November 8, 2017

RE: Pharmacy & Therapeutics Meeting, November 16, 2017

On behalf of the thousands of individuals living in Iowa that are receiving behavioral health benefits, the Depression and Bipolar Support Alliance (DBSA) is writing today to provide comment about the Pharmacy & Therapeutics upcoming meeting on November 16, 2017, to evaluate the effectiveness of tardive dyskinesia inhibitors.

The leading national organization focusing on mood disorders: depression and bipolar disorder. The organization was founded over thirty years ago and has for its entire existence been led by people with the lived experience of mood disorders. Today, reaches three million people, including free, in-person peer support provided to 49,000 individuals who attend the more than 600 support group meetings led by our nationwide network of 239 chapters.

Believes that every person deserves the opportunity not just to survive, but to thrive and to do that, true wellness needs to be the end-goal for mental health treatment. Not allowing patients to be treated with access to all FDA-approved treatments for their condition is both cruel as well as costly.

Assessing the effectiveness of TD inhibitors cannot be untangled from the effects on whole health to treating bipolar disorder. Any drug utilization review must consider the role TD plays in attaining true wellness and whole health.

1. While it is true that a provider who feels strongly about a patient remaining on a particular medication could submit documentation (orally or in writing) that would allow for that medicine to be maintained, his recommendation ignores the most important person involved: the patient. When a medication choice is made, it's based in part of on the patient's needs, values and preferences. Ideally, doctors and patients discuss these factors in a process known as shared decision-making (SDM). This is one of three pieces of the prescribing puzzle. When clinicians make drug decisions, they rely on their own clinical expertise as physicians, the best available scientific evidence, and the patient's unique perspective. Requiring prior approval overlooks the reality and concerns for psychiatrists who are already pressed for time and forced into already too short 15-minute appointment slots with patients.

2. The first priority for treatment is ensuring that a person living with depression or bipolar disorder is provided a pathway out of crisis and onto stability. However, all too often, this baseline stability is also the end goal established for successful long-term care. "Stable" or "better" are not always synonymous with "well. Limiting access to medications and the appropriate dosage that are used to treat mental health conditions can create serious challenges for people who have these mental health disorders. When it comes to the treatment of mental health conditions, the clinical management of real world patients often involves "trial and error." Treating mental health conditions is not like treating pneumonia, where an oral antibiotic medicine is started and (in almost all instances) the illness goes away and the medication is stopped several weeks later. In contrast, the treatment of mental health conditions is

almost always “trial and error,” and in many instances requires long-term treatment. In fact, the available published evidence suggests that only 25 percent to 33 percent of people who have a mental disorder experience a complete clinical response to the first two to three medications, even when prescribed in the presence of ongoing psychotherapy. Suggesting that a person lowers their dosage undermines their ability to manage the underlying concern which can cause further physical and mental health.

3. The cost of settling for reduced symptoms is simply too great. And for many, it can be a matter of life and death. Comorbidity—medical conditions that exist simultaneously while independent from another condition—is common for people living with mood disorders. Individuals living with mood disorders are more likely to have life-threatening co-occurring conditions, such as heart disease, hypertension, and diabetes, for example. Those most vulnerable to cost related non-adherence are people living with four or more chronic conditions. These comorbid conditions are a huge factor in why individuals with mental health conditions die, on average, 25 years younger than those without mental health conditions. As a result, denying access to first line, FDA approved medications to treat Tardive Dyskinesia is counter-productive as it jeopardizes the whole health of the individual and can ultimately lead to the management of far more serious conditions. As a result, granting access to FDA-approved medications to treat appropriate patients with Tardive Dyskinesia is vitally important. respectfully requests the Iowa Pharmacy & Therapeutics committee members to allow patient access to these innovative therapies indicated to treat patients with Tardive Dyskinesia.

Given the wide variety of medications, the different side-effects associated with them, and the fact that symptom relief is not the greatest benefit a patient is seeking, strongly encourages that the Iowa Pharmacy & Therapeutics committee examine all of the ramifications associated with denying access to front-line, FDA approved TD inhibitors.