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February 22, 2007

Electronic Submission

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

Re: Docket Number 2007N-0005
Notice of Public Meeting
Prescription Drug User Fee Act

Ladies and Gentlemen:

The National Health Council¹ (NHC) submits these comments in response to the U.S. Health and Human Services Department's (HHS's) proposed recommendations for the reauthorization of the Prescription Drug User Fee program for the human drug application review process for fiscal years 2008 to 2012. NHC also takes this opportunity to comment upon the comprehensive activities the Food and Drug Administration (FDA) has undertaken to improve its drug safety system and to optimize its performance, including the activities that FDA initiated pursuant to its on-going assessment of its drug safety program, those taken consistent with the report of the Institute of Medicine (IOM) entitled, "*The Future of Drug Safety—Promoting the Health of the Public*," and those proposed as part of the Prescription Drug User Fee Act (PDUFA) agreement. NHC supports FDA's PDUFA agreement and encourages Congress to act on PDUFA. However, NHC reserves comment on drug safety proposals that are currently being -- or may be -- considered in Congress.

NHC commends FDA's commitment to enhancing its drug safety system while ensuring that consumers have timely access to safe and effective medicines. New drugs and biologics present the greatest opportunity to save or prolong the lives of those with serious, chronic, or life-threatening diseases or unmet medical needs. As FDA officials have stated, "The number of lives saved and prolonged by new

¹ The Council and its 115 member organizations share a common objective: improving the health of all people, particularly those with chronic diseases and/or disabilities. Through communication, collaboration and consensus, the Council's member organizations — representing all segments of the health care community — work to achieve this important objective.

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therapies outweighs the risks that the treatment themselves pose.”¹ NHC commends the agency for recognizing that it must balance any regulatory steps taken to enhance drug safety with access and innovation to ensure that new treatments are made available to patients as soon as possible. Placing undue emphasis on drug safety without taking adequate account of drug benefit -- including the severity of the underlying disease or condition and the effectiveness of the product and the availability of alternatives -- could result in denying chronically ill patients new and innovative treatments and the benefit of a chance.

NHC applauds the tremendous effort FDA has made to enhance and modernize its drug safety system while taking a balanced approach to ensure that chronically ill patients have the benefit of a chance. FDA has launched a number of important new initiatives that will benefit patients. Most notable of these is the Critical Path Initiative, which has the potential to revolutionize the practice of medicine and streamline the drug review process. NHC recommends that FDA and Congress make a greater investment in this program as it will result in more targeted treatments -- with a reduced potential to cause adverse events in the targeted population -- and get such treatments into the hands of those suffering from serious, chronic and life-threatening diseases more quickly.

In addition, the agency has announced its intention to implement a number of risk communication strategies, including an advisory committee on communication, newsletters on drug safety and reports on postmarket surveillance findings. NHC would like to work with the agency on developing its risk communication strategies -- to ensure that an appropriate balance is reached so that persons with serious and life-threatening diseases will not be unduly denied access to essential medications. Moreover, NHC urges FDA -- consistent with its balanced perspective -- to provide a consistent stream of information about new findings of the efficacy of treatments as more and more people have taken a drug.

PDUFA IV Agreement

Under the PDUFA agreement, the agency is seeking authority to collect \$392.8 million in user fees with \$37.9 million of this funding to fund proposed important new initiatives to enhance its premarket and postmarket drug safety activities and proposed plans to increase the agency's efficiency and effectiveness. NHC supports the agency's request as these activities will benefit patients and help ensure that they have timely access to safe and effective medicines. However, NHC urges caution as FDA continues to increase its reliance on industry user fees to fund the drug review and safety system. With the industry paying an ever increasing percentage of FDA's costs, the appearance of impropriety also increases. Congress should consider capping the percentage of user fees and committing to provide FDA with an appropriate level of funding. FDA is critically underfunded, which has caused FDA to focus on its premarket responsibilities and to not focus as much attention on its postmarket activities. While many of FDA's recent activities are an attempt to fix this lopsided review, many activities that would be very helpful to

¹ Scott Gottlieb, M.D., Deputy Commissioner for Medical and Scientific Affairs, The Manhattan Institute, New York, New York, November 13, 2006

patients with chronic illnesses and unmet needs cannot be accomplished given the lack of funding. NHC urges Congress to increase appropriations to the FDA for its drug safety and communication activities.

Premarket Review Enhancements.

In the area of premarket review, the agency is proposing initiatives to expedite the drug development process and to reduce the potential for wasted experimentation to occur. NHC encourages the agency to work with industry to reduce the potential of experimentation that will not inform the drug review process and will unnecessarily slow the drug review process and as a result, will slow access to new drugs to seriously ill patients who need them.

The agency is also seeking \$4 million to “enable the agency to commit to several information technology performance goals that would move FDA and industry towards an all-electronic environment, which would increase the efficiency of the review process.” NHC applauds the agency for increasing the efficiency of the drug review process.

Modernizing the Postmarket Drug Safety System.

Of the \$37.9 million in new user fees sought for new pre and postmarket enhancements, the majority (\$29.3 million) would be used to modernize the drug safety system. While the recommendations do not outline the specifics of what the agency will do to upgrade the current drug safety system, the agency states that “potential activities in this area might include integration of certain proposed recommendations made by the Institute of Medicine’s drug safety report issued in September 2006.” On January 2007 the agency made public its response to the IOM’s recommendations and outlined its comprehensive plan to enhance drug safety and to optimize its performance. As previously mentioned, NHC supports FDA’s efforts and would like to work with FDA to ensure that these programs are implemented to serve patients, particularly those suffering from severe and life-threatening illnesses. Further, NHC supports additional enhancements to the postmarket evaluation system. For example, NHC supports FDA taking a systematic approach of applying regular assessments of drugs that may present risks throughout the life of a drug -- provided that such assessments are conducted in a manner that would not impede access to new medical products that can be used safely and effectively by patients suffering from chronic or unmet medical needs. In addition, some NHC members are concerned with FDA’s decision not to complete medication safety reviews, such as FDA’s decision to terminate a proposed safety study on medications to treat AD/HD. We understand that FDA felt compelled to terminate this research due to its anemic appropriations. NCH urges FDA to reestablish such safety studies with PDUFA funding or increased Congressional appropriations. Completing this type of postmarket studies will allow doctors and patients and their families to make informed choices about the safety and efficacy of their medications.

NHC also supports the agency’s recommendation to remove the legal language that limits the length of time after product approval in which user fees may be used to fund drug safety

activities. This will allow the agency to conduct postmarket surveillance throughout the life of the drug product.

The agency also proposes using new user fees to obtain access to additional databases, in addition to its current adverse event reporting system, to better detect adverse events and monitor drug safety. On January 18, the agency announced its intention to establish a Sentinel Network to create a systematic "real time" postmarket surveillance system.² NHC encourages the agency to move from a passive reporting system to an active surveillance system by creating an automated systematic approach to drug surveillance through a network of databases. NHC encourages FDA to enhance the system with experts to mine and analyze large data sets and innovative tools to continually enhance the process. NHC recognizes that in order to create this system, FDA will require significant additional resources, employee training programs and a commitment to the integration of science through the Critical Path Initiative. This automated and systematic approach to postmarket surveillance will improve the agency's ability to detect the risks and the benefits of a new drug. For this reason, NHC urges FDA to not only establish a comprehensive program to inform physicians and patients about the risks a marketed drug may present, but also the benefits that a drug may provide.

Conclusion

NHC supports FDA's PDUFA recommendations and applauds the agency's efforts to enhance and modernize its drug safety system while taking a balanced approach to ensure that chronically ill patients have the benefit of a chance.

Respectfully submitted,



Marc Boutin
Executive Vice President

² Sentinel Network To Promote Medical Product Safety; Public Meeting, 72 Fed. Reg 2284 (January 18, 2007).