds the FDA's steps to eliminate the scientific and regulatory policy barriers to the entry of "complex" generic medicines.

HLC strongly supports the use of digital technologies to allow consumers to connect and collaborate with medical professionals. We commend the FDA's approach to modify and adapt its regulatory rules in accordance with the evolution of technology. In particular, HLC applauds the FDA's Pre-Certification Pilot Program and its customized method of meeting the demands of digital innovation within healthcare. Digital health tools provide consumers the opportunity to make evidence-based decisions for their health.

As a diverse coalition of healthcare leaders, HLC believes it is crucial the FDA's scientific workforce is prepared to meet the challenges of rapid advancements in science and increases in consumer demand. We laud the FDA's efforts to strengthen and harness the talent of their workforce. We urge the FDA to ensure medical professionals are empowered to practice to the full extent of their qualifications (including an expanded role for pharmacists in healthcare delivery). Lastly, HLC supports the FDA's initiative to modernize its "regulatory toolbox", which aims to ensure FDA generated requirements enable scientific breakthroughs to rapidly reach consumers in the healthcare marketplace.

HLC applauds the FDA's efforts to meet the challenges of an increasingly complex healthcare landscape. We look forward to continuing to collaborate with you on our shared priorities. Should you have any questions, please do not hesitate to contact Tina Grande at (202) 449-3433 or tgrande@hlc.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary R. Grealy". The signature is fluid and cursive, with the first name "Mary" being the most prominent.

Mary R. Grealy
President