



JUST THE FACTS¹

43.4 M

AMERICAN ADULTS HAD A MENTAL ILLNESS IN 2015

9.8 M

ADULTS HAD A SERIOUS MENTAL ILLNESS WITHIN THE PAST YEAR

20%

OF CHILDREN AGES 13-18 HAVE A DEBILITATING MENTAL ILLNESS

\$300+ B

ANNUAL DIRECT AND INDIRECT COSTS OF MENTAL ILLNESS TO THE U.S. ECONOMY

IN
PARTNERSHIP
WITH



MEDICINES IN DEVELOPMENT | 2017

MENTAL ILLNESS

Biopharmaceutical Research Companies Are Developing More Than **140 Medicines** to Treat Mental Illness

Mental illnesses exact a heavy human and economic toll in the United States. The National Institute of Mental Health (NIMH) estimates that nearly 18 percent of American adults and 20 percent of children experience a mental illness in any given year amounting to more than \$317 billion annually in the United States in lost wages, health care expenditures and disability benefits.

While the impact of mental illness is considerable, biopharmaceutical research companies have helped to alleviate some of the burden and improve the quality of life for many living with a mental illness. Recent advances have transformed certain mental illnesses into highly treatable and manageable conditions. For example, medicines for treating depression are helping millions of people live productive lives and advances in schizophrenia medicines have enabled patients to avoid hospitalization and receive treatment in an outpatient setting.

Due to fundamental changes that occur in the brain which disrupt the ability to control impulses in patients struggling with addiction, addictive disorders are regarded as mental illnesses. The impact of addiction in the United States is substantial. The opioid crisis takes the lives of 91 Americans every day,² devastating communities across the country and weighing heavily on our economy with \$78.5 billion in annual health care costs and productivity losses.³ The treatment of substance use disorders is complicated by the fact that many with substance use disorders also often struggle with other mental illnesses. In fact, 8.2 million adults in the U.S. have both a substance

use disorder and a mental illness.⁴ The presence of co-occurring mental and substance use disorders can increase symptom severity, complicate treatment and create adherence challenges. Breaking the cycle of addiction thus will require a comprehensive approach that includes bringing forth new medication-assisted treatment (MAT) for addiction, including those that can be administered more easily and less frequently, and increasing patient adherence, particularly among those who may also have a mental illness.

Research has revolutionized our understanding of addiction but alternatives to treat addiction and overdose are limited. Recognizing the substantial unmet need and the scientific and regulatory hurdles to drug development in this area, America's biopharmaceutical companies are engaging with the National Institutes of Health and National Institute on Drug Abuse to advance a potential public-private partnership to accelerate the development of new formulations and combinations of medications to treat opioid use disorders and to prevent and reverse overdose.⁵

Medicines for Mental Illnesses in the Pipeline

Therapeutic advances are still needed for people who are not helped by current treatments, or for those who may experience negative side effects. Researchers are seeking to leverage a growing understanding of the brain to develop new treatments. Current studies are examining how existing treatments work and are identifying biomarkers that can be used to both improve diagnoses and also to assess a patient's response to therapies. Biomarkers are also increasingly being used to find new therapeutic targets through identification of the pathologies or mechanisms contributing to mental illness.

America's biopharmaceutical researchers are working on cutting-edge medicines needed to bring new treatments to patients with mental illness. Today, 145 medicines⁶ are in development by biopharmaceutical research companies to help the millions of Americans suffering from some form of mental illness. The potential new treatments include:

39 for depression, including major depressive disorder which affects 6.7 percent of adults and 12.5 percent of adolescents aged 12 to 17 in the United States.¹

37 for schizophrenia, which affects approximately one percent of U.S. adults.¹

18 for attention-deficit/hyperactivity disorder which affects 4 percent of U.S. adults and 9 percent of adolescents aged 13 to 18.¹

14 for anxiety disorders with lifetime prevalence rates of 28.8 percent of U.S. adults and 25 percent of adolescents aged 13 to 18.¹

40 for substance use disorders. Nearly 29 million Americans aged 12 and older—or 10.6 percent of the U.S. population—have reported using an illicit drug in the past month.⁷

Innovative Approaches to Research

The development of new and effective treatments for patients with mental illness can be very challenging. The complexity of the diseases creates hurdles for researchers, with diagnoses often made based on symptoms rather than underlying pathology. There is a limited understanding of how current treatments work in the brain and a need for robust and qualified biomarkers to help clinicians diagnose accurately, measure disease progression and assess treatment response.

Despite these challenges, researchers have many innovative new approaches in development. Some innovative potential new medicines include:

- A dopamine/norepinephrine reuptake inhibitor in development for attention-deficit/hyperactivity disorder (ADHD) with an extended treatment window, showed significant improvement in both inattentive and hyperactivity/impulsivity ADHD symptoms in clinical trials. The medicine has also shown to have low potential for abuse.
- A once-daily, oral medicine designed to rebalance brain function that is dysregulated in the brain in patients with major depressive disorder. The medicine offers a novel mechanism of action which is immensely promising for the millions of patients who do not respond to standard antidepressant therapies.
- An intranasal medicine, with a rapid therapeutic effect, is in development for treatment-resistant depression. It targets a glutamate receptor in the brain that may restore communication among brain cells that breaks down in depression. Most antidepressants typically take four to six weeks to work in patients, leaving them unsure whether the medicine will work for them.
- A medicine in development for schizophrenia inhibits the biological response of both dopamine and serotonin receptors in the brain, affecting both the positive and negative symptoms of the disease. With its novel pharmacological profile, it is thought that the medicine will reduce the occurrence of adverse events associated with current antipsychotic treatment.
- A subcutaneous, long-acting formulation of buprenorphine is in development for opioid use disorder. Buprenorphine is an approved MAT that works by reducing cravings. MAT medications, such as buprenorphine, are used in combination with counseling and behavioral therapies for the treatment of opioid dependency. Current formulations of buprenorphine are dosed daily. The subcutaneous formulation is designed to release the therapeutic over a period of one month and is administered in a health care setting to improve patient adherence for patients struggling with addiction.

Adherence to Treatment Saves Money

A large body of evidence demonstrates how better use of medicines can lead to reductions in other sources of health care spending across a broad range of chronic conditions. Better management of and adherence to treatment for mental health disorders can save \$22.8 billion annually.⁸ In Medicaid, research shows increased use of medicines among patients is associated with reductions in expenditures from avoided use of inpatient and outpatient services.⁹ For example, among patients with schizophrenia, improved adherence to antipsychotic medicines has shown to yield annual net savings of up to \$3.3 billion, or \$1,580 per patient per year. This savings is driven by lower hospitalizations, outpatient care and criminal system involvement.¹⁰

“All medical research needs more funding and support, but especially mental health conditions. Research has led to the development of new medications and it is important to find out why medications work and why the same medications won’t work for everyone or why they stop working.”

— Cami, NAMI Member

A PIPELINE OF PROMISE IN MENTAL HEALTH



NAMI, the National Alliance for Mental Illness, has been advocating for the millions of Americans affected by mental illness for more than 35 years. Across the United States, NAMI works with its local affiliates, state organizations and volunteers to raise awareness and to provide support, education and advocacy for people with mental illness and their families.

For people living with mental illness, finding the best treatment plan is an important step in the recovery process. Since mental illness affects each person differently—even people with the same diagnosis—treatment needs are highly personal. Fortunately, innovations in evidence-based medications, therapy and other services and supports have made recovery a reality for many people with mental health conditions.

For millions of people, medication is an important part of an effective treatment plan. While existing medications can be helpful, they often have significant limitations, such as requiring weeks to take effect, failing to relieve all symptoms or resulting in severe side effects. In addition, some people have complex or treatment-resistant conditions that do not respond to available medications.

New medications are urgently needed to better treat mental illness. The current drug pipeline, medications in development, and investments in research at the National Institutes of Health (NIH), including the BRAIN Initiative (Brain Research through Advancing Innovative Neurotechnologies), offer great promise. But, more is needed. The NIH and National Institute of Mental Health (NIMH) should work aggressively with private sector partners to develop breakthrough disease-modifying interventions that bring the hope of recovery to everyone who lives with mental illness.

Sources:

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**America's
Biopharmaceutical
Companies**

GOBOLDLY