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June 9th, 2014

The Honorable Fred Upton
Chairman, Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn H.O.B.
Washington, D.C. 20515

The Honorable Diana DeGette
U.S. House of Representatives
2368 Rayburn H.O.B.
Washington, D.C. 20515

Dear Chairman Upton and Representative DeGette,

On behalf of the American Psychiatric Association (APA), the medical specialty society representing more than 35,000 psychiatric physicians and their patients, we thank you for your leadership in organizing the 21st Century Cures Initiative. APA is deeply invested in the importance of promoting research on mental illnesses and substance use disorders in order to identify and utilize the 21st century treatments for our patients. Remedying regulatory barriers to improve medical innovation and treatment for mental illnesses and substance use disorders is critical to the future of psychiatric research. APA appreciates this opportunity to be a resource to your committee.

Our patients and their families need access to a range of treatment options and deserve to experience the promise of future psychopharmacological breakthroughs. While medications have been developed to address the symptoms of serious mental illnesses and substance use disorders, no cures have yet been identified. Medications, as part of a comprehensive treatment plan, can make the difference between an active life in the community and reliance on caretakers and income supports. The side effects of medications can be difficult for some patients to manage and still others may not adequately respond to currently available treatments.

The reduction of federal and private investment in psychiatric medications is greatly concerning. For the past five years, the National Institutes of Health's appropriations have not kept pace with biomedical inflation. Sequestration has further eroded the



NIH's ability to fund new research opportunities and develop the careers of young biomedical researchers. Private investment in psychiatric research and innovation has waned due to regulatory uncertainty, length of time to bring treatments to market, and the intrinsic complexity of psychiatric disorders, among other reasons.

Scope of Mental Illness and Substance Use Disorders

The prevalence of serious mental illness and substance use disorders is staggering. The National Institute of Mental Health (NIMH) conservatively estimates the total costs associated with serious mental illnesses, those disorders that are severely debilitating and affect about 6 percent of the adult population, to be in excess of \$300 billion per year including \$193 billion in loss of earnings, \$100 billion in health care expenditures, and \$24.3 billion in disability benefits. The costs associated with mental illness stem from both the direct expenditures for mental health services and treatment (direct costs) and from expenditures and losses related to the disability caused by these disorders (indirect costs). Indirect costs include public expenditures for disability support and lost earnings among people with serious mental illness. More specific diagnostic tools, treatments with fewer side effects, and the potential of genomic-sensitive treatments should be research priorities for both government and industry. Investigating the important differences that occur in patterns of mental illness/mental health care services use between genders, and among ethnic minorities, is another priority that must be emphasized. For example, gender and ethnic differences exist in the development, clinical course, and treatment outcomes of bipolar disorder and schizophrenia. We need to understand the reasons for these disparities and develop methods of addressing them.

Substance use disorders (SUDs) have strikingly negative consequences for individuals, families and society. Estimates of the total overall costs of SUDs in the United States, including productivity plus health and crime related costs exceed \$600 billion annually. This includes approximately \$181 billion for illicit drugs, \$193 billion for tobacco, and \$235 billion for alcohol. As staggering as these numbers are, they do not fully describe the breadth of destructive public health and safety implications of drug abuse and addiction such as family disintegration, loss of employment, failure in school, domestic violence, and child abuse. The National Institute on Drug Abuse (NIDA) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA) are tasked with developing and implementing new treatments for addiction and identifying the causes and contributors of addiction. The need has never been greater for the development of novel, non-opioid medications to manage pain and for treatments that ameliorate the impact of alcohol on liver disease.

An analysis by Milliman for the APA showed that patients with mental health and substance use disorder use almost \$292 billion of health care services more per year than those without these disorders, the vast majority for increased general medical services. When paired with the known early mortality of those with mental health and substance use illness these disorders need substantial research investment.

Recommendations

APA urges sustained, robust funding for biomedical research given the heavy medical and economic burden of mental and substance use disorders. Attention must also be paid to improve the delivery of evidence-based treatments in the changing health care landscape. In March 2013, the American Psychiatric Foundation convened a “Pipeline Summit” that included researchers, patient groups, biomedical investors and federal government representatives who discussed ways to remedy the shrinking pipeline for psychiatric medications. The meeting encompassed all aspects of research and identified several potential regulatory improvements which could speed medical innovation. These included:

- Improve data sharing mechanisms between researchers and industry in pre-competitive collaboration in order to speed target identification and validation, identify biomarkers and standardize clinical trial protocols including common benchmarks for meaningful effect sizes in clinical trials.
- Improve industry and federal research collaborations. For example, jointly maintaining a voluntary registry of people living with schizophrenia to provide longitudinal information of symptom manifestation and potentially identify patients for clinical trials.
- Speed the development of a neuroscience community data sharing portal at the Food and Drug Administration (FDA) to establish a clinical trials registry for psychiatric investigation. A clinical trials registry would allow for systemic evaluations of failed trials which in turn would better inform subsequent research designs.
- Explore incentives for investment such as market exclusivity for “first in class” novel medications, patent extensions and data package protections. Modest extensions could provide companies more predictability in the regulatory approval process. More predictability may encourage investors to invest in psychiatric research. Any patent incentives would have to be balanced with the needs of patients.

Current Regulatory Efforts

APA is encouraged by recent federally-led efforts to improve the regulatory environment to strengthen research collaboration including the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative and the National Center for Advancing Translational Sciences (NCATS).

The BRAIN Initiative promises significant breakthroughs to treat neurological diseases, including mental illness and substance use disorders, which require technological innovations to develop new ways of mapping neurological pathways. The BRAIN Initiative began in 2014 and will yield tremendous advances in understanding the foundations and future of neurosciences. The BRAIN Initiative’s three federal funding agencies, NIH, National Science Foundation (NSF) and Defense Advanced Research Projects Agency (DARPA), are collaborating with private organizations to leverage advances in nanoscience, imaging, engineering and informatics. The coordination of scientific advances for a common purpose – improving psychiatric research tools -- will accelerate the development of better diagnostics and treatments for brain ailments. The inclusion of improved identification neural circuitry and genetic markers are important

complements to the ongoing mapping research. APA urges the committee to support these vital research efforts.

The National Center for Advancing Translational Sciences (NCATS) is the newest of 27 Institutes and Centers (ICs) at the National Institutes of Health (NIH). This Center was established in December 2011 to catalyze innovative methods and technologies to enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of human illnesses. Among NCATS' important initiatives is the "Discovering New Therapeutic Uses for Existing Molecules" program. NCATS collaborated with four private pharmaceutical companies to make 26 therapeutic agents available to researchers to crowdsource ideas for new uses. NIH, working together with industry partners, can improve therapeutic development process and speed treatments to patients in need. Both the BRAIN Initiative and NCATS are supported with existing appropriations; not additional funding support. As important as the BRAIN Initiative and NCATS are to overcoming regulatory barriers; neither is a substitute for sustained, robust funding of biomedical research. APA seeks the Committee's support to encourage Congressional appropriators to restore NIH's eroded purchasing power.

APA is encouraged by bipartisan interest in authorizing additional funding for NIMH to study the causes and potential treatments for self and other directed violence as well as the BRAIN Initiative. This effort is promoted by Representative Tim Murphy in his Helping Families in Mental Health Crisis Act (H.R. 3717) and included in Representative Ron Barber's Strengthening Mental Health in Our Communities Act (H.R. 4574). It is APA's hope that bipartisan recognition of the need to fund psychiatric research will translate into bipartisan action to enact additional funding to support these critically needed activities within NIMH.

Thank you for the opportunity to share APA's recommendations to ameliorate regulatory barriers to medical innovations and support the federal investments necessary to identify and utilize 21st century cures. APA is happy to be a resource for psychiatric research expertise and we look forward to working with you as the Committee's investigation continues.

Sincerely,



Paul Summergrad, M.D.
President



Saul Levin, M.D., M.P.A.
CEO and Medical Director