

November 29, 2016

The Honorable Paul Ryan
Speaker
U.S. House of Representatives
Washington, DC 20515

The Honorable Nancy Pelosi
Minority Leader
U.S. House of Representatives
Washington, DC 20515

The Honorable Mitch McConnell
Majority Leader
U.S. Senate
Washington, DC 20510

The Honorable Harry Reid
Minority Leader
U.S. Senate
Washington, DC 20510

Dear Speaker Ryan, Leader McConnell, Leader Pelosi, and Leader Reid:

On behalf of the American Association for Cancer Research (AACR), we wish to express our sincere appreciation for your leadership and your commitment to the National Institutes of Health (NIH) and the National Cancer Institute (NCI). With more than 37,000 members from the United States and 107 other countries around the world, the AACR is dedicated to the prevention and cure of all cancers through research, education, communication, collaboration, and research funding.

We are writing today to convey our strong support for the 21st Century Cures Act, and we urge you and your colleagues to pass this legislation before the end of the lame duck session. We are especially grateful for the bill's establishment of an NIH Innovation Account, through which \$1.8 billion in supplemental funding over seven years is designated for cancer research, and specifically for the National Cancer Moonshot Initiative.

Extraordinary scientific opportunities exist today for making major advances against the more than 200 diseases we call cancer. As described in the [AACR Cancer Progress Report 2016](#), definitive advances continue to be made to effectively prevent, detect, diagnose, and treat many forms of cancer. However, continued rapid progress against cancer depends on robust, sustained, and predictable funding increases, and the 21st Century Cures Act would provide significant supplemental support for many of the initiatives and programs that have been recommended to advance the National Cancer Moonshot Initiative.

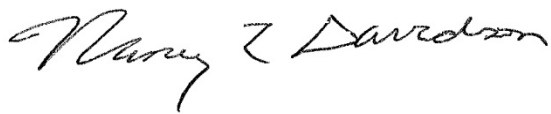
In fact, the National Cancer Moonshot Initiative has involved an incredible level of cooperation and coordination among cancer researchers, physician-scientists, patient advocates, government officials, and industry leaders, and these efforts have resulted in a robust and comprehensive list of innovative proposals and approaches for transforming

the ways we prevent and treat cancer. For example, the Cancer Moonshot Blue Ribbon Panel Report that was released in early September provides a strategic roadmap comprising 10 cutting-edge scientific recommendations for realizing the Vice President's goal of achieving a decade's worth of progress in the next five years.

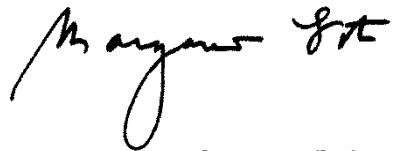
Therefore, by passing the 21st Century Cures Bill and providing the necessary funding to advance these innovative proposals, we will be making a major difference for cancer patients and their loved ones. Failure to seize upon the opportunities today to accelerate progress for the benefit of all cancer patients is simply not an option.

Thank you for your dedication to this vitally important cause, and for your consideration of our views.

Sincerely,



Nancy E. Davidson, MD
President
American Association for Cancer Research



Margaret Foti, PhD, MD (hc)
Chief Executive Officer
American Association for Cancer Research



November 30, 2016

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
Washington, DC 20515

Dear Chairman Upton and Ranking Member Pallone:

On behalf of the 3,700 individual and 99 institutional members of the American Association for Dental Research (AADR) I am writing to express our support of the National Institutes of Health provisions (Title I and Title II) in the 21st Century Cures Act released on November 25, 2016 as a text of House amendment to the Senate Amendment to H.R. 34. Our members are dental, oral and craniofacial researchers from throughout the country who rely on funding from the National Institutes of Health (NIH) especially the National Institute of Dental and Craniofacial Research (NIDCR). In particular, we greatly appreciate the provision in the 21st Century Cures Act reauthorizing NIH to ensure stability for the biomedical enterprise during the upcoming three years.

The targeted investments made via the NIH Innovation Account over a ten year time frame coupled with increased funding in the annual appropriations bills for NIH will ensure long-term and needed investments in the biomedical research enterprise. In particular, we are pleased with the \$30 million investment for regenerative medicine as our members are currently engaged in efforts to use stem cells to form bone and cartilage for dental, oral and craniofacial purposes. Also, the additional funding for cancer research is a necessary infusion so we can learn more about the early detection of HPV-related oropharyngeal cancer as well as prevention and treatment approaches.

We are also grateful to Congress for calling attention to the next generation of researchers and increasing the loan repayment program from \$35,000 to \$50,000. These focused initiatives will improve the pipeline and enhance programs designed to train, recruit and retain a diverse biomedical workforce. Moreover, reducing administrative burdens on scientists; improving coordination related to minority health and health disparities; and issuing recommendations on the rigor and reproducibility of science are important endeavors.

Finally, as supporters of the public health continuum we are disappointed that the scheduled increases in funding for the Prevention and Public Health Fund (PPHF) were used to as a pay-for in this legislation. We look forward to working with Congress in the upcoming months to protect and promote the base funding for PPHF because it continues to be a vital investment for many initiatives at the Centers for Disease Control and Prevention.

Thank you for your time and thoughtful efforts to craft this important bill.

Sincerely,

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

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Darrell G. Kirch, M.D.
President and Chief Executive Officer

November 30, 2016

The Honorable Paul Ryan
Speaker
U.S. House of Representatives
Washington, DC 20515

The Honorable Nancy Pelosi
Democratic Leader
U.S. House of Representatives
Washington, DC 20515

Dear Speaker Ryan and Leader Pelosi:

I write to extend the continued support of the Association of American Medical Colleges (AAMC) for the updated text of the 21st Century Cures Act released on November 25, 2016 (House Amendment to the Senate Amendment to H.R. 34). In particular, the AAMC commends Congressional leaders and leadership of the House Energy & Commerce and Ways & Means Committees, as well as the Senate Health, Education, Labor and Pensions (HELP) and Finance Committees for recognizing the importance of sustained investments in medical research, taking important steps to address the administrative burden on researchers, addressing the role of socioeconomic status (SES) in the Medicare Hospital Readmissions Reduction Program (HRRP), and clarifying that off-campus teaching hospital outpatient departments (HOPDs) under development should continue to receive Medicare outpatient payment rates.

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members comprise all 147 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their nearly 160,000 faculty members, 83,000 medical students, 115,000 resident physicians, and thousands of graduate students and postdoctoral trainees in the biomedical sciences.

We commend House Energy & Commerce Chair Fred Upton (Mich.), Rep. Diana DeGette (Colo.), Ranking Member Frank Pallone (N.J.), Senate HELP Chair Lamar Alexander (Tenn.), Ranking Member Patty Murray (Wash.), and all members of the Energy and Commerce and

The Honorable Paul Ryan
The Honorable Nancy Pelosi
November 30, 2016
Page 2

HELP Committees, for their landmark effort through the 21st Century Cures Act to enhance the process for getting safe treatments, devices, and cures to patients, and to support the critical role of the National Institutes of Health (NIH) and NIH-supported researchers in that process. We praise the bipartisan approach to crafting Division A and the concerted effort throughout the process to better understand the challenges that the patient and research communities face in seeking improved health for all.

As the nation's premier hubs of medical discovery and innovation, medical schools and teaching hospitals welcome the legislation's recognition of medical research funding as a top national priority through the Innovation Account, which will enable appropriators to enhance the budgets of the NIH and Food and Drug Administration (FDA) over several years (Sec. 1001 and Sec. 1002). These dedicated resources will offer added funding stability to specific, multi-year initiatives at the agencies, including the Precision Medicine Initiative, the Cancer Moonshot, and the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative.

Coupled with timely enactment of the annual spending bills, this targeted funding will be an important supplement to the yearly NIH base budget increases that are essential to advance the full spectrum of research to study all diseases. We are grateful that the bill reauthorizes NIH with continued, steady budget growth (Sec. 2001). To maximize the potential of medical research, the scientific community has supported a budget trajectory that keeps pace with and enables additional growth above inflation, and we will work with lawmakers toward that goal. We also urge Congress to pass before January a full FY 2017 NIH appropriation of \$34.1 billion, as approved by the Senate Appropriations Committee, and avoid the delays and inefficiencies that further continuing resolutions would impose on life-saving research. The commitment to ensure that the NIH Innovation Account augments, rather than supplants, the base NIH appropriation in FY 2017 and beyond is consistent with the intent of the original legislation and subsequent iterations, and is especially important since funding in the Innovation Account is half of the level originally approved in H.R. 6. We also strongly urge lawmakers to include the FY 2017 funding provided through this bill in any spending package enacted in December to allow its immediate use.

The AAMC applauds the bill's provisions to address some of the administrative burdens that detract from time and resources that could be invested in medical research. In particular, the AAMC is strongly supportive of Sec. 2034, which would implement many of the recommendations of the National Academies of Sciences, Engineering, and Medicine report *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century: Part 1*. For example, the AAMC is pleased that the bill would establish a Research Policy Board as the Academies recommended but broadened the membership to include individuals with relevant expertise as urged by AAMC. We also strongly support the provisions that would reduce obligations related to monitoring subrecipients of NIH grants,

require a review of various regulations concerning conflicts of interest and for research with laboratory animals to streamline and harmonize these requirements, and require a review of requirements on the reporting of financial expenditures.

This thoughtful approach to mitigating the burden of excessive or outdated federal policies will help researchers maximize their efforts toward the pursuit of cures while maintaining the highest level of integrity and transparency in their work. Similarly, we appreciate Sec. 3023, which requires the Secretary of Health and Human Services to harmonize differences in human subject regulations at federal agencies, and Sec. 3024, which allows the FDA the same flexibility as NIH and HHS in informed consent requirements for clinical trials with minimal risk.

Additionally, we praise the bill's authors for their efforts to strengthen mechanisms at NIH to assemble better data to address health disparities, improve utilization of diverse study populations, and enhance collaboration and coordination across NIH-funded clinical research projects (Sec. 2038). These provisions will greatly enrich the quality of research and better inform efforts to promote health equity. The AAMC also welcomes the bill's attention to the next generation of researchers (Sec. 2021), by reinforcing the directions that NIH and the research and research training communities have been taking to support early-career investigators. We support NIH efforts to coordinate policies and programs focused on promoting opportunities for new researchers and earlier career independence, and we support efforts around career development of trainees.

We appreciate the authors' interest in regenerative medicine, as stem cell therapies hold great promise. The bill requires regenerative medicine products to complete Phase 3 clinical trials with the opportunity for accelerated FDA approval, which would allow such therapies to advance on the basis of surrogate endpoints. In this burgeoning field of medicine, the AAMC strongly supports managing such therapies through the FDA regulatory process to ensure demonstration of safety and effectiveness before resulting therapies are used widely by patients.

With respect to the hospital and health care provisions in Division C of the package, the AAMC thanks House Ways & Means Committee Chair Kevin Brady (Texas), Health Subcommittee Chair Pat Tiberi (Ohio), Ranking Member Sander Levin (Mich.), Health Subcommittee Ranking Member Jim McDermott (Wash.), Senate Finance Committee Chair Orrin Hatch (Utah), Ranking Member Ron Wyden (Ore.), and members of both committees for their ongoing support and inclusion of the bipartisan "Helping Hospitals Improve Patient Care Act of 2016" (H.R. 5273). The AAMC strongly supports provisions included in Division C, including language that incorporates SES into the HRRP and exempts off-campus HOPDs that either attested that the regulatory requirements were met prior to December 2, 2015 or were "mid-build" upon passage of the Bipartisan Budget Act of 2015 (BBA '15) from "so-called" site-neutral payment policies.

The AAMC strongly supports Sec. 15002 as a first step towards inclusion of SES factors into hospital quality programs. The section is based on the “Establishing Beneficiary Equity in the Hospital Readmission Program Act of 2015” (H.R. 1343/S. 688), bipartisan, bicameral legislation introduced by Reps. Jim Renacci (Ohio) and Elliot Engel (N.Y.) and Sens. Rob Portman (Ohio) and Joe Manchin (W.Va.). AAMC-member teaching hospitals work hard to prevent every potentially avoidable readmission. However, the causes of hospital readmissions are complex. Those that are related to poor quality or poor care coordination should be the targets of continual vigilance. Other admissions, however, are the result of patient-level or community-level factors that make it harder for patients to thrive upon release from the hospital. Failure to adjust for these factors particularly affects major teaching hospitals, whose missions include caring for the underserved in their communities. The SES provision in the hospital package represents an important effort toward minimizing the likelihood that teaching hospitals are unfairly penalized for factors outside their direct control.

We also strongly support Sec. 16001 which would exempt off-campus HOPDs that were under-development upon passage of the BBA '15 from “so-called” site-neutral payment policies. The AAMC is extremely concerned about the impact of reductions in HOPD reimbursement as this will lead to a reduction of services that affect vulnerable patient populations, especially those with complex medical problems, and may limit the ability to fully train the next generation of health professionals in these outpatient settings. Major teaching hospital HOPDs care for more challenging patient populations and are frequently the sole sources of care for low-income and otherwise underserved populations of Medicare beneficiaries, accepting patients who otherwise face difficulty being seen in physician offices.

While the AAMC appreciates the mid-build exemption, we were disappointed that bipartisan, bicameral flexibility championed by Reps. Devin Nunes (Calif.) and Joe Crowley (N.Y.) and Sens. Portman and Charles Schumer (N.Y.) that would allow for relocation of grandfathered off-campus HOPDs was not included in the compromise legislation. Off-campus HOPDs tailor the services they provide in response to the needs of their communities, and payment cuts due to relocation will directly impact these communities. Additionally, rapid advances in technology and treatments demand that HOPDs adapt and change to offer state of the art services to patients. These changes sometimes necessitate expansion of existing buildings or even relocation to new sites. We strongly believe that exempted HOPDs should not lose their ability to bill under the OPPI if they choose to relocate in response to changes in clinical care and the needs of their patients. We look forward to working with the 115th Congress to address these concerns.

Similarly, though the bill includes some welcome language with respect to the unintended barriers that privacy regulations impose on research, we are disappointed that the updated package does not directly address these challenges. For example, the impediments to research arising from the HIPAA Privacy Rule have been well-documented by the Institute of Medicine

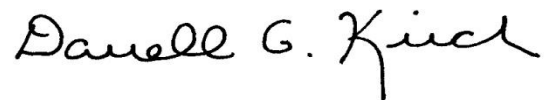
The Honorable Paul Ryan
The Honorable Nancy Pelosi
November 30, 2016
Page 5

and others. The protection of the privacy and well-being of research subjects should be adequately addressed through overarching regulations such as the Common Rule, and the inclusion of research data as protected health information has necessitated authorizations under the Privacy Rule separate and apart from the informed consent required elsewhere, a duplicative and confusing process for researchers and research subjects. Rather than appointing a new working group (Sec. 2063) to repeat a long-studied conclusion, the provision in H.R. 6 to treat research as health care operations under the Privacy Rule would have helped remove obstacles to research without jeopardizing or disadvantaging patients or research subjects.

We also must register our concern that Sec. 5009 of the package repurposes scheduled increases in the Prevention and Public Health Fund, rather than investing new resources into the worthy initiatives supported through this legislation. We recognize the difficult choices you faced in crafting this package, but reallocating existing investments across the health continuum ultimately will be counterproductive to making cures more accessible to all Americans. We are heartened that, in addition to the initiatives described above, the bill supports critical investments in opioid abuse prevention and treatment activities, and we look forward to working with Congress to better preserve the important resource that the Prevention Fund provides for public health activities vital to the nation's health and well-being.

Once again, we appreciate the unrelenting dedication and commitment of lawmakers to advance this important legislation and the health of America's patients. We urge its swift passage.

Sincerely,

A handwritten signature in black ink that reads "Darrell G. Kirch". The signature is written in a cursive, flowing style with a long, sweeping underline.

Darrell G. Kirch, MD
President and Chief Executive Officer

IDSA Applauds Passage of Legislation Promoting Antibiotic R&D, Scientific Workforce

Statement from William G. Powderly, MD, FIDSA, IDSA president

November 30, 2016

The Infectious Diseases Society of America (IDSA) commends the House of Representatives for promoting biomedical innovation through passage of the 21st Century Cures Act earlier today. IDSA strongly supports elements of the legislation that address antibiotic resistance and is encouraged to see provisions that support the next generation of scientists. Importantly, the bill also addresses the opioid epidemic that is contributing to a surge in new HIV and hepatitis C infections.

Antibiotic resistance continues to threaten patient safety, public health and national security. The House-passed bill takes an important step to reduce regulatory barriers to antibiotic and antifungal research and development.

We know that the population of individuals who have a specific antibiotic-resistant infection at any given time is relatively small, which makes populating a traditional large-scale clinical trial nearly impossible. For that reason, IDSA has long advocated for a new limited population approval pathway at the FDA for antibiotics and antifungals that treat serious or life-threatening infections with an unmet medical need. The bill permits these smaller and more efficient trials and includes safeguards to guide the appropriate use of the drugs that are developed.

IDSA has also highlighted the need for federal policy to attract and support the next generation of infectious diseases physician-scientists. We are pleased that Cures includes the creation of a Next Generation Researchers Initiative within the National Institutes of Health (NIH). We also believe that the increase in the NIH loan repayment annual maximum from \$35,000 to \$50,000 is a meaningful step towards making research careers more feasible.

Additional policy solutions will be required to address antibiotic resistance, bolster the scientific workforce and combat new and emerging threats. However, IDSA believes that the Cures Act represents a considerable life-saving step forward. We urge the Senate and President Obama to approve the legislation.



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IDS A

Infectious Diseases Society of America

November 30, 2016

The Honorable Mitch McConnell
Majority Leader
U.S. Senate
Washington, DC 20510

The Honorable Paul Ryan
Speaker
U.S. House of Representatives
Washington, DC 20515

The Honorable Harry Reid
Minority Leader
U.S. Senate
Washington, DC 20510

The Honorable Nancy Pelosi
Minority Leader
U.S. House of Representatives
Washington, DC 20515

Dear Leader McConnell, Leader Reid, Speaker Ryan, and Leader Pelosi:

On behalf of the Infectious Diseases Society of America (IDSA), thank you for continued efforts to spur biomedical innovation through approval of the new 21st Century Cures Act. IDSA particularly appreciates measures within the bill that help address the public health crisis of antimicrobial resistance (AR), support the next generation of scientists, and deal with the opioid epidemic that is contributing to a surge in new HIV and hepatitis C infections. We urge Congress and the president to approve the legislation as soon as possible.

Antimicrobial resistance claims new victims every day and this threat continues to grow. More than 10 million deaths are expected annually by 2050 due to superbugs, according to the *Review on Antimicrobial Resistance, Tackling Drug-Resistant Infections Globally*. While AR has increased, research and development for new antibiotics and antifungals has dramatically decreased. Public health authorities and experts such as the Centers for Disease Control and Prevention, World Health Organization, and the President's Council of Advisors on Science and Technology have stated that the scientific, regulatory and economic obstacles to research and development for new antibiotics and antifungals must be addressed to effectively combat AR.

The latest version of 21st Century Cures legislation represents an important step forward to reduce regulatory barriers to antimicrobial research and development. The number of people who have a highly antibiotic-resistant infection at any given time may be relatively small and spread over a wide geographic area that makes it nearly impossible to adequately conduct a traditional large-scale clinical trial. For that reason, IDSA strongly supports the provision in the Cures Act that establishes a new FDA limited population approval pathway for antibiotics and antifungals that treat serious or life-threatening infections with unmet medical needs. The bill allows for conduct of smaller and more efficient trials while including necessary safeguards to guide their appropriate use.

IDSA also strongly supports the provision in the Cures Act that speeds the updating of antimicrobial susceptibility interpretive criteria, which are commonly referred to as ‘breakpoints.’ Breakpoints are used in antibiotic susceptibility testing (AST) devices that serve to instruct clinicians on which drugs appear to work against a given organism. Health care facilities rely on accurate AST devices to identify patients with dangerous, multi-drug resistant infections for whom certain infection control protocols must be activated to prevent the further spread of the resistant organism.

IDSA has identified the need for federal policy to attract and support the next generation of infectious diseases physician-scientists as important to combating existing and emerging public health threats. We are pleased that the Cures Act includes the creation of a Next Generation Researchers Initiative within the National Institutes of Health (NIH). Further, we believe that the increase in the NIH loan repayment annual maximum from \$35,000 to \$50,000 is a meaningful step towards making research careers more feasible.

While additional resources and legislative efforts are necessary to further these areas, we believe that the 21st Century Cures Act represents an important step forward. We strongly urge passage of the bill prior to the conclusion of the 114th Congress. Once again, thank you for the leadership demonstrated while advancing this important legislation.

Sincerely,

A handwritten signature in cursive script, reading "Bill Powderly". The ink is dark and the signature is fluid, with a long, sweeping tail on the last name.

William G. Powderly, MD, FIDSA
President, IDSA