



**STATEMENT OF MARY GILIBERTI  
CHIEF EXECUTIVE OFFICER, NATIONAL ALLIANCE ON MENTAL ILLNESS  
TO THE HOUSE VETERANS AFFAIRS COMMITTEE SUBCOMMITTEE ON HEALTH**

**APRIL 20, 2016**

Chairman Benishek and members of the Subcommittee, I am Mary Giliberti, Chief Executive Officer of NAMI (the National Alliance on Mental Illness). I am pleased to offer NAMI's views on the draft bill before the Subcommittee directing the Secretary to establish a list of drugs that would require a new set of informed consent protocols.

NAMI is the nation's largest grassroots advocacy organization dedicated to building better lives for the millions of Americans affected by mental illness. NAMI State Organizations and over 900 NAMI Affiliates across the country raise awareness and provide support, education and advocacy on behalf of people living with mental health conditions and their families.

Through our NAMI Veterans and Military Council, our state and local NAMI organizations are engaged with VA Medical Centers in working with veterans and their families. The VA recently renewed a Memorandum of Understanding (MOU) with NAMI that allows us to continue to offer NAMI's "Family-to-Family" and "Homefront" classes to veterans and their families.

NAMI would like to thank the Subcommittee on the important bipartisan work it has done in recent years to improve treatment and services for veterans living with mental health conditions. While enormous challenges still confront the VA in lowering wait times and expanding access to evidence-based practices such as Assertive Community Treatment (ACT) and crisis intervention, progress has been made in reaching veterans earlier. We encourage the Subcommittee to build on these accomplishments by continuing its oversight activities and supporting investments in evidence-based practices for treatment and services for mental illness.

NAMI, however, would like to raise a number of concerns regarding the draft bill before the Subcommittee.

- 1) **The proposal unfairly singles out mental health conditions and the medications used to treat them as part of a new mandatory protocol that stigmatizes both these disorders and their treatment** – NAMI believes that this proposal sets forth a dangerous precedent by singling out a category of medications, "psychotropic drugs" (referenced in Section 7335), as part of a separate informed consent protocol. While NAMI supports the goal of improving clinical care in the VA through appropriate informed consent, any new requirement designed to achieve this laudable goal should apply across all therapeutic areas: orthopedics, endocrinology, pulmonary medicine, neurology, nephrology, etc. Mental health medications should NOT be singled out in federal policy for different or separate treatment protocols.

- 2) **The proposed mandatory informed consent requirement has enormous potential to limit access to psychiatric treatment in the VA**—NAMI is extremely concerned that this mandatory, inflexible informed consent protocol would serve as a significant barrier to veterans engaging in needed mental health treatment. Forcing clinicians to go through a multi-step mandatory checklist which, as currently drafted in this legislation, informs a veteran only about negative risks is exactly the wrong way to engage individuals in treatment. Effective practice dictates that engagement in mental health treatment needs to be done carefully and on the patient’s terms. Imposing a government-mandated protocol would be enormously disruptive to the process of engagement.
- 3) **The proposed requirements in the draft legislation for disclosure contain a number of inaccurate statements regarding the FDA market approval process and authority over labeling of products** – Page 5, line 4 of the draft legislation requires prescribers to state that “the FDA has not approved any psychiatric drugs to be used in combination with other psychiatric drugs.” In fact, the FDA never approves medications to be used in combination with other therapies. Instead, in the pre-market approval process, the FDA reviews data from randomized controlled trials submitted by sponsors to ensure safety and efficacy of individual products. Further, page 4, line 15 of the current draft sets forth a requirement for the disclosure of “unknown dangers of mixing drugs and dosages in sizes and combinations that have not been approved or tested by the FDA.” NAMI is concerned about any requirement dictating that prescribing physicians talk to their patients about “unknown dangers.” Instead, NAMI feels strongly that physicians should be guided by evidence-based practice and peer reviewed treatment guidelines to tailor treatment and services to the unique person they are working with.
- 4) **Use of the term “psychotropic” medications in the draft legislation lacks precision** – It is unclear from the text of the legislation what the term “psychotropic medications” actually means. In fact, there are a broad range of therapeutic classes that are utilized for on-label treatment for mental health conditions. These include antipsychotics, antidepressants, anticonvulsants, benzodiazepines and others. Within these therapeutic classes, there are many other conditions for which there are FDA on-label indications. Does the legislation intend to apply these new disclosure mandates on this broad range of disorders and indications?
- 5) **Discussion of alternative treatment should be grounded in evidence-based services** – NAMI supports physicians discussing with their patients the broad range of available therapies and options throughout the course of treatment. This is especially important with mental health conditions where individuals often experience periodic acute episodes of symptoms such as mania, psychosis or suicidal ideation. However, in discussing therapeutic interventions and alternative therapies, it is critical that the options being discussed be limited to and grounded in evidence-based practice. Physicians in the VA, and any other health care setting, should not be forced to disclose treatment options for which there is no scientific basis for safety and efficacy.

### **Better Education and Training of Prescribing Physicians in the VA Will Improve Care**

NAMI supports the goal of this draft legislation in promoting enhanced communication to veterans about diagnosis, treatment, outcomes and alternatives. A mandatory, inflexible informed consent protocol will not achieve this common goal. In order to achieve the goal of better-informed and engaged patients in the VA, Congress should require the VHA to develop training and consultation programs that promote communication and engagement with individual

patients. Such a training program should apply across all areas of clinical practice in the VA, not just the prescribing of medications to treat mental health conditions.

As an organization that embraces veterans living with mental illness, NAMI is eager to assist the VA in developing a program of best practices for patient engagement. This would include developing a curriculum for primary care physicians and specialists in internal medicine as these clinicians write the majority of prescriptions for psychotropic medications in the VA.

Despite the progress that has been made in recent decades, there is still stigma associated with mental health conditions. Particularly among veterans, there is often reluctance to acknowledge symptoms such as depression, anxiety, mania and delusional thoughts associated with conditions such as schizophrenia, bipolar disorder, depression and PTSD. Engaging veterans in treatment is a careful and nuanced process, one that can only occur effectively on the individual veteran's terms. A mandatory, inflexible informed consent protocol will not achieve this goal. Education and training of prescribing physicians is the answer.

This Subcommittee has made significant progress in expanding access to mental health care in the VA. This record of accomplishment can be improved through training and education, not new government-mandated protocols that interfere with engagement and treatment.

Thank you for the opportunity to offer NAMI's views on this legislation.