



March 4, 2016

The Honorable Ron Wyden
The Honorable Charles Grassley
Committee on Finance
United States Senate
Washington, D.C. 20510

Dear Senators:

On behalf of the National Alliance on Mental Illness (NAMI), I am pleased to submit the following response to your January 21, 2016 request for comments on the Senate Finance Committee's report on Hepatitis C treatments. NAMI is the nation's largest grassroots mental health organization dedicated to building better lives for the millions of Americans affected by mental illness. Through our 900 affiliates across the country, our members advocate on behalf of people living with mental health conditions such as schizophrenia, bipolar disorder and major depression.

NAMI appreciates the opportunity to provide input to the Committee on the financial impact of breakthrough therapies, the importance of ensuring access to these therapies, and improvements to the current marketplace to ensure greater transparency for patients and their families.

NAMI is concerned about three key issues—cost, coverage and value—as they impact our goal of ready access to effective, well-tolerated medications for the treatment of mental health conditions.

For individuals living with mental illness and their families, as for any patient population, out of pocket cost can be a significant barrier to obtaining medications or taking them as prescribed. In other words, cost has an impact on access.

Coverage is another potential barrier to access to the most effective, well-tolerated medications. Currently, the six protected classes in Medicare Part D include protections to help preserve access to a range of antipsychotics and antidepressants for individuals living with mental illness. NAMI urges Congress to press the Centers for Medicare and Medicaid Services (CMS) to avoid changes in the protected classes. In addition, we urge Congress to reject increases in cost-sharing for Low Income Subsidy (LIS) and dual eligible beneficiaries in Medicare Part D and for Medicaid beneficiaries. These important protections help ensure access to the most effective mental health medications for people living with mental illness.

Value—both of incremental improvements to existing therapeutic classes of mental health medications and breakthrough or disease-modifying treatments—also plays a vital role in NAMI's goal of ready access to effective, well-tolerated mental health medications. NAMI recognizes that, despite significant advances in medications, current medications often do not fully treat symptoms and/or have side effects that may impact adherence and health outcomes.

In a recent report from the National Alliance for Caregiving, *On Pins & Needles: Caregivers of adults with mental illness*, one in four caregivers whose care recipient takes medication reported that their loved one's mental illness is *not* well-managed with that medication and only 36% feel it is managed

well with medication. Further, three in ten said it was difficult for their loved one to take their medication regularly.

Weight gain, for example, has been cited by young adults as a major barrier to taking medication. Incremental improvements in drug therapies, such as reducing weight gain, can be critical to increasing adherence to medication.

Other improvements, such as alleviating negative symptoms like social withdrawal, addressing deficits in cognition and concentration, or minimizing side effects such as chronic dry mouth or metabolic syndrome, are of enormous value to individuals living with mental health conditions and can have an invaluable impact on finding and keeping employment or attaining education, establishing relationships with peers, reducing co-morbid chronic medical conditions and increasing life expectancy. Consequently, improvements in existing drug therapies can reduce the public health burden associated with mental illness and can stimulate the economy as more adults living with mental illness return to the workplace.

Disability, morbidity and mortality among people living with mental illness is high, The World Health Organization notes that depression is the leading cause of disability worldwide. 68% of adults with mental illness have a co-morbid medical condition. In addition, mental illnesses are associated with a two-to-fourfold elevated risk of premature mortality.

If a break-through or curative therapy became available, it would have a profound effect on the health and well-being of millions of Americans affected by mental illness and an equally profound impact on the cost of disability, morbidity and mortality.

NAMI would like to stress that the value of innovation in medications to address mental illness is high and, to that end, we support policies that will incentivize innovation. We recognize that there is a need for any organization, whether public or private, to feel that the financial risks of research and development will be appropriately off-set by the promise of appropriate gain. NAMI would also like to note that there is also significant value in paying for research “failures” that can be critical to the long-term process bringing us a breakthrough disease-modifying intervention. It is important that we recognize the real cost of innovation— particularly with respect to the most novel advances in therapy. It is through high risk-high value research that we hope will one day bring us breakthrough or disease-modifying treatments for conditions such as schizophrenia. When this type of breakthrough occurs for a serious illness such as Hepatitis C, we are hopeful everyone living with the condition will be able to access the innovative therapy and get a chance at an improved quality of life. And we hope that, some day, the news of such a breakthrough will be about mental illness.

Thank you for the opportunity to provide input on this important issue. NAMI looks forward to continue working with the Finance Committee to make improvements in the Medicare and Medicaid programs.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary Giliberti". The signature is written in a cursive, flowing style.

Mary Giliberti, J.D.
Executive Director