



WELL BEYOND BLUE

Elevating lived experience in support of wellness for depression

Report of the Externally-led Patient-Focused Medical Product Development Meeting on Major Depressive Disorder

Meeting Date: November 16, 2018

Report Date: March 2019



Depression and Bipolar
Support Alliance

Report of the Externally-led Patient-Focused Medical Product Development Meeting on Major Depressive Disorder

Authors(s) and Collaborators(s): Phyllis Foxworth, Depression and Bipolar Support Alliance, nothing to disclose.

Disclosures: Nothing to disclose

Funding: Funding was received from the following sources. None of the funding bodies participated in the design, collection, analysis and/or interpretation of data, and/or writing this resource.

- Alkermes, Allergan, Janssen, Lundbeck, Myriad, Otsuka, Sunovion, Takeda

Reporter Date: March 2019

This document has not been revised and/or modified in any way after the version date listed on the cover page.

DBSA has all necessary permission to submit the external resource and linking from the FDA website will not violate the proprietary rights of others.

Point of contact: Phyllis Foxworth, Depression and Bipolar Support Alliance pfoxworth@dbsalliance.org

Introduction



Michael Pollock, Chief Executive Officer

On November 16, 2018, Michael Pollock, Chief Executive Officer of the Depression and Bipolar Support Alliance (DBSA), stood in front of a packed ballroom at the Tommy Douglas Conference Center in Silver Spring, MD, and shared the DBSA vision to transform wellness for people living with mood disorders:

A ten-year initiative to ensure that peer-desired treatment outcomes are incorporated in the delivery of mental health care throughout the entire healthcare ecosystem for people living with mood disorders.

Attendees at the meeting included individuals living with symptoms of depression (peers), caregivers, and other patient representatives. Staff from the U.S. Food and Drug Administration (FDA) and persons associated with medical product developers attended as active listeners. Mr. Pollock shared the organization's hope that a better understanding of the impact, the burden on whole health, treatment options that are working, and peer-

desired treatment outcomes will lead to innovation in research and development of new products among medical product developers and regulators.

The meeting was a parallel effort to the Food and Drug Administration's (FDA) patient-focused drug development initiative to hear directly from individuals living with health conditions. Dr. Mitchell Mathis, Director, Division of Psychiatry Products, Center for Drug Evaluation and Research, Food and Drug Administration underscored the importance of the meeting by sharing, "We come here to learn and to unlearn—if there's something we need to unlearn—and to take that information back and do a better job at regulating medications."

"I am bigger than my diagnosis" summed up much of what Dr. Michelle Campbell, Clinical Outcomes Assessment Staff, Center for Drug Evaluation and Research, Food and Drug Administration, shared she learned and would be taking back with her in her remarks at the end of the meeting. Commenting on a key theme she heard throughout the day, she observed: "The concept of thriving is something we need to examine as an outcome."

This report provides an overview of the peer perspective in living with and navigating through life while experiencing a mood disorder. The report examines the peer perspective on the impact on life and whole health in session one, and the efficacy of treatment options and unmet needs in session two. This session also provided the unique opportunity to gain the perspective of those attending the meeting on a new tool FDA has approved for exploratory use in clinical trials.

DBSA uses the term "patient" to describe those discrete periods when an individual is interacting with the medical community. The word "peer" is used to describe an individual outside of that engagement. As a chronic condition, the majority of an individual's life is spent outside of engagement with the medical community and, therefore, "peer" is used mostly throughout the report to describe a person experiencing symptoms of Major Depressive Disorder (MDD) when not directly engaging with clinicians.

Table of Contents

Introduction	2
Overview of Major Depressive Disorder	4
Session 1	5
Session 2	10
Appendix 1	16
Appendix 2	17-18
Appendix 3	19



Overview of Major Depressive Disorder

Major Depressive Disorder (MDD) is a treatable medical condition involving an imbalance of brain chemicals called neurotransmitters and neuropeptides. People who experience MDD have had at least one major depressive episode (five or more symptoms for at least a two-week period). For some people, this disorder is recurrent, which means they may experience episodes once a month, once a year, or several times throughout their lives.

The exact causes of depression are not clear. While depression sometimes runs in families, many people with depression have no family history of MDD. Both genetics and a stressful environment or life situation can contribute to the onset of MDD. Symptoms of depression include prolonged sadness or unexplained crying spells; significant changes in appetite and sleep patterns; irritability, anger, worry, agitation, anxiety; pessimism, indifference; loss of energy, persistent lethargy, feelings of guilt, worthlessness; inability to concentrate, indecisiveness; inability to take pleasure in former interests, social withdrawal; unexplained aches and pains; and recurring thoughts of death or suicide.

An estimated 16.2 million adults in the United States have had at least one major depressive disorder episode (MDE). In 2016 this equated to 6.7 percent of adults aged 18 or older. Additionally, 4.3 percent of adults (10.3 million adults) experienced a MDE with severe impairment. The prevalence of MDE was higher among adult females (8.5%) compared to males (4.8%). The prevalence of adults experiencing a MDE was highest among individuals aged 18-25 (10.9%).¹



I lost my aunt who died by suicide when I was 24. Unfortunately, mental health was not discussed growing up and even after we lost her. So with my diagnosis of depression, I am more determined than ever to not stay silent about mental health concerns.

Seeking a Life Well Lived

We believe all stakeholders share the goal of fostering innovative therapies that provide peers with the ability to lead the lives they want and deserve. It is the hope that the peer perspective gathered from this meeting, and compiled in this report, will inform medical product developers when developing new products and provide FDA direction when providing guidance to industry before submitting new drug applications. For example, one outcome would be inclusion of a peer-defined patient reported outcomes (PRO) in future clinical trial design.

Throughout the meeting, several key themes emerged:

- MDD is a chronic condition that can interfere with and delay natural life transitions.
- Medical product development innovation focusing on whole health is under-prioritized.
- Progressive nature of the condition leads to concerns about ongoing efficacy of treatment options.
- Peer-desired outcome go beyond surviving. Peers seek the opportunity to thrive.



Session 1

Impact on Life and Demands on Whole Health

The first topic of discussion focused on the demands living with MDD places on an individual's ability to participate fully in daily life, including managing a co-occurring health condition. This is particularly relevant since having a physical condition increases the risk of developing MDD. Further, DBSA was interested in learning how chronicity and progression impact peers' ability to navigate through natural life transitions. Throughout this session, it became clear the complexities of managing whole health and a quality of life that goes beyond the clinical benefit of survival, symptom management, and functioning are intertwined and difficult to untangle. But more important was the revelation that people living with MDD are frustrated with the current medical product options that suggest a functioning life is good enough.

This session began with insights from four panelists:

Allison—a woman in her 40s whose experience with depression has affected her ability to work at the level for which her training and expertise equipped her. Her current personal wellness plan includes working at a lower level of employment in order to avoid stressors which may trigger symptoms.

Shelby—a woman in her 30s who experiences MDD and a co-occurring health condition which includes chronic pain. She highlighted the tradeoff of choosing to treat one condition and not the other because each medication negatively affects the other condition.

Alli—a woman in her mid-20s whose experience with depression created a barrier to completing a graduate program. She currently manages her depression through a personal wellness plan that does not include medication so as to avoid unpleasant side effects.

Christy—a woman in her mid-60s who has experienced MDD throughout her life. She highlighted the progression of MDD throughout life stages as well as trade-offs she has lived with to avoid unpleasant side effects—and the side effects she chose to live with to avoid even worse outcomes.

MDD as a chronic and progressive condition.

The panelists' testimonies provided a variety of views about the progression of the condition, the trade-offs made around natural life transitions, and the difficult choices peers face when trying to manage whole health outcomes. The frustration of living with a chronic condition that creates barriers to whole health was evident. Just as importantly, participants expressed a desire to move beyond functioning in the world to experiencing a world where they could thrive.

To engage the audience, the facilitator asked them to respond to polling questions and provide comments regarding several discussion questions. When asked to respond to a polling question that queried how long it had been since first experiencing symptoms of depression, 78% stated that it had been six years or longer. The results of this polling question suggest that those in attendance were representative of the unmet need population—the two-thirds research reveals do not achieve remission from the first treatment protocol.²

For many attending the meeting, MDD began early in life:

- *The first manifestation of the disease occurred with my first suicide attempt at the age of 13.*
- *My first depression was when I was 14.*
- *My first experience with depression started before I went in the military. At the age of 16 I signed up for Vietnam and I wanted to commit suicide.*

And is experienced as a chronic condition:

- *I've lived with depression or a form of it for more than 25 years.*
- *I still experience symptoms of depression although much less frequently than I used to.*
- *My symptoms are managed. But I'm still depressed.*
- *Individuals like me are dependent on medication for the rest of their life.*

Effect on natural life transitions.

Living with a chronic and progressive condition that begins early in life and is not responding adequately to treatment interferes with the natural progression of life events—especially around aspects of transitioning into adulthood. The complexities of successfully moving through these transitions while managing symptoms that can act as barriers was revealed through participants' comments. To facilitate this discussion, the audience was shown a slide that highlighted areas of life impacted by MDD:

- Education, academic performance, or attainment
- Choice of profession, employer, or position; possibly the need to take less demanding jobs or ones with certain employee benefit programs that support you
- Professional advancement
- Finances
- Family, spousal, and romantic relationships and friendships
- Family responsibilities

The audience was asked to comment on the impact living with MDD had in these areas. These categories were chosen to represent quality of life categories commonly associated with the Sheehan Disability Scale. However, we learned that, while the Sheehan Disability Scale measures functional impairment, the audience discussion revealed a strong desire to move beyond functioning to thriving. Much of the audience discussion can be summed up by the following comment: *[the whole period was a lot of starts and stops in my life.*

This delayed transition through natural life events was

further underscored by comments shared around a polling question asking the participants to comment on aspects of wellness. This polling question was presented to gain deeper insight into the Supporting Wellness survey conducted by DBSA in partnership with the Milken Institute Center for Strategic Philanthropy in the months leading up to this meeting.

This survey asked respondents to prioritize aspects of wellness and research opportunities. From the over 5,300 responses, the highest-ranked aspect of wellness was *Ability to be independent or act according to my own will*. When polled on how to define this aspect of wellness (see Appendix 2 for polling questions and results), the highest-polling categories focused on professional growth around academics and employment. Therefore, it is not surprising much of the audience's comments centered around academic and workplace performance delays.

It was apparent from the shared comments of both the in-person and online attendees that living with MDD can often mean a life interrupted. Academic pursuits are delayed, careers paths are adjusted to acknowledge tolerable stress levels and decreased cognition, and many of the natural adult transitions are put on hold.

Noteworthy from this session was the theme of under-employment. Conversations with active listeners at the conclusion of the meeting revealed this was new information, yet this theme was so prevalent in the comments provided by peers. This disconnect underscores an identified goal articulated by Dr. Mathis in his opening remarks: "If it's important to patients and its clinically relevant, then it should be considered a legitimate drug target." Going forward, employment capacity could be a potential clinical trial endpoint.



I am currently under-employed. In my case it's working for that rate and level below my qualifications. I have had key positions in my life. I had to take a medical leave of absence that was brought on by stress. I have to supplement my business and my under-employment. I work as a substitute teacher. That is not the best use of my executive MBA.



MDD can interfere with academic and professional advancement:

- *I had a sense of terror and isolation and that led me to drop out of the program mid-semester and I forfeited my scholarship.*
- *I'm a registered nurse. When I had my breakdown, my colleagues blackballed me.*
- *I had a successful career in hospital administration, but I think I could have been so much more powerful and effective had I not had these episodes of my life.*
- *I was not able to interact with supervisors in a way that I could advance.*
- *I no longer have the job I had before my major depressive disorder episode.*
- *It's very difficult to get back into the workforce at a level at which I believe I could be capable.*

MDD can hinder ability to work and affect financial stability:

- *I had seven different jobs in a ten-year period.*
- *All the different jobs I've kept going to and walking off and wondering why I did it.*
- *I spent months not working, and I really wasn't sure why I wasn't working.*
- *I haven't been able to work full time since 2007.*
- *In the past and present, I have not been able to make as much money.*
- *In the future, this is going to affect how I'm going to be able to take care of myself.*
- *I'm on about 40% of what I used to live on.*

MDD can affect personal relationships:

- *I started feeling those symptoms after I broke off an engagement to be married and I felt guilty about that. I felt I had ruined my fiancé's life, so I should ruin my life as well.*
- *I didn't receive society in my life until I turned 50. And I ended up getting a wife at that period of time.*
- *I have lost friendships, been shunned by family members, and seen the end of my marriage.*

Impact on whole health.

Because there is a high comorbidity of depression with other physical conditions, DBSA wanted to understand from peers and caregivers the nature of these physical conditions and the trade-offs peers make to manage what is often two competing treatment plans. For example, DBSA learned from a survey of its community that 20.1% of respondents indicated that impact on physical health was a main reason for switching medications. The same study revealed that, among those not taking medication, 50.7% stated impact on physical health was a reason for not taking medication to treat MDD.³ This fact was further emphasized when the meeting facilitator revealed that 43% of respondents to the Supporting Wellness survey indicated their overall health had worsened since first experiencing depression symptoms.

To facilitate this discussion, participants were asked to provide feedback on how living with a comorbid health condition and depression impacted life in the following areas:

- Balancing health care strategies
- Achieving optimal health outcomes
- Coordinating care among clinicians
- Managing financial concerns

Most of the discussion focused on the interaction of medications to treat MDD with the medications to treat the comorbid physical condition. Examples shared included dystonia—a neurological condition, Long QT Syndrome—a congenital heart disorder, and polycystic ovary syndrome. The commonality shared among these participants was the difficulty managing treatments for the physical condition and MDD. More troubling, many participants shared that the inability to treat to whole health had life-and-death consequences, inasmuch as inadequate treatment of MDD led to suicidal ideation.

Prevalent during this discussion was the burden women experienced in navigating depression symptoms throughout the reproductive stages of their lives. This discussion revealed how changes women experience, from puberty through menopause and post-menopause, are directly related to their experience of depression. This includes lack of treatment efficacy, contraindicated medications to treat reproductive health conditions, and mood disorders, to the need to change or adjust treatments as women cycle through these stages.

Sleep disorders were also a prominent topic of conversation. For many, effectively managing sleep apnea played a significant role in managing depression symptoms. Treating insomnia had similar benefits but, as with women's reproductive issues, the contraindications for treating insomnia while living with depression proved challenging for many participants.



So many of us, as patients, feel like we have to take on so much to control, not only our conditions that we're diagnosed with but the comorbidities, and manage medications, manage relationships, manage everything. Yet we're left alone. We felt let down.



Session 2

Unmet Need and Treatment Effectiveness

Topics of discussion for the second session gathered perspectives from peers and caregivers around the approaches and strategies they use to manage the condition. Participants were also given the opportunity to provide feedback on the Symptoms of Major Depressive Disorder Scale—a new FDA-approved scale for exploratory use in MDD clinical trials.

Kicking off the session, four panelists shared their experiences as inspiration for the broader audience dialogue. The panelists spoke not only about the treatment options they have used, but also factors they considered when making decisions about their recovery.

Panelists included:

Yvette—a woman in her 50s who traces her condition back four generations and experienced her first suicide attempt at age 13. Throughout her life, symptoms have made it difficult to maintain full employment. She has foregone treatment to cover basic necessities of food and shelter.

Patrick—a man in his 60s whose daughter lives with depression. He highlighted the journey of family engagement and of peer recovery supported when all parties acknowledged the need to learn how to manage a chronic condition.

Sinuet—a man in his 50s reflected on how cultural norms affect treatment. He shared a need for more implementation of integrative principles— which he has benefited from—to provide better treatment outcomes.

Keith—a man in his 50s who has experienced MDD throughout his life, he highlighted a variety of treatments he has tried. He shared that, while not yet achieving the outcomes he is seeking, his faith in science gives him hope for better days ahead.

Managing a chronic and progressive disorder

Results from the Supporting Wellness survey shared during the meeting highlighted the chronicity of MDD, with two-thirds indicating they have experienced up to 10 discrete periods of symptoms or that symptoms are persistent. DBSA used polling questions to better understand what management approaches peers use to attain peer-desired treatment outcomes while living with a chronic and often progressive condition.

While 23.7% of polling respondents shared they take a medication, participants expressed frustration “at this trial and error, throw things against the wall approach to psych meds.” Indeed, literature from Star*D research supports what peers tell us: two-thirds of patients do not become symptom free or experience remission after one pharmaceutical intervention to treat symptoms of depression is administered over a 12-14-week period.⁴

So how do peers manage symptoms of depression if a medical product intervention is not successful? The meeting polling results revealed a wide range

of approaches are deployed. While talk therapy was the third-highest vote-getting category (21%), few participants commented on its effectiveness one way or another. The vast majority of comments focused on approaches within the control of the individual.

These approaches represented the highest vote-getting category at 24.5%:

- diet, dietary supplements
- meditation, mindfulness
- sleep, physical activity

Given the preponderance of management approaches identified by participants who focus on self-care outside of the clinical model, it raises the question of how these approaches are accounted for in clinical trial design. One participant suggested this: “In terms of intervention trials... it may not be anything that is being necessarily monitored or collected as you’re looking at whether another type of therapy is effective or not. And it could be differences that are occurring in some of those other things—that we’re not even asking.”

Clinical trials
would benefit from
understanding past
treatment history.

23.7% of respondents to polling question take medication to treat MDD.

21.5% work with their clinicians to make adjustments during a time when symptoms impact their life.



It took me four years to find a set of medicines that got me to a baseline so that I feel ok, so that I don't think about stepping in front of a train every time it pulls into the station.

Unmet need: moving beyond symptom mitigation

A general theme throughout the day was, “Better is not well.” Many participants shared the hope for themselves or their loved ones to one day be more productive, more financially secure, and more engaged in personal relationships. This idea of leading a thriving life rather than merely functioning in it was shared by many.

Aspects of wellness identified from the Supporting Wellness survey—purpose in life, getting through the day, following through on ideas and intentions—were shared and subsequently explored with the audience. Several parents shared that the lack of confidence to embrace the day is a barrier faced by their loved ones. In particular, one parent expressed a desire for a medical product to “jump start or get [us] out of the moment” as necessary.

The observation was made that self-care is a valued and respected management plan, but it doesn't work if one can't muster the motivation for even minimal self-care. For others, the concepts of purpose in life or getting through the day could be found in the views expressed by author Andrew Solomon: “The opposite of depression is not happiness, but vitality.”

Advancing the science around personalized medicine for treating MDD was raised by several participants as a solution to the trial-and-error trap in which many peers find themselves. Specifically, peers were interested in advancements around genetic testing that could identify the efficacy of a particular class of medication over another because this could shorten the trial-and-error time period. The potential to save lives around this science cannot be overlooked, as many people abandon any hope of a pharmaceutical intervention during this frustrating period.

SMDDS—peer perspective

A major goal of the Beyond Blue initiative is to ensure that patient-desired treatment outcomes are reflected in the design of clinical trials. One vehicle to meet this objective is the use of a valid scale that measures peer-desired treatment outcomes. Current clinical trial design incorporates two well-known scales: the Hamilton D17 Depression Rating Scale and the Montgomery Asberg Depression Rating Scale. In his opening remarks, Dr. Mathis shared that, when treating a patient, it is very important to know what the patient thinks about his disease, and that he would not rely solely on the Hamilton D17. DBSA agrees with that assessment and further suggests that, if it is not the sole indicator in treating a patient, it should not be the sole indicator in evaluating the efficacy of medical product interventions.

Therefore, the last topic of the day was devoted to peer input on a new scale—the Symptoms of Major Depressive Disorder Scale (SMDDS). A number of medical product developers collaborated to develop this new scale that the FDA recently approved for exploratory use in clinical trials. This scale provides opportunities for patients to report on their experience rather than relying solely on a clinician-interpreted report as to how well a patient is progressing. This element of reporting is referred to as patient-reported outcomes (PROs). The current scales most commonly used in clinical trials rely on clinician-reported outcomes of symptoms. Using this protocol, the clinician observes the patient's symptoms along the scale and reports their assessment of improvement. The SMDDS is the first scale for clinical trials that introduces PROs. The first topic for this group discussion asked for thoughts on the use of PROs in a clinical trial assessment tool.

Feedback was mixed. Among caregivers, there was a desire to include caregiver-observed outcomes. This feedback centered on a trust factor: their loved one

was not willing or unable to be truthful in reporting outcomes. Peers welcomed observed reporting of symptoms, but felt that putting this observation solely in the hand of a 15-minute psychiatric visit was limiting. Instead, they felt that observations should include professionals who spend time with peers: talk therapists, social workers and peer support specialists.

Another feature of this new scale is the discrete time periods of evaluation. The traditional time period used in clinical trials reports a change over a 30-day period. The SMDDS asks patients to reflect back and provide recall on symptoms over the past seven days. Peer insights acknowledged that their symptoms do fluctuate—for some, several times a day. To account for these variances, many participants shared that using a daily mood tracker such as the DBSA Wellness Tracker or a similar app could eliminate the problem of reporting on a specific day, regardless of the discrete period—whether 30 days or 7 days.

Participants, who were shown the items in the scale and asked for their reactions, expressed concern that the scale emphasized what patients did not do at the expense of what they did do. Yet peers candidly noted that MDD, in its most unchecked state, tended to rob them of the motivation to better manage their life circumstances (diet, sleep, exercise, etc.). Participants often felt that the scale did a better job of documenting missed opportunities than of affirming the importance of effective self-care. This was referred to as an “asset-based perspective,” and participants seemed hungry to see more of it integrated into the scale. They were especially anxious that the scale not cloak “self-blame” for succumbing to MDD symptoms, but affirm even small steps towards better self-management of feelings and energy levels. Here is an example provided by one

participant: “[I need] a chart [so] that every day I could say, ‘I’m not very hopeless today. This is really a good thing.’ Or, ‘I’m overwhelmed, but I know why and I’m going to get over it, and by the end of the day I will not be overwhelmed.’”

Of concern were the triggering aspects of the scale because of the high prevalence of co-occurring disorders. For example, questions about diet could be triggering for someone living with both a mood disorder and an eating disorder.

Finally, participants noted that the concept of “What is normal?” is a complicating factor. Without a baseline of what “normal” self-regulation looks like, subjective reporting on one’s state of mind and behaviors seems somewhat arbitrary. That was not necessarily viewed as a flaw in the design of the scale: it seemed more like a cloud hanging over all such attempts to quantify the patient experience. Participants simply wanted the scale to acknowledge how overwhelming self-reporting can feel, since patients know that their self-observations do not necessarily align with those of people in the general population. Participants noted this contradiction: only peers can accurately report on their internal experiences, yet their self-reporting is skewed by the very mood disorders on which they are commenting.

Participants were not hostile to the new scale: they simply felt there was ample room for improvement, and that the clinically objective perspective needed to yield even more to the outcomes self-reported by patients. These outcomes may be statistically “messy” and sometimes contradictory, but participants felt they are a necessary and viable path to gaining an accurate assessment of what living with MDD is like.



Conclusion

DBSA is grateful for the courage, candor, and honesty shared by the peers and caregivers who participated in-person, via the live webcast, and through submitted comments. DBSA believes that, first and foremost, it is through understanding how those living with MDD define success that we will achieve meaningful new innovations in medical product interventions to treat MDD.

In his closing remarks, Mr. Pollock observed gaps in the current medical product development environment which, when addressed, have the potential to spur innovation. The first is the need for FDA to provide guidance acknowledging there are differing levels of severity, and that MDD manifests as a chronic and progressive condition for many people. This sentiment was echoed by panelist Yvette, who asked medical product developers to conduct female longitudinal clinical studies to understand the role different female reproductive phases have on treatment efficacy throughout a woman's life span.

The notion of prioritizing whole health in medical product innovation was repeated by panelist Sinuet who asked medical product developers to consider treating the whole person because "it's not just one item that you are focusing on [or] one medical condition."

DBSA believes embracing these peer requests can give rise to innovation. Moving away from a singular focus on symptom reduction creates an environment for creativity leading to medical product breakthroughs. This sentiment was shared by panelist Christy when she asked, "How do we know whether a serotonin reuptake inhibitor might do the job?"

Mr. Pollock referenced Commissioner Gottlieb's September, 2018 comment, "The FDA must be flexible and open-minded to new approaches that best meet the needs of patients so that patients can have confidence in the results and the treatments that come from it." Specifically, Mr. Pollock asked for consideration of genetic testing that can save lives, as well as increasing patient access to post-marketing information that can assist them in assessing the risks and benefits based on their own personal circumstances and desired outcomes.

Further, DBSA believes every person deserves the opportunity to not just survive, but to thrive. We can no longer accept the paradigm that better is good enough. Therefore, it is imperative to identify a pathway to incorporate a peer-desired thriving outcome for inclusion in clinical trial design. The DBSA model of strength and resiliency in achieving recovery should become part of the strategy. We need to understand why some people are able to get over depression in spite of symptoms. Identifying and understanding these factors will lead to clinical trial protocols that result in major medical product development breakthroughs, which in turn support the quality lives people living with MDD desire and deserve. This includes extending clinical trials to an appropriate timeframe that can accurately identify resiliency elements that take time to materialize.

In closing, DBSA recognizes that this report reflects the input of those who participated in the Patient-Focused Medical Product Development meeting. There are varying views and opinions on how best to treat MDD. DBSA respects and welcomes all views because, ultimately, an inclusive dialogue supports the idea of self-directed care—a core belief of the organization.

DBSA is grateful for the participation of the medical product developers and FDA staff who participated in the November 16, 2018 meeting, and who continue to make themselves available as resources in support of our mission: to improve the lives of people living with mood disorders.

Citations

¹ 2016 National Survey on Drug Use and Health (NSDUH) <https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.htm>

² <https://www.nimh.nih.gov/funding/clinical-research/practical/stard/allmedicationlevels.shtml>

³ Rosenblat JD, Simon GE, Sachs GS, et al. Factors that impact treatment decisions: results from an online survey of individuals with bipolar and unipolar depression: Prim Care Companion CNS Disord. 2018; 20(6): 18m02340.

⁴ <https://www.nimh.nih.gov/funding/clinical-research/practical/stard/allmedicationlevels.shtml>



Appendix 1

Meeting Agenda

11:45 - 12:30 pm	Registration
12:30 – 12:45 pm	Opening Comments Michael Pollock Chief Executive Officer Depression and Bipolar Support Alliance Mitchell Mathis, M.D. Director, Division of Psychiatry Products Center for Drug Evaluation and Research Food and Drug Administration Gary Sachs, M.D. Associate Clinical Professor at Harvard Medical School and Co-Director, Bipolar Clinic and Research Program, Massachusetts General Hospital
12:45 – 1:10 pm	Overview of Depression Demographic Polling
1:10 – 2:30 pm	Session 1: Impact on Life and Demands On Whole Health Panel (4) Topic 1: Impact on Life Topic 2: Demands on Whole Health Topic 3: Impact on Will
2:30 – 2:45 pm	Break
2:45 – 4:05 pm	Session 2: Unmet Need and Treatment Effectiveness Panel (4) Topic 1: Treatment Effectiveness: What Works Topic 2: 3:30-3:50: Unmet Need–What I Want from Treatment Topic 3: SMDDS
4:05 – 4:30 pm	Closing Remarks Michael Pollock Chief Executive Officer Depression and Bipolar Support Alliance Michelle Campbell, Ph.D. Clinical Outcomes Assessment Staff Center for Drug Evaluation and Research Food and Drug Administration

Appendix 2

Polling Questions

1. What is your age?
 - a. 18 – 24 years old: 6.45%
 - b. 25 – 34 years old: 9.68%
 - c. 35 – 44 years old: 22.58%
 - d. 45 – 54 years old: 25.81%
 - e. 55 – 64 years old: 25.81%
 - f. 65 – 74 years old: 9.68%
 - g. Over 75: 0%

2. What is your gender?
 - a. Male: 32.69%
 - b. Female: 65.38%
 - c. Non-binary/third gender: 0%
 - d. Prefer to self-describe: 0%
 - e. Prefer not to say: 1.92%

3. Which of the following apply?
 - a. I am living with depression or have experienced it in the past: 35.19%
 - b. I am in a relationship with and/or am a family member of one or more individuals who experience depression: 27.78%
 - c. Both of the above: 29.63%
 - d. Other: 7.41%

4. How long has it been since you first experienced symptoms of depression?
 - a. Less than 1 year: 5.88%
 - b. 1-2 years: 3.92%
 - c. 3-5 years: 11.76%
 - d. 6-10 years: 11.76%
 - e. More than 10 years: 66.67%

5. When reflecting on "Ability to be independent or act according to my own will," which best defines this aspect for you?
 - a. Ability to do work I have done previously or have received training or advanced education to do: 10.81%
 - b. Ability to engage in social activities that I have enjoyed in the past: 2.7%
 - c. Ability to explore new employment, training or academic opportunities: 10.81%
 - d. Ability to explore new leisure time activities or social situations: 5.41%
 - e. All of the above: 54.05%
 - f. I don't know: 2.7%
 - g. Other: 13.51%

Appendix 2

Polling Questions *con't*

6. What if any tools do you use as a management approach for treating depression? (Vote once for each that applies)

- a. Peer support: 13.16%
- b. Talk therapy: 21.05%
- c. Medication therapy: 23.68%
- d. Medical devices such as TMS, neurostimulation, electro-convulsive therapy: 1.75%
- e. Diet, dietary supplements, sleep, physical activity, meditation, mindfulness, and other non-clinical approaches: 24.56%
- f. Personal wellness plan: 7.89%
- g. Other: 7.02%
- h. I don't have a management approach to treat depression: 0.88%

7. If you take medication to help treat depression, which of the following do you currently take? (Vote once for each that applies)

- a. I don't take medication: 8.93%
- b. SSRIs—Prozac, Paxil, Pexeva, Zoloft, Celexa, Lexapro, Luvox, Vibryd: 23.21%
- c. SNRIs—Cymbalta, Effexor XR, Pristiq, Khedezla, Fetzima: 14.29%
- d. "Atypicals"—Desyrel, Serzone, Remeron, Trintellix, Brintellix, Wellbutrin, Aplenzin, Forfivo XL, Rexulti, Abilify, Seroquel, Latuda, Geodon: 28.57%
- e. Tricyclics—Tofranil, Pamelor, Elavil, Vanatrip, Sinequan, Quitaxon, Aponal, Norpramin, Anafranil, Surmontil, Vivactil, Asendin, Ludiomil: 0%
- f. MAOIs—Parnate, Nardil, Marplan, Emsam: 0%
- g. Other: 21.43%
- h. I don't know: 3.57%

8. During the time when symptoms impacted your life, what if any adjustments did you make to your management approach? (Vote once for each that applies)

- a. Increase peer support: 15.89%
- b. Increase talk therapy: 21.5%
- c. Work with my clinician to change my medication therapy: 21.5%
- d. Work with my clinician to incorporate or change use of medical devices such as TMS, neurostimulation, electro-convulsive therapy: 2.8%
- e. Made changes to my diet, sleep schedule, physical activity, meditation, mindfulness, or other nonclinical approaches: 26.17%
- f. I didn't do anything different: 2.8%
- g. I don't know: 1.87%
- h. Other: 7.48%

Appendix 3

Resources

DBSA recognizes that many stakeholders were not able to participate in the meeting either in person or the live webcast. Stakeholder engagement is valued and important to creating a community that advances treatment options to reflect patient-desired treatment outcomes. Therefore we hope you will not only avail yourself to the resources below, but will share them with others who will benefit.

Meeting Videos

<https://www.dbsalliance.org/dbsa-externally-led-patient-focused-drug-development-meeting/>

Transcripts

<https://www.dbsalliance.org/pdfs/WellBeyondBlue/PFDD/Transcripts.pdf>

Post Meeting Comments

<https://www.dbsalliance.org/pdfs/WellBeyondBlue/PFDD/Comments.pdf>

Online Comments

<https://www.dbsalliance.org/pdfs/WellBeyondBlue/PFDD/OnlineComments.pdf>

Supporting Wellness Survey Results

<https://www.dbsalliance.org/pdfs/WellBeyondBlue/PFDD/SupportingWellnessSurvey.pdf>

FDA

<https://www.fda.gov/drugs/development-approval-process-drugs/cder-patient-focused-drug-development>