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American Association for Dental Research (AADR), Outside Witness Testimony
Senate Appropriations Committee Hearing: Driving Innovation through Federal Investments
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Future advances in health care depend on a sustained investment in basic research to identify the fundamental causes and mechanisms of disease, accelerate technological development and discovery, and ensure a robust pipeline of creative and skillful biomedical researchers. On behalf of the 11,000 individual and 44 institutional members of the International and American Associations for Dental Research (AADR), I am pleased to submit testimony emphasizing the importance and value of federal investments that benefit the health of all Americans while at the same time spurring innovation–leading to the development of businesses, products and jobs.

During the past half century the improvements in oral health are largely credited to research funded by the National Institute of Dental and Craniofacial Research (NIDCR). NIDCR is the largest institution in the world dedicated exclusively to research to improve dental, oral and craniofacial health. The health of the mouth and surrounding craniofacial (skull and face) structures is central to a person's overall health and well-being. Left untreated, oral diseases and poor oral conditions make it difficult to eat, drink, swallow, smile, talk and maintain proper nutrition. Scientists also have discovered important linkages between gum disease, or periodontal disease, and heart disease, stroke, diabetes and pancreatic cancer.

In spite of these improvements, however, treating oral health conditions is costly with $110.9 billion in expenditures on dental services in 2012.[i] While tooth decay and gum disease remain the most prevalent, complete tooth loss, oral cancer, and craniofacial congenital anomalies, like cleft lip and palate are also health and economic burdens to the American people. Moreover, oral health disparities exist for many racial and ethnic groups. A sustained and growing federal investment in research is needed so our members, universities, scientists and entrepreneurs can continue to innovate and build upon the gains of the past decades by creating less invasive, cost effective and more efficient ways to improve oral health.

Often innovative projects rooted in research supported by NIDCR that have commercial application will receive funding via the National Institutes of Health (NIH) Small Business Innovation and Research (SBIR) Awards. For example, the Sonicare toothbrush was developed with support from a NIH SBIR award. In 1987, David Giuliani, an entrepreneur joined with Drs. David Engel and Roy Martin from the University of Washington.[ii] Together through research and with funding support from private investors and NIH SBIR they developed the prototype of the toothbrush. This toothbrush uses electric power which moves the brush head rapidly either by back and forth oscillation or by rotation oscillation.[iii] In 2000, the product was acquired by a division of Philips. Today, Philips Sonicare serves one third of the U.S. market for electronic toothbrushes, generating $70 million in revenue annually and serving more than 17 million people from around the world.

In addition to spurring economic innovation, researchers have demonstrated the utility the clinical effectiveness of Sonicare and other electric powered toothbrushes in reducing plaque and gingivitis among adolescents with braces.[iv] Moreover, the benefits of using electronic toothbrushes by the elderly and disabled populations are widely documented.

Drs. Neal Clinthorne and Predrag Sukovic are entrepreneurs who also benefited from a SBIR grant from NIH. While sitting in a dental chair at the University of Michigan Sukovic realized that the X-rays were taking a long time to develop and thought it would be easier if the students had 3-D model of his teeth. In collaboration with his professor, Neal Clinthorne, he created a dental scanner and received phase I and phase II funding from the NIH SBIR mechanism.[v] Clinthorne and Sukovic developed cone beam computed tomography (CBCT) dental scanners that were cheaper and more efficient than the models on the market, which led to the creation of Xoran Technologies based in Michigan. After developing prototypes under SBIR funding, Xoran licensed the dental application to Imaging Sciences International (ISI) of Hatfield, PA and went on to develop medical applications of the technology. Introduction of the iCAT dental CT scanner increased ISI's revenue by 300% over the previous year and the scanner preceded viable competitors by three years. ISI was sold to Danaher Corporation of Washington, DC in December 2006. To date the company has sold ~4500 dental CT scanners for revenue of ~$600mm. Moreover, a robust dental CT market has developed. Strong competition continues to drive innovation and is reducing the cost of cone-beam computed tomography while increasing access.

For the medical markets, Xoran used this technology to create low radiation-dose CBCT scanners targeted to sinus and temporal bone imaging as well as a unit dedicated to intraoperative CT scanning, which has found use in cochlear implant surgery. Market penetration stands at perhaps 15% currently and Xoran still dominates with approximately 80% market-share. Xoran employs over 50 people in Ann Arbor, Michigan and has realized revenue of more than $100mm since inception. It's important to note that this was accomplished primarily with SBIR support and with no venture investment.

The introduction of the CBCT provides opportunities for dental practitioners to review 3-D images of the craniofacial area to better diagnose, treat and evaluate a myriad of conditions, including but not limited temporomandibular joint dysfunction and diseases of the jaw.[vi]Specifically, CBCT directs a x-ray beam to the area of interest, thus minimizing the radiation dose by up to 98% when compared to conventional CT systems[vii] while at the same time improving image accuracy. This technology also enables pre-surgical assessment for dental implants, potentially leading to less trauma to the neurovascular bundle—nerves providing sensory to the lower lips and chin--and minimizing risks associated with this surgery.

Finally, one of the greatest public health achievements of all time is water fluoridation and the resulting dramatic decline in dental caries (tooth decay or cavities). Over 100 years ago researchers observed children living in areas with naturally high levels of fluoride in drinking water had brown stained teeth, but they were resistant to decay. These observations led to the careful studies in the 1930's by NIH scientist Dr. H. Trendley Dean who found fluoride at 1.0 parts-per-million protected teeth from decay with minimal staining (now known as fluorosis). Finally, in 1945 a community water fluoridation study in Grand Rapids, Michigan sponsored by

the U.S. Surgeon General found that the fluoridation of public water supply decreased the caries rate among children by more than 60 percent. [viii] Today fluoridation of the water supplies is one of the most effective and least expensive measures to prevent tooth decay, which has greatly improved the oral health of Americans. According to the Centers for Disease Control and Prevention for communities of more than 20,000 people where it costs about 50 cents per person to fluoridate the water, every $1invested in this preventive measure yields approximately $38 in savings in dental treatments.[ix]

Building on the foundation of these accomplishments the promise of oral health research is bright. In the field of dental research, there are many opportunities, such as salivary diagnostics, that are on the cusp of producing critical breakthroughs in the detection of and fight against disease, as well as generating positive economic activity. Salivary diagnostics are less invasive, relatively inexpensive and have the potential of showing more immediate results, which is particularly beneficial when results are urgently needed. Salivary diagnostics are measures that collect and analyze saliva (spit) to test for conditions such as HIV, HPV, substance abuse, caries, periodontitis and oral cancer. Through the work and support of NIDCR over the last decade, these diagnostics are showing great promise in screening for diabetes, heart disease, lung cancer, ovarian cancer and pancreatic cancer. Salivary diagnostics only require collecting saliva, unlike traditional methods that rely on withdrawing blood or on doing tissue biopsy. As a result, salivary diagnostics are less invasive. In addition, they are relatively inexpensive and have the potential of showing more immediate results, which is particularly beneficial when results are urgently needed.

Additionally, projects focused the oral microbiome hold great potential as well. It is estimated that more microorganisms live inside the human mouth than people inhabit the world. According to researchers evidence is accumulating which links oral bacteria to a number of systemic diseases including cardiovascular disease, stroke, preterm birth, diabetes and pneumonia. NIDCR research continues to lead the way in determining how the members of these complex oral communities interact with each other and with the human body to influence health and disease. The goal of the NIDCR funded Human Oral Microbiome Database is to provide the research community with direct access to DNA-sequence information for the hundreds of oral microbiota enabling a deeper understanding of the role of bacteria in immune function.

These accomplishments and future potential advances in dental, oral and craniofacial research to not happen in a vacuum. It is therefore reasonable to assume that the recent federal austerity measures and declines in funding will slow or limit future breakthroughs. Specifically, the recent federal austerity measures–sequestration, government shutdown and the continued uncertainty–had a significant impact on our members, universities and research supported via NIH and NIDCR. In actual dollars, NIDCR lost $23 million in funding in fiscal year 2013 and only $10 million was restored in fiscal year 2014. However, when adjusted for inflation, the NIDCR budget is 22 percent, or $75 million, less than it was in 2002, resulting in the lowest number of research grants awarded in 13 years. This creates an atmosphere that is very discouraging to new scientific investigators whose research proposals are good enough to be funded but were not because of the budget cuts. We are at risk of losing them and their

promising research ideas—ideas that might lead to significant advances in dental, oral health and craniofacial health.

For example, at The Forsyth Institute—the only independent research institute in the United States specializing in oral health—the federal austerity measures not only affected the recruitment of new researchers, but the support network on which those scientists rely. During the past year, Forsyth laid off approximately 20% of its administrative staff. The loss of staff has slowed the progress of the Institute's work linking oral disease to other systemic diseases, and its ability to exploit its unique knowledge of the oral microbiome for the development of new probiotics and other interventions to improve health.

Grants training the next generation of scientists were cut as a result of sequestration. Specifically at the University at Buffalo - SUNY support from the National Institutes of Health T-32 Institutional training grant was cut by two thirds. This grant supported students in the oral biology Ph.D. program which historically supported ten to twelve students and now the current funding only supports four students.

These two stories illustrate the significant and lingering impact of the federal austerity measures. Our members remain concerned that unless Congress fully reverses the erosion caused by sequestration our ability to attract the next generation of scientists will stall; our standing as a world leader in science will decline; and innovation necessary to push the boundaries of research will be stymied. Without a strong scientific research foundation from which our innovators of tomorrow can build off of, where does that leave us? Accordingly, we strongly urge members of Congress to work in a bipartisan manner to prioritize funding for biomedical research this year and undo sequestration permanently in fiscal year 2016 and beyond to ensure investments in research will continue to benefit and improve the health of all Americans and the economy.

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[ii] "Sonicare," accessed April 2014, http://en.wikipedia.org/wiki/Sonicare

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[ix] "Cost savings of Community Water Fluoridation" Centers for Disease Control and Prevention, accessed April 2014, http://www.cdc.gov/fluoridation/factsheets/cost.htm