The Nation's Voice on Mental Illness

February 23, 2007

Division of Dockets Management (HFA-305)
Food and Drug Administration
U.S. Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir/Madam:

On behalf of the 210,000 members and 1,200 affiliates of the National Alliance on Mental Illness (NAMI), I am pleased to submit the following comments on the Prescription Drug User Fee Act IV agreement. As the nation's largest organization representing people with severe mental illness and their families, NAMI would like to express support for PDUFA IV.

NAMI has long placed the highest value on scientific advance and development of newer and more effective treatments for serious illnesses such as schizophrenia, bipolar disorder, major depression and severe anxiety disorders. Over the past two decades, we have seen a revolution in the development of new treatments for these disorders. While this advance has helped millions of individuals living with these illnesses move toward recovery, more is needed. NAMI feels strongly that both publicly funded research and the commercial market must move toward a new generation of medications that reach toward cures for severe mental illness.

NAMI is hopeful that the goals of PDUFA IV will help foster an environment in which this new generation of medications can be rapidly made available to millions of Americans living with these illnesses, and their families. As a patient advocacy and family organization, NAMI has a strong interest in PDUFA IV bringing the FDA forward as a stronger agency that is well resourced, develops modern information technology systems and is able to recruit and retain talented scientists.

In NAMI's view, PDUFA IV should help FDA progress toward being an agency that:

- Engages in effective pre-market review of products,
- Fosters expedited drug development,
- Moves toward rapid progress for fully automated drug reviews,

- Invests in full funding and staffing of the Critical Path Initiative (this agreement is a first step toward that goal), and
- Brings about a transformed post-market drug safety system at the agency.

It is on this final goal that NAMI believes PDUFA IV makes important progress. It is clear that additional resources are needed to address the increasing volume of adverse event reports. In NAMI's view, the FDA simply cannot keep pace with this increase in volume by relying solely on an expectation that Congress increase appropriated funds over the short term. Clearly, additional resources beyond appropriated funds are in order for the agency to engage in effective post-market safety beyond the current limited 3-year window. PDUFA IV moves us toward making sure that the agency has the resources to engage in this important safety review activities.

As the FDA moves forward to enhance post-market safety review, NAMI urges that the agency, and members of Congress that fund and oversee the agency, not lose sight of what is the greatest risk for people living with severe mental illness and their families, not being able to access available treatments. NAMI strongly supports individuals living with mental illness being able to access the full array of available treatment options. They should be able to work with their physician to weigh efficacy, side effects, patient and family history and other factors to make an individualized treatment decision. NAMI's hope is that PDUFA IV will move toward an environment in which those treatment options are broadened.

In commenting on this PDUFA IV agreement, NAMI would make the following observations:

1. There is widespread agreement that the FDA has been hampered by a lack of resources, both in terms of financial resources and human capital. PDUFA IV is a significant step forward in terms of drug development, drug safety and information technology. NAMI also feels strongly that Congress must also step forward with additional appropriations for the agency.
2. Since the early 1990s, PDUFA has succeeded in expanding the drug review process, what was once a 3-4 year process has been reduced to less than a year in many instances.
3. People living with mental illness and their families – like other patients who live with significant chronic illness – understand that there are risks associated with any prescription medication. What patients and their families want most is to have a variety of treatment options and clear understanding of the risks and benefits of each treatment option and to make an informed decision in consultation with their doctor. PDUFA can, and should, help expand and illuminate these important treatment decisions.

Finally, NAMI would like to go on record with concerns about the process for enactment of legislation in Congress that is needed to make this agreement a reality. NAMI recognizes that this process of passing legislation is beyond the control of the agency. Nonetheless, it is important to go on the record with a clear statement that the Commissioner should work hard with Congress to ensure that the reauthorization process

not be delayed. Such delays have enormous potential to derail drug reviews, hurt agency morale and in the long run, limit access to new medications. NAMI urges the FDA and Congress to move the reauthorization process forward expeditiously.

Thank you for your attention in this important matter.

Sincerely,

Michael J. Fitzpatrick, M.S.W.
Executive Director