NAMI

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ON BEHALF OF NAMI – THE NATIONAL ALLIANCE FOR THE MENTALLY ILL

BEFORE THE FOOD AND DRUG ADMINISTRATION ADVISORY PSYCHOPHARMACOLOGIC DRUGS ADVISORY COMMITTEE

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NAMI | The Nation's Voice on Mental Illness
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Good afternoon. My name is Maureen Schweers and I am a member of NAMI (formerly, National Alliance for the Mentally Ill). I am representing NAMI today in providing our views of clozapine and the frequency of blood test requirements.

My younger brother is a true clozapine success story. He completed his bachelor's and master's degrees in engineering, graduating with honors, and is now working on his Ph.D.—all while taking Clozaril. This medication has worked wonders for my brother, giving him back his life. But after five years of regular blood testing, I must say that it is a constant source of frustration. The frequent blood tests are an obstacle for him as he tries to maintain a normal school and work schedule. The weekly blood testing has not proven simple for him—it often involves complicated coordination between the doctor, lab, and pharmacy—much of which my mother has handled. His doctors have tried placing him on other medications because of the testing requirement, but no other medication has been as successful as Clozaril. After more than five years on this medicine, incident-free, my brother would be the perfect candidate for reduced testing.

Many NAMI members have a similar story to tell. In the last week, NAMI staff circulated some questions about clozapine to consumers and family members around the country on its member website. In two days, 112 individuals provided feedback.

The overwhelming message from NAMI members was the success story clozapine has proven for so many of them, like my brother. Dozens of consumers and family members told how clozapine saved their lives—prevented hospitalizations, permitted greater independence and productivity—when other medications failed.

One family wrote that their son "has been stable on Clozaril for a few years…this medication has changed his life and given him the ability to go back to school, succeed academically, and reclaim a part of his life we all thought would be lost forever. He has fully embraced the reality of his illness, and maintains his scheduled medical care by himself. He will be 26 this month, was diagnosed with paranoid schizophrenia almost

seven years ago, and returned to school (an Ivy league college) last year. He has one term left."

Another parent wrote to us that "after several hospitalizations and attempts to treat his illness with various medications, my son was placed on Clozaril about ten years ago. Since that time he has not been hospitalized, and has maintained a part-time job. Today he is stable and happy with his life."

So, the first point I want to make is how important clozapine is to so many consumers with schizophrenia.

Most of the NAMI members who wrote to us last week also favored less frequent blood testing, some describing the frustration they encounter with this requirement. One mother wrote "Every two weeks, as a mother, I deal with the doctor, pharmacy and labs to ensure that my son gets his prescription. I have encountered so much trouble, heartache, and anguish getting this medicine, if I was the patient and had to go through all the hassle I would have quit long ago." Another family member stated that "I think there needs to be flexibility here. Our family members stopped using this medication because it was too hard to get the prescriptions filled because the lab was always late sending the blood test results. Plus as a working parent taking our family members to get blood work always had to be done on Saturday and there were not many labs open making us have to drive long ways." In addition, my brother's two-week testing period once fell during a holiday, and only a pharmacy's error months earlier which gave us an extra pill, gave him enough medication to prevent a potential hospitalization; an extremely detrimental setback in what has been a truly amazing recovery. The comments raise questions about which we do not have data, to my knowledge—how big a problem is biweekly blood testing to consumers, families, and providers? What issues are commonly faced by patients? We think that the problems presented by frequent blood testing should be studied so that decisions about it are more fully informed by the clinical reality faced by consumers and family members and that specific problems can be addressed. We believe that clozapine is grossly underutilized and could benefit many more consumers and that the risks and blood testing requirements

contribute to the underutilization. We also believe consumers and family members should be more involved in the risk-benefit analysis and determination with their provider of the best blood testing schedule after the first year.

Many NAMI members gave voice to the view that weekly and biweekly blood testing is not a problem, it may even have some benefits. This opinion reflected an acceptance of medical requirements to safely stay on a medication that has proven so helpful. It also reflected the view that the safety of consumers is paramount to our members. One consumer wrote: "Clozapine is a miracle medicine for me. No other medicine was able to give me the same level of sanity. Where I once had needle-phobia, I am no longer afraid to have my blood taken." Another family member stated: "Clozapine has saved our son's life. The blood tests are a hassle, but if it takes blood tests to keep the medicine, we will definitely continue." Still another parent stated: "Despite the fact that the need for frequent blood testing of my son made using Clozaril prohibitively inconvenient for me, I would not advocate less frequent testing unless sufficient ...data indicated minimal risk." Still another family member wrote: "I would want the scientific evidence of safety to be paramount--that extending the time between blood draws poses no greater risk, or that risk rates after extended use of Clozaril are no greater than that of other [medications]... My daughter takes the Clozaril blood draws in stride, as a "cost factor" attached to a medication which has restored her sanity and rescued her life." Another NAMI member told us that: "My daughter was one of the first 10 clients in Alaska to receive Clozaril. It was the first medication that allowed her to handle her symptoms and be released from the State Hospital. She is now 50 years old and had been on every medication available since the onset of her illness at age 19. She has never seemed to mind the blood draws. They are just routine for her. If we could be assured that less frequent testing would be safe that would be fine but continuing as it is no problem either."

Several consumers and family members reminded us with their comments that this medication does pose risks—including decreased blood cell counts, but also weight gain and others. We also should note that many people with schizophrenia not only have a

chronic illness, but have complex co-morbidities and take more than one medication. How do these factors affect the impact of clozapine on white blood cell counts?

A couple of NAMI members even suggested that ongoing blood testing, at weekly and biweekly intervals, may have benefits, improving compliance and assuring regular contact with a medical professional—which is so important for individuals with schizophrenia. Still, we also heard that blood testing does not always go hand in hand with seeing a physician regularly, and a few individuals noted that appointments with a psychiatrist were far less frequent than the biweekly blood tests.

We are not in a position to scientifically assess the serious blood count risks and how different schedules of blood testing protect patients. The data offered for today's meeting suggest that monthly testing after an initial period of more frequent tests can protect patients, although we noted that the experiences in the U.K. and Australia did lead to higher rates of agranulocytosis with monthly blood testing. We can state that for many consumers taking clozapine, weekly and biweekly testing have proven frustrating, costly, even an obstacle to living a normal life. We also want to make it clear that protecting the safety of these individuals is paramount to our members and that for many frequent blood testing is a price that they are willing to pay. Given the unanswered questions, such as those about the barriers posed by biweekly blood testing in the real world, and the results of monthly testing in terms of the risks posed to consumers with these chronic and complex conditions, we would like to suggest that less frequent testing—on a monthly basis—be implemented and studied in the United States. We also believe that monthly testing will be sufficient for those who have been on the medication for several years—and think that this should be the population first given the option of monthly testing, and the results of this changed protocol be studied and reported on. We urge further exploration of barriers and benefits posed by weekly, biweekly, and monthly blood testing in this population, so that such data can inform future decision-making by the FDA.

Thank you for your consideration and the opportunity to present our view today.