

August 2, 2024

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

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

Re: Request for Information on the Next Generation Cures Bill.

via email: cures.rfi@mail.house.gov

The American Association for Dental, Oral, and Craniofacial Research (AADOOCR) is the leading professional community for multidisciplinary scientists who advance dental, oral, and craniofacial research. The 21st Century Cures Act and the legislative proposal, Cures 2.0, has played and continues to play a critical role in biomedical research funding and innovation, mental health care reform, drug development, and health information technology.

As part of the 21st Century Cures Act, the Regenerative Medicine Innovation Project facilitates accelerated progress in regenerative medicine and has provided support to the National Institute of Dental and Craniofacial Research (NIDCR) to support research that develops evidence-based regenerative medicine therapies and speeds their translation from the laboratory to the clinic. This sustained financial support is crucial as oral health is a key indicator of overall health, well-being, and quality of life and enables individuals to perform essential functions such as eating, breathing and speaking, and encompasses psychosocial dimensions such as self-confidence, well-being and the ability to socialize and work without pain, discomfort and embarrassment¹.

AADOOCR recognizes and applauds Representatives DeGette and Bucshon for their consideration of a new set of reforms under the banner of the broader 21st Century Cures initiative. We appreciate the opportunity to provide information that will shape the next generation of this lifesaving and transformative legislation for patients with intractable diseases. To respond to this request for comments, AADOOCR engaged its Science Information Committee and its Board of Directors.

AADOOCR has considered the three key questions posed in reflection of the goals of the 21st Century Cures Act and Cures 2.0 and has applied this lens to the sections of the bill noted below.

Sec. 105. Developing Antimicrobial Innovations

AADOCR supports *Sec. 39900. Establishment of Committee; Subscription Model; Advisory Group*. Dentists are responsible for approximately 10% of antibiotic prescriptions², and utilize or recommend antiseptics on a large scale, for both in-office use or oral home care³. It would therefore be important to include oral infections within the list of infections for which new antimicrobial drug development is needed [(c) Duties (1)] and a representative from the NIDCR or those with dental research expertise should also be included on the Committee [(b) Members (1)]. In that vein, AADOCR supports *SEC. 399RR. Encouraging Appropriate Use of Antibiotics and Combating Resistance*. Antimicrobial Resistance (AMR) is considered one of the leading causes of death worldwide with global median figures of 1.27 million deaths directly attributable to AMR and 4.95 million deaths associated with AMR⁴. The overuse or even misuse of antimicrobials are known as main drivers in the development of AMR. Due to prescription issuance, the dental profession has a pivotal responsibility to contribute to reducing the unnecessary use of antimicrobials and combating AMR. Consequently, AADOCR supports the inclusion of dental practitioners and clinicians within the (a) Establishment of Hospital Grant Program and (b) Surveillance and Reporting of Antibiotic Use and Resistance. This will also facilitate the U.S. alignment with the World Health Organization's [Global Action Plan on AMR](#) approved by Member States in 2015.

Sec. 202. Increasing Health Literacy to Promote Better Outcomes for Patients

AADOCR is enthused by the effort to promote increased health literacy specific to patients and caregivers. It is estimated that only 1 in 10 adults in the United States can fully understand written material on health⁵. Health literacy provides the foundation for oral health literacy, and therefore persons with low health literacy are also more likely to have low oral health literacy^{5,6}. Oral health literacy exists within the context of culture and society, the education system, and the interaction that individuals have with the health system, knowing that oral health literacy leads to and complements health, oral health, and health outcomes and costs⁶. Therefore, AADOCR supports further research to discern culturally competent best practices to improve oral health literacy. Additionally, there is a current dearth of specific programs or websites that educate patients and caregivers, including family caregivers, about the medical hierarchy and the insurance billing structure. Therefore, AADOCR supports adequate funding to strengthen efforts to increase transparency of the healthcare billing system and subsequent health literacy efforts. Additionally, AADOCR supports the identification of digital tools and health information portals within (1) the identification of culturally competent, evidence-based interventions. AADOCR also supports the inclusion of

defined measurable outcomes to assess the effectiveness of the implemented health literacy initiatives, such as patient satisfaction with information received, adherence to treatment plans, and health outcomes improvement.

Sec. 203. Increasing Diversity in Clinical Trials

Promoting diversity in clinical trials for oral diseases is essential for advancing equitable health outcomes and ensuring that all populations benefit from effective oral health interventions. Diversity in clinical trials is crucial to ensure (i). generalizability of results, (ii). understanding variability in disease expression, (iii). improving drug development, (iv). designing tailored interventions, (v). addressing health disparities, and (vi). increasing cultural competence^{7,8}. Therefore, AADOCR supports updated reporting on inclusion of demographic subgroups to increase the trust and credibility of the dental, oral, and craniofacial biomedical workforce; AADOCR also supports the public awareness campaign and the task force to make clinicaltrials.gov more user friendly.

Sec. 301. Report on Collaboration and Alignment in Regulating Digital Health Technologies

AADOCR encourages the use of new technologies and scientific tools to promote oral health and prevent dental diseases. Emerging preventive technologies can be utilized at home to empower consumers who seek to gain more control over their personal health. Medical solutions and services, such as mobile and direct-to-consumer smart devices, are becoming increasingly popular for patients looking to monitor their blood pressure, glucose and heart rate, physical activity, nutrition, and medical conditions. Cures legislation should support these tools, including technologies to help consumers monitor and improve their oral health and advance better at-home oral hygiene. Examples include educational and caries risk assessment apps, toothbrush tracking, and intraoral biosensor platform to monitor saliva. As the costs of these technologies decrease with greater adoption, preventive care innovations will enhance oral health and create value for consumers, providers, and payers.

Sec. 310. Recommendations to Decentralize Clinical Trials

AADOCR is appreciative of the effort to decentralize clinical trials specific to the Food and Drug Administration. The incorporation of telehealth and digital technology which extends the original act to promote health information technology and its utilization is especially critical to foster innovation in healthcare delivery, improve patient outcomes, and accelerate the development of new treatments and therapies across medical and potentially dental, oral, and craniofacial domains. AADOCR supports the specific

integration of dental professionals and dental research organizations (item F) as a Covered Representative (1). As oral healthcare delivery has been historically marginalized from the rest of the healthcare system⁹, the inclusion of these covered representatives within the referenced stakeholder group defining innovative approaches and incentives to adopt decentralized clinical trials ensures that the recommendations consider the unique aspects of dental care alongside medical treatments.

Sec. 404. Coverage and Payment for Breakthrough Devices Under the Medicare Program

The Centers for Medicare and Medicaid Services (CMS) has instituted herculean efforts to expand dental services for Medicare patients through changes in the Physician Fee Schedule Rules including (i). broadening the scope of dental services covered under Medicare, particularly for patients with complex medical conditions that require dental care as part of their overall treatment, (ii). integrating dental services with medical care, allowing for reimbursement of dental procedures that are necessary for treating underlying health issues, (iii). fostering interdisciplinary collaboration among healthcare providers (medical and dental) to facilitate a more holistic approach to patient care. Therefore, AADOCR supports the amendment of “Part E of title XVIII of the Social Security Act (42 U.S.C. 1395x et seq.) to strike Section 1862(a)(12) from the Social Security Act which prohibits Medicare from making payments for “...services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth.” This amendment would further accelerate efforts to integrate dental care within primary health care for those receiving Medicare services ensuring that dental health is part of overall health management.

Sec. 407. Precision Medicine Answers for Kids Today

AADOCR supports the provision within Cures 2.0 that would establish a program at the Department of Health and Human Services (HHS) allowing state Medicaid programs to provide coverage for genetic and genomic testing for individuals under the age of 21 and for former foster youth under the age of 26. Next Generation Cures legislation must expand access to diagnostic testing so that children born with rare diseases, disabilities and congenital anomalies receive appropriate clinical care, therapy, and treatment. The Centers for Disease Control and Prevention (CDC) reports that approximately four percent of children in the United States suffers from a congenital anomaly yet many private health insurance companies routinely deny or delay advanced diagnostic testing causing those families to turn to Medicaid. State programs are a lifeline for these children who, with highly personalized diagnostic plans to assess and oversee their

treatment and development, can receive the early intervention and care they need to grow and function normally.

Sec. 411. Meaningful Access to Federal Health Plan Claims Data

AADOCR supports the effort to increase access to health plans claims data specific to the Centers for Medicare & Medicaid Services. In that vein, AADOCR corroborates Congress' findings on the subject and consequently is supportive of the establishment of a new program. AADOCR encourages the consideration of medical-dental integration by the promotion of a novel database inclusive of both medical and dental claims and expenses. This facilitates comprehensive analysis and integration within healthcare decision systems and promotes interdisciplinary collaboration, improving the accuracy and relevance of integrated healthcare decision-making. AADOCR also supports the regular reporting and evaluation of this database to ensure continuous improvement and alignment with patient-centered care goals.

Sec. 501. Advanced Research Projects Agency for Health

AADOCR continues to support the efforts of ARPA-H to accelerate the development of breakthrough technologies that could revolutionize how we cure a range of diseases. AADOCR is specifically enthused that ARPA-H has integrated an oral surgeon as one of the program managers overseeing a project on Novel Innovations for Tissue Regeneration in Osteoarthritis. However, there is still more ground to cover as there are a variety of oral conditions and diseases, such as cleft lip and palate, oral and oropharyngeal cancer, temporomandibular joint dysfunction (TMJD), and periodontal disease, for which advanced data science could be used to identify common risk factors and reduce the inequities and disparities in access to oral health care. Bold and innovative approaches are needed to disrupt these diseases, using deeper knowledge of biologic pathways, environmental and societal influences, and social determinants of health. It is critical to emphasize that any diversion of funding from the National Institute of Health will jeopardize the momentum that has been achieved through fundamental research in uncovering the underlying mechanisms of health and disease. Therefore, it is imperative that Congress ensure that parallel increases in funding are provided for ARPA-H and for traditional research in the existing federal biomedical research system. In that vein, it is critical that the structure and operations of ARPA-H be maintained separate and apart from the National Institutes of Health (NIH) and should not be incorporated within any Institutes or Centers as Congress considers restructuring of the NIH. This will ensure that ARPA-H can maintain (i). strategic autonomy to set its own

strategic priorities and focus on emerging health challenges without competing interests, (ii). agility and innovation to foster rapid innovation and high-risk research, (iii). cross disciplinary collaboration across different sectors and fields and explore diversified funding models.

Other Considerations

Division B of the 21st Century Act contained provisions for Helping Families in Mental Health Crisis specific for provisions within Substance Abuse and Mental Health Services Administration (SAMHSA). However, this is not addressed within Cures 2.0. AADOCR supports the inclusion of the emphasis on healthy families with a mental health lens. Research has shown that mental health and oral health may be correlated, with associations demonstrated between mental health problems and tooth loss, periodontal disease, and tooth decay^{10,11}. Additionally, left untreated, dental diseases may lead to teeth loss such that persons with severe mental illness have 2.7 times the likelihood of losing all their teeth, compared with the general population¹¹. It is therefore critical that SAMHSA policies include a holistic approach that involves adequate funding to support research to better understand the connection, integrate care approaches, educational initiatives, and community engagement.

AADOCR also encourages the authors to add language from the Ensuring Lasting Smiles Act (ELSA) to close an insurance coverage loophole for people born with congenital anomalies who need complex oral restorative care. Private health insurance plans should be required to cover the diagnosis and treatment of craniofacial, oral, or maxillofacial congenital anomalies and birth defects, including all services that functionally improve, repair, or restore any body part that is medically necessary for normal bodily functions or appearance. Importantly, ELSA includes dental, orthodontic and prosthetic support from birth until function is restored, including coverage for post-adolescence procedures.

NIDCR's [Oral Health in America: Advances and Challenges report](#) provides a comprehensive story of the state of oral health in the United States. The report sheds light on how persons in the U.S. experience oral health differently, based on their age, economic status, and other social and commercial determinants. Importantly, it provides a foundation for the work that still needs to be done to ensure that oral health care is equitably available across U.S. In Section 6, Emerging Science and Promising Technologies to Transform Oral Health, the report outlines the tremendous advances


have occurred in the technology supporting dental practice, including new, bio-inspired dental materials, innovative chairside diagnostic strategies, 3D bioprinting, and improved digital imaging. The section also discusses promising new opportunities to use science and technology to spark innovation in health care delivery, with the goal of improving oral health and realizing better treatment outcomes at lower cost and greater convenience to patients. It would be hugely disruptive to furthering these NIDCR advancements should an ill-thought-out wholesale restructuring of the NIH occur, and Americans lose the only institute in the world dedicated to dental, oral, and craniofacial research. It would also take us away from the call to action supported by the U.S. Surgeon General, former Director of the NIH, and Director of the NIDCR to train, support, and mentor more oral health scientists and academics to ensure a robust workforce who can extend and effectively use the advances in science that are so critical for delivering care in the changing landscape of oral health. After all, good oral health is an important indicator of overall health, well-being, and quality of life¹.

AADOCR appreciates the opportunity to provide comments on the next generation cures bill. AADOCR stands ready to work with Congress on this effort towards medical innovation that may undoubtedly assist in addressing the needs of the dental and oral health research community. We are extremely grateful for your leadership on this issue and devotion to the federal medical research enterprise. If you have any further questions, please contact Dr. Makyba Charles-Ayinde, Director of Science Policy, at mcayinde@iadr.org.

Sincerely,



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Chief Executive Officer



Effie Ioannidou, DDS, MDS
President

¹World Health Organization. (2024). Oral Health. Retrieved from: https://www.who.int/health-topics/oral-health#tab=tab_1. Accessed on: July 15, 2024.

²Ramanathan S, Yan CH, Hubbard C, et al. (2023) Changes in Antibiotic Prescribing by Dentists in the United States, 2012–2019. *Infect Control Hosp Epidemiology*. 44:1725–1730.

³Cieplik F, Jakubovics NS, Buchalla W, et al. (2019) Resistance Toward Chlorhexidine in Oral Bacteria – Is There Cause for Concern? *Front Microbiol*. 10:587.

⁴Antimicrobial Resistance Collaborators, Murray CJ, Ikuta KS, et al. (2022) Global Burden of Bacterial Antimicrobial Resistance in 2019: A Systematic Analysis. *Lancet*. 399:629–655.

⁵U.S. Department of Health and Human Services, Administration for Children and Families. (2023). Improving Oral Health Literacy. Retrieved from: <https://eclkc.ohs.acf.hhs.gov/oral-health/brush-oral-health/improving-oral-health-literacy>. Accessed on: July 15, 2024.

⁶National Academies of Sciences, Engineering, and Medicine. (2013). Oral Health Literacy: Workshop Summary. Washington, DC: The National Academies Press. <https://doi.org/10.17226/13484>.

⁷Schwartz AL, Alsan M, Morris AA, Halpern SD. (2023). Why Diverse Clinical Trial Participation Matters. *N Engl J Med*. 388: 1252 – 1254.

⁸National Institute on Minority Health and Health Disparities. (2024). Diversity and Inclusion in Clinical Trials. Retrieved from: <https://www.nimhd.nih.gov/resources/understanding-health-disparities/diversity-and-inclusion-in-clinical-trials.html>. Accessed on: July 15, 2024.

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¹⁰Tiwari T, Kelly A, Randall CL, Tranby E, Franstve-Hawley J. (2022). Association Between Mental Health and Oral Health Status and Care Utilization. *Front Oral Health*. 2:732882. doi: 10.3389/froh.2021.732882.

¹¹Kisely S.(2016). No Mental Health without Oral Health. *The Canadian Journal of Psychiatry*. 61(5):277-282.