July 16, 2021

Honorable Diana DeGette
Honorable Fred Upton

Comments on Cures 2.0 Discussion Draft

Via Email: Cures2@mail.house.gov

Dear Representatives DeGette and Upton:

Thank you for your continued bi-partisan efforts to advance medical innovation benefitting patients. Heart Valve Voice US is a nonprofit patient advocacy organization providing a united voice for people living with heart valve disease. We advocate for early detection, meaningful support, and timely access to appropriate treatment for those affected by heart valve disease. We welcome the opportunity to provide these comments and look forward to working with you through the legislative process.

Section 201: Educational Programs and Training for Caregivers

Heart valve disease patients tend to be older and more reliant on caregivers. (We prefer use of the term "care partner.") The physical and emotional burden placed on care partners is often not acknowledged. As such we recommend that you consider adding programs that provide emotional support to caregivers among eligible activities.

Section 203: Increasing Diversity in Clinical Trials

Heart Valve Voice US is very supportive of efforts to include diverse populations in clinical trials. We are dismayed, however, that in the nearly five years since the 21st Century Cures Act was passed so little progress has been made in making ClinicalTrials.gov more user friendly. We recommend more aggressive timelines for implementing changes to ClinicalTrials.gov, greater accountability to ensure enhancements are made and, if needed, additional funding and resources be provided to the National Library of Medicine to ensure implementation.

Section 204: Patient Experience Data

While we support the collection and consideration of Patient Experience Data, we are concerned that requiring this data would add more complexity and burden to the clinical trials process for patients and researchers, potentially further limiting participation. Perhaps the

collection of Patient Experience Data could be "encouraged" if not "required" with some incentive for the collection of this data. We would also recommend extending this section to include medical devices, not limiting it to drugs.

Section 301: Report on Collaboration and Alignment in Regulating Digital Health Technologies

We recommend that this report also include recommendations on a framework for CMS coverage of Digital Health Technologies. Further, the alignment between FDA and CMS should include coordination on evidence gathering to ensure efficient data collection to meet the dual purposes of product approval and coverage.

Section 302: Grants for Novel Trial Designs and Other Innovations in Drug Development

We recommend extending this section to medical devices as well as drugs. Clinical trial innovation, including adaptive trial designs, is needed for medical technology development, as well as for drugs.

Section 304: Increasing Use of Real-World Evidence

As with Section 302, we recommend including medical devices in this section. Further, just as patient organizations should be included on the ClinicalTrials.gov task force, the patient perspective would provide invaluable insight into the best methods to acquire, analyze, and use Real World Evidence. As such, patient organizations should be represented on this RWE task force.

Section 305: Improving FDA-CMS Communication Regarding Transformative New Therapies

We recommend Section 305 be expanded to include "breakthrough" or other similarly designated medical devices. Again, we cannot emphasize enough the need for coordination between FDA and CMS on data collection and evidence development to avoid duplication, streamline processes and ensure consistency. FDA post-market requirements can be synchronized with CMS evidence development requirements.

Section 401: GAO Study and Report

At present, there is no formal mechanism or requirement for CMS to consider patient preferences within its coverage and reimbursement decisions. As such, we recommend the following addition Section 401(1): "enhance coverage and reimbursement approaches under the Medicare program under title XVIII of the Social Security Act for innovative technologies

that increase access to health care, ***reflect patient preferences***, improve health care quality, decrease expenditures under such program, or otherwise improve the Medicare program or health care for beneficiaries under such program…."

Section 403: Extending Medicare Telehealth Flexibilities

Heart Valve Voice US strongly supports extending Medicare flexibilities for telehealth. According to a patient survey we conducted, nearly half of those in our patient community availed themselves to telehealth during the COVID pandemic. The survey also found: 97% of these patients said they were very or somewhat satisfied with the telehealth experience; 72% said they expect most of their future medical appointments to be via telehealth; and 62% felt well-prepared for their appointments. Nevertheless, technology also remains a challenge for patients, with 40% reporting this as the biggest barrier to a successful telehealth appointment. Our community mainly consists of patients 65 or older, and with appointments moving digital they may have not been prepared for the technological shift.

In subsequent engagements with our patient community, we have identified another implication of the shift to telehealth. While telehealth provides numerous efficiencies, and increases access for many, an overreliance on technology can have significant negative ramifications for patients. For example, we are currently exploring the potential gaps in patient-provider communications that can occur from reliance on online portals to transmit information, such as test results, to patients without further consultation from the health care professional. A lack of access to technology, a lack of ability to use technology, or an inability to understand results without context, may create increased risk for patients.

We recommend that while CMS explores expanded flexibilities in telehealth, it also considers policies that encourage ongoing direct patient-provider communication and examines the most effective use of online portals to ensure those who lack access or technical skills, including the elderly, are not discriminated against or placed at additional risk.

Section 404: Coverage and Payment for Breakthrough Devices Under Medicare Program

Heart Valve Voice US strongly endorses the concept of providing automatic Medicare coverage for innovative technologies upon their FDA market authorization. Patients deserve the certainty of having access to the most innovative medical technology without concerns over coverage and reimbursement. This should be a fundamental patient right.

We read Section 404 as codifying the current proposed Medicare Coverage for Innovative Technology regulation. We applaud this effort which would serve to bring these treatments to

patients 9-12 months sooner than through the current, often convoluted, National Coverage Determination process.

While we are hopeful MCIT may be implemented before Cures becomes law, we nevertheless support the clarity and certainty provided by codification in statute.

We have two suggestions for improvement to the MCIT concept. First, there should be additional consideration of patient preferences in what constitutes "innovative" technology. FDA has been pro-active in incorporating the patient voice into its regulatory consideration and this approach should flow through the coverage determination process as well. Second, MCIT represents the prime example of the necessity for coordinated data collection requirements between FDA and CMS, in consultation with manufacturers. Patients and providers need reliable, consistent data to determine the risk-benefit of any new treatment. FDA post-market data requirements should be aligned with CMS needs for evidence development to ensure consistency and avoid redundancy.

Integrated data collection may consist of real-world evidence sourced through a new or existing data registry, electronic health records, patient-reported outcomes, or other similar mechanisms. The aforementioned coordination between agencies and manufacturers should include the transmission of predictable methods and parameters of data collection that would both inform mandatory data collection efforts for the benefit of coverage and approval while also allowing manufacturers to demonstrate the value of the device for market purposes.

Thank you for the opportunity to comment on this important draft legislation. We look forward to working with you to further develop these concepts that speed new and innovative technologies to market for the benefit of patients. If you have any questions, please feel free to contact me at 202-285-5726 or john@heartvalvevoice-us.org.

Sincerely,

John Lewis

John Lewis
Executive Director