September 29, 2015

Mitch Mathis, MD  
Director of the Division of Psychiatry Products  
Office of New Drugs in the Center for Drug Evaluation and Research (CDER)  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Building 22, Suite 4200  
Silver Spring, MD 20993  
mitchell.mathis@fda.hhs.gov

Vicky Chan, Pharm.D., BCPS, LCDR, USPHS  
FDA/CDER/OSE /OPE /DPV I  
Safety Evaluator  
Vicky.Chan@fda.hhs.gov

Drs. Mathis and Chan:

I am writing to you today on behalf of the membership of the College of Psychiatric and Neurologic Pharmacists (CPNP). CPNP is a professional association representing nearly 1800 psychiatric and neurologic pharmacists. Seventy percent of the members of CPNP are Board Certified as Psychiatric Pharmacists (BCPP) by the Board of Pharmacy Specialties. CPNP’s membership consists of specialty pharmacists who are trained in pharmacology, pharmacokinetics, drug-drug and drug-disease state interactions, and in optimizing medication adherence.

Psychiatric and neurologic pharmacists:

- Prescribe, adjust, and discontinue medications independently or under collaborative practice agreements.
- Develop drug use policy, treatment guidelines, and disease management protocols.
- Manage annual drug budgets and formulary decisions.
- Provide comprehensive medication management which involves assessing the efficacy of psychiatric and neurologic medications, performing medication histories, and providing treatment strategies for a therapeutic plan.
- Increase treatment adherence.
- Evaluate and manage comorbid health conditions in collaboration with other providers.
- Perform patient assessments such as metabolic monitoring; order and interpret medication-related tests.
- Train and educate other healthcare professionals.
CPNP applauds the decision of the FDA to consolidate six disparate Clozapine registries into a single Clozapine REMS program. However, we are very concerned that within the Pharmacy Enrollment Form, in the section labeled Authorized Representative Information, the credential BCPP is omitted. We strongly urge the FDA to instruct the administrator of the Clozapine REMS program to correct this omission and include the BCPP credential as an additional check box. As noted above, the BCPP credential is commonly carried by pharmacists who specialize in psychiatry and these individuals are most likely to be the Authorized Representative completing the Pharmacy Enrollment Form.

CPNP appreciates your attention to this matter. If you have any questions or if CPNP can assist the FDA in matters related to the Clozapine REMS Program, please feel free to contact me.

Sincerely yours,

Ray Love, PharmD, BCPP
President, CPNP