December 7, 2017

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

Re: Docket No. FDA-2017-N-5093, "Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration."

Dear Dr. Gottlieb:

Thank you for your thoughtful and outstanding leadership of the Food and Drug Administration (FDA). The Healthcare Leadership Council (HLC) welcomes the opportunity to share our thoughts with you on steps the FDA can take to strengthen and modernize its regulatory framework.

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.

Like you, HLC strongly supports healthcare innovation and believes that American ingenuity is critical to achieving a healthcare system that is efficient, effective, and of the highest quality. The products and industries regulated by the FDA are job creators and an important part of our nation's economy. Additionally, Americans are able to live healthier and longer lives, have fewer disabilities, and spend less time in the hospital because of these innovations. Unfortunately, the following costly, ineffective, and time-consuming regulations threaten this culture of discovery.

<u>Conflict-of-Interest Policies</u>
The processes and criteria for evaluating conflicts of interest should be revised to allow scientific experts to serve on advisory committees and panels. These experts are best suited to provide advice to the FDA, and the agency should not be denied access to their knowledge. Similarly, the FDA should revise its hiring policies to ensure that highly

qualified individuals can be hired for staff positions. The agency currently has a substantial number of job vacancies, which is slowing approval of new drugs and devices. The FDA should revise its policies to allow scientists with a possible conflict of interest to serve on panels and on the agency's staff while requiring their recusal from FDA decisions that might affect their patents or holdings.

New Product Approvals

The FDA has a backlog of over 4,000 generic drug applications that are awaiting approval. It takes, on average, nearly four years to bring these medicines to market. This backlog is slowing Americans' access to effective treatments and cures. It is also preventing competition, which could lower the cost of non-generic drugs. The FDA needs to streamline its approval processes and operations and make them more transparent. We appreciate that you are working to address this backlog.

Information Sharing Among Stakeholders

Currently, the FDA restricts the economic and clinical information a drug manufacturer can communicate to payers and providers before the product is approved. This restriction prevents those stakeholders from having the information necessary to evaluate the drug's potential impact. As payers and providers take on increased risk in value-based payment arrangements, information about the clinical and economic outcomes of new products becomes ever more critical. Health plans need this information 12 to 18 months before FDA approval in order to apply it to coverage and budgetary decisions. Providers also need this information to determine which patients can best benefit from these potentially breakthrough therapies. Knowledge of the economic and clinical impact of a drug can, therefore, improve the efficiency of the healthcare system while also enhancing patient care. The FDA should allow meaningful, fact-based discussions between manufacturers and the purchasers of their products prior to approval, while still maintaining the protections that prevent premature marketing of the drug.

Thank you again for your work at FDA. HLC looks 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.

Sincerely,

Mary R. Grealy
President