



American Association
for Dental Research

December 16, 2019

The Honorable Diana DeGette
Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

The Honorable Fred Upton
Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

Dear Representatives DeGette and Upton:

The American Association for Dental Research (AADR), which represents 3,400 individual and 107 institutional members across the country, greatly appreciates the opportunity to provide feedback on “Cures 2.0.” We remain grateful for your continued leadership to create legislation that will bring new advances and innovations—more quickly and efficiently—to the patients who need them.

AADR recognizes that Cures 2.0 is intended to build upon 21st Century Cures’ focus on discovery and development by creating legislation with a focus on *delivery*, modernizing both coverage and access to cures. This is a welcome focus; in order to reach its full potential, science must not merely enhance knowledge, but should be used and delivered in a way that benefits patients and society at large. AADR urges you to keep oral health in mind as you consider coverage of and access to new life-saving cures. Advances in dental research play a key role in improving oral and overall health in the United States and must not be forgotten in our broader discussions of health care and health coverage.

Further, as you consider the future of Cures, AADR asks that you maintain an emphasis on research by carrying over certain research and development (R&D) elements from 21st Century Cures—incorporating evidence-based practices and policies, bolstering relevant federal research agencies, and measuring the progress of the coverage and access to new life-saving cures.

Supporting R&D and Workforce Elements from 21st Century Cures

The 21st Century Cures Act was a comprehensive piece of legislation that touched upon multiple priorities within the federal research enterprise—from providing funding for specific research areas to reducing the regulatory burden for researchers and research institutions. We believe Cures 2.0 should maintain a focus on reducing the administrative burden placed on scientists, improving coordination related to minority health and health disparities, and exploring how to improve the rigor and reproducibility of science.

There were also several research initiatives that excelled as part of 21st Century Cures. While AADR is supportive of investigator-initiated research in order to generate unprompted ideas from the research community, we also believe that certain initiatives from 21st Century Cures, including the Regenerative Medicine Innovation Project, have provided value. Research into regenerative medicine is harnessing knowledge from multiple federal research entities, including the National Institute of Dental and Craniofacial Research (NIDCR). The team at NIDCR, along with its colleagues across the government, have recognized the promise of regenerative medicine for treating a variety of injuries, conditions and diseases, including the repair or replacement of teeth, joints, bone and other tissues. Some examples of

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NIDCR-supported research in regenerative medicine include generating stronger cartilage, using stem cells from human fat tissue to grow bone and re-engineering salivary glands to increase the flow of saliva to alleviate dry mouth.

Another element from 21st Century Cures that AADR would like to see continued is the provision increasing the loan repayment program amount from \$35,000 to \$50,000. According to the American Dental Education Association, for the class of 2019, the average educational debt for all indebted dental school graduates was \$292,169. These costs are overwhelming for anyone, let alone a new graduate. The increased loan repayment amount is mutually beneficial for students and our society. Not only does the increase reduce students' early career debt, but it can also encourage these students to take research positions within the federal government, which they may not be able to afford otherwise.

Incorporating Evidence-Based Practices and Policies

There are several ways that Cures 2.0 could build evidence into the final legislation package. These include ensuring that the bill contains tools to measure progress, finding ways to incentivize the use of evidence- and research-based programs and dedicating funding to evidence- or research-based programs.

AAADR appreciates that in the Cures 2.0 vision document not only highlighted the 21st Century Cures Act's challenge to the Food and Drug Administration (FDA) to "evaluate and utilize real world evidence (RWE)," but that the document also mentioned a desire to build upon that work at FDA and beyond. It is through research and evidence that we can better understand what's working and what's not—and why—and use that information to make progress. The Framework for FDA's Real-World Evidence Program importantly noted the multifaceted nature of the program, which would involve "demonstration projects, stakeholder engagement, internal processes to bring senior leadership input into the evaluation of RWE and promote shared learning and consistency in applying the framework, and guidance documents to assist developers interested in using real-world data (RWD) to develop RWE to support Agency regulatory decisions." AADR appreciates the interest in building on those elements to inform policy and practice decisions and hope this will be prominent in the final Cures 2.0 legislation.

Utilizing Appropriate Federal Research Agencies

Cures 2.0 is a powerful piece of health care reform legislation that will require participation and support from several partners and stakeholders. AADR would encourage lawmakers to consider how to use the resources already available, namely federal research agencies, so the bill has the best chance for achieving success.

Agencies, including the Agency for Healthcare Research and Quality (AHRQ), the Office of the National Coordinator for Health Information Technology (ONC) and Centers for Medicare and Medicaid Services (CMS), have expertise that could prove valuable for a bill focused on coverage and access issues. Similarly, agencies such as the National Institutes of Health (NIH) could be consulted for relevant research elements in the bill. Federal research agencies will be important partners in the bill's implementation, and AADR would encourage lawmakers to consult and rely upon agency staff as subject-matter experts. Their insights could be valuable in helping legislators understand how we might use Cures 2.0 to build upon already-established policies and practices and where we need to develop new and innovative solutions.

Cures 2.0 is a tremendous undertaking, and AADR appreciates your leadership to carry out this important work. As you weigh the myriad proposals for this legislation, AADR will reiterate our requests: to keep the role of oral health—

and dental, oral and craniofacial research—top of mind as you consider proposals related to coverage and access and to incorporate research components wherever possible so that we can measure success and build upon the knowledge generated from Cures 2.0 for future policies and legislation.

Once again, AADR thanks you for the opportunity to comment on the vision document for Cures 2.0. If you have questions or need additional information, please contact AADR Assistant Director of Government Affairs Lindsey Horan at lhoran@aadr.org or 703.299.8098.

Sincerely,

A handwritten signature in blue ink, appearing to read "Chris Fox".

Christopher H. Fox, DMD, DMSc
Chief Executive Officer
American Association for Dental Research