

Message

From: Courtney Johnson [cjohnson@alpinegroup.com]
Sent: 7/18/2017 5:31:49 PM
To: Long, Erika [Erika.Long@mallinckrodt.com]; Martello, Kendra [Kendra.Martello@mallinckrodt.com]
CC: Rai Downs [rdowns@tdyllc.com]
Subject: House Labor H Report
Attachments: HRPT-115-HR-p2.PDF

Hi team,

I tried to capture everything that is relevant to you, but certainly could have missed something. See below.

Thank you.
Courtney

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Rare Diseases.—The Committee encourages HRSA to examine programs to increase primary care physician's preparedness in the diagnosis of rare diseases.

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Office of Pharmacy Affairs The Committee provides \$10,238,000 for the Office of Pharmacy Affairs (OPA), which is the same as the fiscal year 2017 enacted level and \$19,000 above the fiscal year 2018 budget request. The Office of Pharmacy Affairs oversees the 340B Drug Pricing Program, which requires drug manufacturers to provide discounts on outpatient prescription drugs to certain safety net health care providers.

The Committee recognizes that the 340B Drug Pricing program was designed to help safety net providers maintain, improve, and expand patient access to healthcare services generally. Since its enactment in 1992, the 340B program has lowered the cost of outpatient drugs to Government funded health clinics, as well as nonprofit and public hospitals that serve a disproportionate share of low-income patients or rural communities.

The Committee is aware that the 340B statute requires HRSA to make 340B ceiling prices available to covered entities through a secure website and continues to be concerned that OPA has failed to meet deadlines to complete work on the secure website. The Committee urges OPA to complete the development of a secure website. The Committee directs OPA to include an update on the status of the secure website in the fiscal year 2019 budget request.

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Duchenne Muscular Dystrophy.—The Committee expects NCBDDD to continue its work to update, evaluate, and disseminate the revised Duchenne care standards; to expand surveillance of Duchenne via the MD STARnet, to develop a Duchenne newborn screening program; and to support refinement of an International Classification of Disease (ICD 10) code for Duchenne and Becker Muscular Dystrophy.

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Using Data to Prevent Opioid-Related Overdosing.—The Committee continues to be very concerned about the high rate of opioid abuse and overdosing and understands that with data, forecasting of overdosing risk by geographic region can be provided. The Committee encourages CDC to begin using data to provide such forecasts that public health officials can use to intervene and prevent overdoses.

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The mission of NIH is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. NIH conducts and supports research to understand the basic biology of human health and disease; apply this understanding towards designing new approaches for preventing, diagnosing, and treating disease and disability; and ensure that these approaches are widely available. The recommendation provides an increase of \$400,000,000 for Alzheimer's disease research; an increase of \$30,000,000 for combating antibiotic-resistant bacteria; an increase of \$80,000,000 for the "All of Us" research program (formerly called the Precision Medicine Initiative); an increase of \$76,000,000 for the Brain Research through Application of Innovative Neurotechnologies (BRAIN) Initiative; an increase of \$8,000,000 for regenerative medicine; and increases to every Institute and Center (IC) to support innovative research to advance fundamental knowledge and speed the development of new therapies and diagnostics to improve the health of all Americans. The Committee also continues to support the Cancer Moonshot Initiative with a total of \$300,000,000 in fiscal year 2018. The Committee expects the 3.2 percent increase of funds over the fiscal year 2017 enacted level to support an increase in the number of new and competing Research Project Grants (RPGs), with a focus on early-stage investigators and investigators seeking first time renewals. The Committee encourages NIH to restore extramural support to at least 90 percent of all NIH funding and to continue to focus on basic research. The Committee expects NIH to support an increased number of Ruth L. Kirschstein National Research Service Awards and to provide a stipend level increase to training grantees that is consistent with any fiscal year 2018 Federal employee pay raise. The Committee continues to provide in bill language specific funding levels for Clinical and Translational Science Awards, Institutional Development Awards (IDeA), the Cures Acceleration Network, the Common Fund (CF), and the follow-on to the National Children's Study. While the Committee appreciates the Secretary's efforts to find efficiencies in NIH research spending, the Administration's proposal to drastically reduce and cap reimbursement of facilities and administrative (F&A) costs to research institutions is misguided and would have a devastating impact on biomedical research across the country. To ensure that NIH can continue supporting both direct and F&A costs as is their current practice, the bill includes a new general provision directing NIH to continue reimbursing institutions for F&A costs according to the rules and procedures described in 45 CFR 75 (with the exception of existing waivers for training grants). This provision also prohibits funds in this Act from being used to implement any further caps on F&A cost reimbursements.

The Committee recognizes that there are opportunities to reduce the administrative burden on research institutions through legislative, regulatory, and administrative means, so that NIH can support more researchers who can in turn spend more time on science and less time on paperwork. The National Academies of Sciences, Engineering, and Medicine 2016 publication "Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century" put forth several recommendations for reducing burden on institutions and investigators. The Committee directs NIH to identify the most appropriate and potentially impactful recommendations and submit a plan to the Committees on Appropriations of the House of Representatives and the Senate within 90 days of enactment of this Act outlining concrete steps to achieving these goals. NIH should consult with academic and independent research institutions, investigators who receive NIH grants, the HHS Office of Cost Allocation, the Office of Management and Budget, and other relevant stakeholders in developing this plan.

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Duchenne Muscular Dystrophy.—The Committee is aware of stakeholder efforts to achieve validated and qualified biomarkers for Duchenne Muscular Dystrophy. The Committee supports these activities and urges NINDS to work with other Institutes and with the Food and Drug Administration to provide the necessary guidance and to assemble a workshop of all stakeholders to advance this work. The Committee is also concerned about a lack of access to Federally-funded data, such as imaging and biomarker data, which could support qualification of an MRI imaging biomarker and directs NIH to ensure all Federally-funded Duchenne investigators are in full compliance with the data sharing requirements included in the 21st Century Cures Act. The Committee also remains optimistic about the potential for additional Duchenne treatments using exon skipping splicing and encourages NIH to work with other Federal agencies to convene a workshop on exon skipping in Duchenne and other neuromuscular diseases.

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Drug Treatment in the Justice System.—The Committee understands that providing evidence-based treatment for substance use disorders offers a valuable opportunity to interrupt the substance use/criminal justice system cycle for people struggling with substance use disorders. Untreated substance use disorder renders prior criminal offenders particularly vulnerable to recidivism and continued health problems, preventing them from being able to find stable employment, jeopardizing public health and safety, and taxing justice and health system resources. When combined with therapy, medication assisted treatment (MAT) has consistently been shown to be more effective in treating substance use disorder than abstinence. The Committee applauds NIDA's focus on adult and juvenile justice populations in its research around substance use disorder treatment. The Committee supports this important work and asks for a progress report on those efforts, including information on the use and success of MAT in the juvenile justice system.

Opioid Misuse and Addiction.—The Committee continues to be extremely concerned about the epidemic of prescription opioids, heroin, and synthetic opioid use, addiction, and overdose in the U.S. Approximately 144 people die each day in this country from opioid overdose, making it one of the most common causes of nondisease-related deaths for adolescents and young adults. This crisis has been exacerbated by the availability of fentanyl and its analogs into many communities. The Committee appreciates the important role that research can and should play in the various Federal initiatives aimed at this crisis. The Committee urges NIDA to (1) continue funding research on medication development to alleviate pain, especially the development of medications with reduced abuse liability; (2) as appropriate, work with private companies to fund innovative research into such medications; and (3) report on what is known regarding the transition from opioid analgesics to heroin and synthetic opioid abuse and addiction within affected populations.

Raising Awareness and Engaging the Medical Community in Drug Abuse and Addiction Prevention and Treatment.—Education is a critical component of any effort to curb drug use and addiction, and it must target every segment of society, including healthcare providers (doctors, nurses, dentists, and pharmacists), patients, and families. Medical professionals must be in the forefront of efforts to curb the opioid crisis. The Committee continues to be pleased with the NIDAMeD initiative, targeting physicians-in training, including medical students and resident physicians in primary care specialties (e.g., internal medicine, family practice, and pediatrics). NIDA should continue its efforts in this space, providing physicians and other medical professionals with the tools and skills needed to incorporate drug abuse screening and treatment into their clinical practices

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Adolescents and Medication-Assisted Treatment.—The Committee applauds the ongoing coordinated efforts at NIH to understand and address substance use and substance use disorders among adolescents and young adults as a specific population. As part of those efforts, the Committee also encourages NIH to examine the effectiveness of medication assisted treatment in adolescents struggling with substance use disorder, and identify any barriers to treatment as well as potential unintended consequences.

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Coordination with the Department of Energy (DOE) and National Laboratories to Implement 21st Century Cures Act.—NIH is encouraged enter into collaborative research programs, as appropriate, with DOE, the National Laboratories, and others determined to be appropriate, to utilize the broader scientific and technological capabilities of DOE and the National Laboratories relevant to the successful implementation of the 21st Century Cures Act (P.L. 114– 255).

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State Targeted Response to the Opioid Crisis.—The Committee includes \$500,000,000 for the second year of continuation funding as authorized under section 1003 of the 21st Century Cures Act. Consistent with the authorization, the Committee recommends States be given flexibility within the existing grant to direct resources in accordance with local needs. SAMHSA should permit States to allocate funds for prevention, training, treatment, recovery, and other public health related activities at levels based on the conditions of each State. The Committee is aware of the significant challenge presented by opioid abuse, and believes that addressing the opioid crisis requires that states coordinate efforts among myriad agencies and organizations. Regional collaborations involving hospital systems, institutions of

higher education, local government, and the judiciary can drive best practices and have shown success in identifying solutions for opioid abuse. Therefore, the Committee encourages SAMHSA to utilize such regional collaborative stakeholder teams.

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Medication Diversion.—The Committee understands the important role of medication-assisted treatment for beneficiaries with opioid use disorder. At the same time, there are reports from several authorities of rising rates of diversion of these Food and Drug Administration-approved medications. The Committee directs CMS to evaluate diversion data from the Drug Enforcement Administration and State sources to determine the scope of this problem and to include in the fiscal year 2019 Congressional Justification options to reduce diversion.

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Opioid Response.—The Committee believes that the Federal response to the opioid epidemic will be most effective if resources made available through the Comprehensive Addiction and Recovery Act and related programs are directed to strategies that are backed by strong evidence or to innovative and promising approaches that will be rigorously evaluated to learn their impact. In implementing new and existing programs that address the opioid epidemic, HHS is urged to utilize evidence-based policymaking principles, tools, and program designs such as those disseminated by the Evidence Based Policymaking Collaborative. The Committee encourages HHS to collaborate with outside researchers and philanthropic organizations that focus on improving the use of rigorous research to inform policy.

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Prescription Drug Monitoring.—The Committee understands that the spread of the prescription drug epidemic throughout the Nation has made the creation, implementation, and use of State prescription drug monitoring programs (PDMPs) and their ability to operate in concert with electronic health record (EHR) and electronic prescribing (e-prescribing) systems more important than ever. The Committee encourages ONC to continue its support for pilot programs to find usability challenges among PDMP, EHR, and e-prescribing systems; develop and award challenge awards to private entities for health information technology innovation; and offer targeted technical assistance to help medical professionals use PDMP, EHR, and e-prescribing systems. The Committee further encourages ONC to collaborate and coordinate its efforts with partner agencies such as the Centers for Disease Control and Prevention and the Bureau of Justice Assistance in the Department of Justice.

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