October 25, 2016

The Honorable Robert Califf, MD
Commissioner, Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Draft Guidance on Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices (FDA-2016-D-2153)

Dear Commissioner Califf:

The National Health Council (NHC) is pleased to provide comments on the Center for Devices and Radiological Health’s (CDRH) and Center for Biologics Evaluation and Research’s (CBER) draft guidance document addressing Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices. We applaud the Food and Drug Administration (FDA) for taking this step to help clarify how the Agency evaluates real-world data (RWD) in the context of regulatory review for medical devices.

The NHC is the only organization that brings together all segments of the health community to provide a united voice for the more than 133 million people with chronic diseases and disabilities and their family caregivers. Made up of more than 100 national health-related organizations and businesses, the NHC’s core membership includes the nation’s leading patient advocacy organizations, which control its governance and policy-making process. Other members include professional and membership associations, nonprofit organizations with an interest in health, and representatives from the pharmaceutical, generic drug, insurance, medical device, and biotechnology industries.

The NHC believes that real-world evidence (RWE) holds great potential to one day revolutionize the health care system, including how drugs and devices are developed and approved. While we support the FDA’s usage of controlled, multi-arm trials, it is important to note limitations that exist and how RWE can fill in gaps created by these limitations. Notably, recruitment in clinical trials is often difficult in smaller patient populations, especially for rare conditions. Additionally, exclusion criteria used in trials, such as comorbidities that require multiple treatments, may often result in the lack of full understanding regarding how a treatment will work in clinical practice. Supplementing controlled, clinical trial data with additional data from clinical practice can: (1) improve our understanding of products, including the benefits and risks to patients, (2) support approval of new indications for devices and drugs, (3) contribute to the post-marketing surveillance of these products, and (4)
reducing pre-market data collection and speeding safe and effective products to patients.

We agree with the FDA that “a wealth of data covering medical device experience exists and is routinely collected in the course of treatment and management of patients,” and we welcome the Agency’s guidance on how it evaluates RWD and when and how this data may be of sufficient quality to inform specific regulatory decisions. Understanding how the FDA evaluates RWD and when the FDA may use RWD in different contexts (e.g., for different regulatory decisions), as well as when an Investigational Device Exemption (IDE) may be required, will encourage and assist manufacturers and other stakeholders to more fully utilize information collected from this practical experience.

While RWE holds enormous potential for improving and streamlining the product development process, we believe it critical to take a purposeful, step-by-step approach to identifying and understanding the opportunities and limits of RWE. This draft guidance lays important groundwork on which to start to identify when and how RWD can contribute to regulatory decision-making. By recognizing in this draft guidance that the value of RWE is an “important contributing factor for understanding and regulating medical devices,” including the examples where RWE was successfully used to impact FDA decisions, FDA will help encourage the use of RWD and advance the practical applications of RWE.

We appreciate that this draft guidance is part of a broader effort by the FDA to understand RWE (e.g., FDA’s implementation of the National Evaluation System for Health Technology), and we support the FDA’s actions to explore and evaluate the use of RWE in product development in a thoughtful and measured way.

The NHC appreciates the opportunity to provide our feedback on this draft guidance and we look forward to continuing to collaborate with the FDA and other stakeholders as we learn more about RWE and its potential for streamlining drug and device development to bring safe and effective products to patients faster.

Please contact Eric Gascho, the NHC’s Vice President of Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0545 or via e-mail at egascho@nhcouncil.org.

Sincerely,

Marc Boutin, JD
Chief Executive Officer