



September 25, 2019

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20510

The Honorable Norman E. "Ned" Sharpless, MD
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

RE: Prohibiting the Reporting of Genetic Information for Use in Depression Treatment Decisions is a Step in the Wrong Direction

Dear Secretary Azar and Commissioner Sharpless:

On behalf of the patients, caregivers and provider organizations that we represent, we are writing to express our serious concern over actions by the Food and Drug Administration (FDA) to prevent clinical laboratories from providing important genetic information from pharmacogenomic testing to health care providers to inform medication decisions for their patients with mental illnesses. Although we appreciate the FDA's mission to protect the public health, in this case we believe the Agency's actions may in fact inflict greater harm on patients and impede innovation.

As leaders in the mental health community, we are concerned by the Agency's recent demand of laboratories to eliminate references to medications and medication classes on mental health pharmacogenomic test reports. We are particularly troubled by how this policy change will impede the ability of psychiatrists and other front-line health care professionals to personalize medication decisions to most effectively treat patients with Major Depressive Disorder (MDD).

At a time when 16 million Americans experienced at least one major depressive episode in the past year, we cannot afford to restrict technology that will provide valuable scientific information to health care providers that may help treat patients more effectively. Today's standard of care for depression is unfortunately trial-and-error of medication selection with patients responding to the first treatment only 50% of the time. This long and frustrating journey rarely leads to remission and can instead lead to symptomatic decline, relapse, and potentially

lead to treatment resistant depression. As a result, health care providers treating mental illness are in desperate need of the promise of personalized medicine – getting the right treatment to the right patient at the right time.

According to the Centers for Disease Control and Prevention (CDC), in 2017 fourteen out of every 100,000 Americans died by suicide. That is equal to a 33% increase since 1999 and is the highest age-adjusted suicide rate recorded in the U.S. since 1942. Combined with the opioid crisis, the staggering incidence of suicide is contributing to lower average expectancy among all Americans.

Further, depression plays a major role in this worrisome suicide prevalence. Depending upon the academic data cited, 60 to 90 percent of people who complete suicide have a mood disorder. Younger persons who take their own lives often have a substance abuse disorder, in addition to having depression. Moreover, extensive studies conducted by the National Institute of Mental Health (NIMH) show that failure on just one antidepressant medication increases both the chances of a second failure and raises the concomitant risk of suicide.

The application of personalized medicine to improve the treatment of mental illness is an exciting scientific area. The NIMH along with academic and private researchers are working tirelessly to find biomarkers to improve the diagnosis of mental illnesses and we have great hope for this science in the future. In the meantime, the application of pharmacogenomic testing to improve the treatment selection of depression medications is providing more than hope. Clinical studies have shown that physicians using genetic information as part of the treatment decision process are seeing more patients achieve remission than treatment as usual. This is remarkable and should be encouraged not stifled.

Given the public mental health crisis confronting our nation, we believe health care providers should have access to more innovative tools and treatments, not less. The FDA actions against laboratories offering pharmacogenomic testing will cause a dramatic scientific and clinical setback for the treatment of mental illness. By contrast, physicians who are treating patients with cancer are seeing an explosion in the application of personalized medicine with help from clinical laboratories providing important information about genetics and medication selection along with encouragement from the FDA.

Now more than ever patients are seeking more personalized treatment options and physicians are seeking to understand how a person's genetics might help inform their recommendations. The FDA should not stand in the way of this emerging and exciting field of science. Physicians must be able to continue to receive information about the impact a patient's genetics may have with medication choices. Instead of restricting information to physicians, FDA should work with the mental health community to educate providers and empower patients in order to facilitate the application of personalized medicine in the treatment of mental illness.

We would like to meet with you at your earliest convenience to discuss FDA's decision-making on this new policy and ways in which we can ensure health care providers continue to receive this valuable genetic information and its impact on medications. We can be reached through Reyna Taylor, Vice President of Public Policy at the National Council for Behavioral

Health at ReynaT@TheNationalCouncil.org for any questions. Thank you in advance for your attention to this important matter and we look forward to meeting with you soon.

Sincerely,



Angela Kimball
Acting Chief Executive Director
NAMI, National Alliance on Mental Illness



Chuck Ingolia
President and CEO
National Council for Behavioral Health



Michael Pollock
Chief Executive Officer
Depression and Bipolar Support Alliance



Paul Gionfriddo
President and CEO
Mental Health America