February 22, 2007

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2007N--0005 Prescription Drug User Fee Act (PDUFA)

On behalf of the National Alliance of Medical Researchers and Teaching Physicians (NAMRTP), I applaud the Food and Drug Administration (FDA) for its proposal to strengthen the Prescription Drug User Fee Act (PDUFA). NAMRTP believes the PDUFA IV plan, as set forth on January 11, 2007, will help FDA improve its ability to review New Drug Applications expeditiously, add and retain physicians and scientists across various therapeutic areas, upgrade and modernize its information technology systems, and make significant improvements in long-term safety monitoring.

ABOUT NAMRTP

The National Alliance of Medical Researchers and Teaching Physicians is a coalition of doctors, scientists and health care providers dedicated to the advancement of medicine through technology. We are doctors who have seen first hand the potential for medical technology to transform the quality of life of persons living with disease. We are researchers who have explored new vistas of the human body through advanced medical procedures, medications, biologics, and devices. And we are public-spirited citizens who believe that access to innovative

pharmaceuticals and medical technology is the key to higher quality and more patient-centered health care for all Americans.

PDUFA IV COMMENTS

CRITICAL PATH

NAMRTP is a proponent of improvements to the drug development process and we are concerned with the lack of a sufficient drug development infrastructure in the U.S. The current system is inefficient and outdated. The result is relatively few new medicines and devices brought to market, even though thousands of potential advancements are discovered and tested every year.

With an aging population and more than 90 million Americans suffering from chronic disease, the public and private sector must work together to improve the drug development infrastructure in order to meet our nation's growing health care needs. The Critical Path Initiative (CPI) is a step in the right direction as it seeks to improve the process through the integration of new scientific tools and technologies. However, NAMRTP is concerned that the resources outlined for Critical Path in PDUFA are not sufficient for this important initiative to succeed. We urge FDA to work with Congress to find additional resources for the Critical Path Initiative.

SAFETY MONITORING

NAMRTP applauds FDA for its role in monitoring the long-term safety of medicines and devices. NAMRTP believes there is room for improvement and we believe PDUFA IV will result in further enhancements to this system. The additional funds and staff that will be assigned to safety monitoring, coupled with industry commitments to long-term monitoring, and

improvements in the adverse event reporting system should, in our view, both improve safety and reassure the public.

FDA RESOURCES

Identifying, testing, and evaluating new medicines is a complex, expensive process. The explosion in genomic data has yielded many more new compounds that are currently in clinical trials. Given the number of compounds being studied and complexity of the entire process, it is vital that FDA have sufficient staff and resources to do its job.

NAMRTP applauds FDA for negotiating a significant increase in industry user fees for the next five years. These additional resources will make it possible for FDA to add staff and should help the Agency retain the experts it currently has on staff. However, NAMRTP is concerned that the funds proposed in PDUFA IV will not be enough to meet the Agency's needs, especially in the out years of this five-year agreement. It is possible additional resources will be required, in which case NAMRTP would urge Congress to use the appropriations process to meet FDA's future needs.

In closing, NAMRTP has two major concerns with the PDUFA IV plan:

- Critical Path requires additional resources;
- Congress should be ready to meet the financial needs of FDA should the user fees prove to be insufficient.

Sincerely,

David Charles, M.D.
Chairman, National Alliance of Medical Researchers