REAL-WORLD EVIDENCE ALLIANCE

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**Via Email**

The Honorable Diana DeGette
2111 Rayburn House Office Building
Washington, DC, 20515-0601

The Honorable Fred Upton
2183 Rayburn House Office Building
Washington, DC, 20515-2206

**Re: Comments on Cures 2.0 Discussion Draft**

Dear Congresswoman DeGette and Congressman Upton:

The RWE Alliance appreciates your leadership in championing the Cures 2.0 initiative and, in particular, for encouraging medical innovation through the use of real-world data (RWD) and real-world evidence (RWE) in regulatory decision making. We are grateful for the opportunity to comment on the discussion draft published in June 2021.

## I. Overview of What We Believe

The RWE Alliance is a coalition of real-world data and analytics organizations with a common interest in harnessing the power of RWE to inform regulatory decision making to improve patients' lives. Our members have deep knowledge and experience working with healthcare data across disease areas and patient populations, and we aim to bring these collective insights to bear in support of RWE policies.

The RWE Alliance envisions a future in which data generated in everyday clinical practice and everyday life through electronic health records, administrative claims and billing data, product and disease registries, personal devices, wearables, and health applications will be used to generate evidence that complements clinical trial data. To achieve this goal, the RWE Alliance advocates for policies that will:

1. Advance FDA's RWE Framework. With your leadership, Congress took important steps in 2016 to advance the use of RWD/E with the passage of the 21st Century Cures Act, which included a provision calling on FDA to publish a framework for the use of RWE for regulatory purposes and guidance on the topic. We support FDA's ongoing work to facilitate the use of RWD and RWE, which

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will add to the understanding of medical product safety and effectiveness to benefit patients.

2. Encourage the Use of RWE to Better Understand Treatment Effects in Underrepresented Populations. RWE can play a role in providing FDA, patients, healthcare providers, and other stakeholders with information on treatment effects among underrepresented populations across therapeutic areas. Clinical trial study populations frequently are not fully representative of relevant patient populations in real-world settings. We will work to support the use of RWE as a resource to help address disparities in healthcare access, treatment, and outcomes.

3. Enhance Opportunities for RWE Organizations to Consult with FDA. We seek and support increased opportunities for RWE organizations to consult with FDA on specific topics relevant to the potential uses of RWE for regulatory decision making across therapeutic areas and to share learnings from our experience. Medical product sponsors benefit greatly from FDA's feedback, and feedback for RWE organizations will also help advance understanding of how and when RWE can be used for regulatory decision making. We will work with FDA and other stakeholders to establish mechanisms and opportunities for RWE organizations to engage on RWE methods and applications.

4. Increase Communication on the Generation and Use of RWE. Communication about FDA's review of RWE in marketing applications is crucial to advancing best practices in the use of RWE for regulatory purposes and to ensuring a widespread understanding of the benefits that RWE ultimately delivers to patients. To increase this communication, we support FDA raising broader awareness about current and potential uses for RWE. We also support FDA providing more detailed guidance on how RWE should be presented in submission packages and product labeling, as well as FDA making public a summary of the Agency's review of RWE when included in original or supplemental marketing applications.

## II. General Comments on Cures 2.0 Discussion Draft

The RWE Alliance applauds the broad range of public health policies advanced by the Cures 2.0 discussion draft, which will help drive medical innovation to improve patient care—including by helping the country to better understand the impact of COVID-19 and prepare for future public health emergencies. The RWE Alliance strongly believes that RWD and RWE serve a critical role in helping to inform decisions about the authorization and use of medical products, especially during public health emergencies. RWD and RWE indeed played an important role in informing the country's

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understanding of the COVID-19 virus, how to treat patients who have been infected, and how to prevent its continued spread. Prime examples include the Reagan-Udall Foundation's COVID-19 evidence accelerators, which were launched in collaboration with Friends of Cancer Research at FDA's request,[1] and ongoing studies of COVID-19 vaccines in a real-world setting.

These extensive efforts to collect RWD and develop RWE have informed healthcare and regulatory decision making in real time. The RWE Alliance is confident that this will continue to benefit the U.S. response to COVID-19 and can serve as a model across therapeutic areas outside of a public health emergency. In particular, the RWE Alliance believes that taking steps now to more fully define and implement FDA's RWE Framework, as contemplated in Cures 1.0, and facilitating the use of RWE in regulatory decision making, will benefit patients in the normal course—not just during a pandemic. At the same time, this progress will also support preparations for future emergencies, during which public health authorities can rely more readily on a framework that is already in place for collecting, analyzing, and using RWD/RWE to inform decision making. To this end, our members support and seek to contribute their expertise to the implementation of Cures 2.0 initiatives, ranging from the learning collaborative for understanding the implications of long COVID to participating in the Real World Evidence Task Force to be established by the Secretary of Health and Human Services.

## III. Conclusion

Thank you for considering these comments and for spearheading the Cures 2.0 legislation. We look forward to working with you on advancing these important public health objectives and would welcome the opportunity to discuss further at your convenience.

Best,

The RWE Alliance

[1] COVID-19 Evidence Accelerator, https://evidenceaccelerator.org/.