



Depression and Bipolar
Support Alliance

March 28, 2016

**Re: April 27, 2016 CMS Medicare Evidence Development and Coverage Advisory
Committee (MEDCAC) Meeting. Eric Scharf Testimony**

Ms. Maria Ellis
Executive Secretary for the MEDCAC
Centers for Medicare & Medicaid Services
Center for Clinical Standards and Quality Coverage and Analysis Group
7500 Security Boulevard
Baltimore, MD 21244

Dear Ms. Ellis:

I am requesting six minutes to provide testimony at the above-referenced meeting. Below, please find a copy of my testimony:

Hello, I want to thank CMS for convening this meeting today and allowing input from stakeholders. My name is Eric Scharf. I am a volunteer participant with the Depression and Bipolar Support Alliance (DBSA). Unlike any other organization of its kind, DBSA is created for and led by individuals who themselves have a mood disorder diagnosis, with our bylaws stipulating that over half of both the governing board of directors and paid professional staff must be people who have, or have had, depression or bipolar disorder. This first-person lived experience informs everything that we do.

I personally live with TRD and receive social security disability benefits. Prior to my TRD diagnosis I was owner of an association management and consulting firm; during my career I have served as Executive Director of four membership organizations and supported the work of many others. During that time I worked at a professional level; I often describe my current situation as going from eight cylinders to four cylinders, often just not having the energy or focus to work like I did previously. I have tried countless medications; with little or no success. Today, with the help of my social security benefits which has provided me some sense of financial stability and new life skills and medications that help to treat some of the symptoms I experience I am able to lead a life with meaning, but lacking in the level of energy and excitement that I once felt.

DBSA's vision is wellness for people with mood disorders, and we believe that an open and collaborative approach to treatment that accounts for the whole person—where she or he is *right now*—is what allows people to achieve what they personally define as wellness. Our collaborators include a Scientific Advisory Board made up of the nation's leading clinical and research experts on mood disorders. We are nationally recognized for Peer Specialist training services, which weave those of us with lived experience of mental health conditions

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into the fabric of care as adjunctive providers of education and support. Ultimately, we at DBSA believe that our balanced, person-centered, wellness-oriented approach is what has allowed us to educate, empower, support, and inspire individuals to achieve the lives they want to lead for our now-30 years in existence.

Moreover, these three decades of peer-led work have enabled DBSA to coalesce a strong base of active participants. In fact, through the more than 700 free, in-person peer support groups provided by DBSA's network of 300 chapters across the country, along with our printed and virtual educational resources and wellness tools, DBSA reaches over three million people each year with current, readily understandable information about depression and bipolar disorder; connections to treatment and community resources; and—crucially—the hope that wellness is possible.

As the foregoing hopefully illustrates, DBSA's three decades of representation of, and engagement with, people who have mood disorders put DBSA in a unique position to assist MEDCAC as they seek to define treatment resistant depression (TRD) and provide guidance on how to conduct studies for treatment options. Overall, we believe that meaningful innovation in treatment will be aided by understanding first and foremost how those receiving the treatment define success, rather than simply relying upon the assessments of clinicians and researchers. Along these lines, the following are five important areas that DBSA asks MEDCAC to consider when providing guidance.

I. *Efforts to improve definition and measurement of success from the perspectives of those who live with TRD.*

For people who live with TRD, the past 25 years have seen anemic progress in the development of meaningful new treatments. Innovation has been incremental. People are consequently frustrated by and losing hope of for a solution. Modest improvement in clinical outcomes is simply no longer enough.

Of course the first priority for treatment is ensuring that a person living with TRD 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."

DBSA believes that every person deserves the opportunity not just to survive, but to thrive, and to do that, we need to ensure true wellness as the end-goal for TRD treatment. Consider this: successful treatment for cancer targets the removal of every cancerous cell—the achievement of complete remission.

II. *DBSA believes measures of treatments' efficacy need to evolve.*

Changing measurement tools to include wellness outcomes as defined by people with



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TRD would greatly improve treatment. For example, MEDCAC could recommend elevating the importance of existing clinical measurement tools that address function, such as the [Sheehan Disability Scale](#), and/or that address wellness, such as the [WHO-5 Scale](#). Both are useful in allowing not only for the mood-related improvements necessary to achieving complete wellness, but also the interpersonal and relational aspects of individuals' experiences of TRD, such as how many productive days a person has had within a week as defined by the individual as opposed to symptom reduction as defined by a medical model.

III. DBSA participants with TRD look to MEDCAC to increase consideration of the whole-health implications of interventions for TRD symptoms.

The weight of TRD negatively affects people with co-occurring conditions, which are frequent and diverse, ranging from diabetes to cardiovascular conditions to cancer. Treating both TRD and any co-occurring conditions—recognizing and allowing for their complex interrelationships—is imperative to achieving optimal outcomes.

IV. DBSA urges MEDCAC to consider implications of chronic, versus episodic, experiences of TRD.

Success should not be defined by controlling this week's, month's or even year's episode, but by reducing the severity and eliminating the reoccurrence of symptoms over the entire lifetime. This is not often the defined objective for clinicians or researchers, but it is of vital importance to people experiencing TRD, as well as their families.

V. DBSA notes that payers, including the Centers for Medicare and Medicaid Services (CMS), hesitate to include novel treatments for depression.

The current measures and criteria for determining that a new treatment is "safe and effective" do not answer payers' questions about whether a new treatment offers benefit over existing treatments and whether these added benefits justify an added cost. Because payers tend to resist coverage for new treatments, an inadvertent disincentive for research and development exists.

DBSA supports MEDCACs initiative around TRD. We sincerely hope that the committee's work will promote an environment that supports the development of better treatment options and encourages exploration of the steps that need to be taken in order to break out from the current dynamic of incremental, slow improvement, to one of exciting breakthroughs. Part of this depends upon a transformation of the way we currently measure success. We urge the committee to look for guidance from those living with to bend the focus of scientific discovery towards the things that matter most to us. Thank you.

Submitted by Eric G. Scharf