June 21, 2024

Dr. Vincent Lo Re III, MD, MSCE
Chair
Drug Risk Management Advisory Committee
Center for Drug Evaluation & Research
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD. 20993

Dr. Rajesh Narendran, MD
Chair
Psychopharmacologic Drugs Advisory Committee
Center for Drug Evaluation & Research
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD. 20993

Dear Dr. Lo Re and Dr. Narendran:

RE: **PROCESS CLARIFICATIONS FOR UPCOMING JOINT ADVISORY COMMITTEE MEETING**

The undersigned organizations are very pleased with the FDA announcement of joint convening of the Drug Safety and Risk Management Advisory Committee and the Psychopharmacologic Drugs Advisory Committee to thoroughly reevaluate the Clozapine Risk Evaluation and Mitigation Strategy (REMS) program.

Schizophrenia and related psychotic disorders, in general, have poor clinical outcomes including high rates of mortality and morbidity. The paucity of the existing treatment armamentarium results in these patients being disproportionately and inappropriately "served" in homeless shelters, county jails, state prisons, and community hospital emergency departments. Clozapine – a 40-year-old generic product -- is the only FDA-approved atypical antipsychotic medication for treatment-resistant schizophrenia. The advantages of the medication include lowering the risk of suicide, reduced risk of a Parkinson's disease-like movement disorder called tardive dyskinesia, and fewer relapses. Although well intended, the REMS process is now operating as a barrier to clozapine access and use by patients. The Clozapine REMS is causing substantial challenges to pharmacists and prescribing clinicians who are seeking to provide their patients with the clinical benefits of clozapine while struggling to adhere to hematologic monitoring and reporting mandates.

The upcoming joint advisory committee meeting is critical to the health and safety of millions of Americans with schizophrenia. We are writing to seek process clarifications in conjunction with the upcoming joint advisory committee convening. ***Please note that our sole objective is to amplify the voice of patients, family members, and the care team to help advisory committee members understand the treatment journey of both patients and persons who care for them.***

Specifically, please provide additional information on the date of the joint meeting. As these joint convenings appear to be rare, please describe how the agenda is established, and what opportunity exists to provide comment during the agenda planning process. When REMS' programs are reevaluated, are there common scientific questions that guide the FDA's deliberations and, if so, what are they? Our goal is to be helpful in identifying and recommending relevant subject matter experts – encompassing scientists, pharmacists,

researchers, prescribers, patients, and family members – who could play a constructive role in the joint convening.

While we have openly advocated for modifications in the Clozapine REMS that would result in a fundamental shift to an education-oriented program for prescribers and pharmacists, we also recognize that the FDA is one of world's premier scientific bodies and its advisory committees are entirely driven by data and clinical evidence.

The undersigned organizations possess the academic and clinical experience and seek to assist the Drug Risk Management Advisory Committee and the Psychopharmacologic Drugs Advisory Committee to gathering the available data on Clozapine.

We look forward to your reply. Thank you for your attention to this important matter.

Sincerely,

American Pharmacists Association
American Association of Psychiatric Pharmacists
American Psychiatric Association
American Psychiatric Nurses Association
American Society of Health-System Pharmacists
CURESZ Foundation
National Alliance on Mental Illness (NAMI)
National Association of State Mental Health Program Directors
National Council for Mental Wellbeing
Schizophrenia & Psychosis Action Alliance
Team Daniel Running for Recovery From Mental Illness, Ann C. Mandel M.D. and Robert S. Laitman, MD
The Angry Moms Clozapine Advocacy Group
Treatment Advocacy Center (TAC)