



NATIONAL HEMOPHILIA FOUNDATION

for all bleeding disorders

January 8, 2002

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

3306 '02 JAN 16 A9:33

RE: Docket Number 98D-0483

Dear Sir or Madam:

The National Hemophilia Foundation, hereinafter referred to as the NHF, is a not-for-profit organization dedicated to improving the quality of life for all individuals with hemophilia and other inherited or acquired bleeding disorders. The NHF wishes to provide written comment to your recently published guidance document for industry on the use of nucleic acid tests (NAT) on pooled samples from source plasma to identify virus-positive donors and to further protect the health of all Americans. Articles recently published in both the professional and lay press about the large number of infected first-time blood donors after the events of September 11, 2001, underscore our efforts to ensure the safety of one of our nation's greatest resources, our blood supply.

NHF is pleased that our previous contributions to the Food and Drug Administration (FDA) were considered by the agency and may have played a part in mandating changes to the testing protocols to accommodate new technologies and to further reduce the risk of transmission of HIV and the hepatitis C virus (HCV). While NAT represents an important breakthrough in our efforts to reduce the risk of infection and protect our nation's blood supply; we must not and cannot believe that our work is now done. The FDA must continue to encourage industry to refine this exciting new technology to further reduce the window periods for HIV and HCV infection.

While HIV and HCV infection have taken a devastating toll on the hemophilia community, they are far from the only pathogens that threaten the health and well being of persons with bleeding disorders. We must be ever vigilant in our efforts to protect persons with hemophilia and the community at large from infection with additional strains of hepatitis and other known pathogens. Currently, there are no FDA-approved nucleic acid amplification tests for screening plasma for hepatitis A or B or for parvovirus contamination. Persons with hemophilia are also at high risk for developing parvoviruses, which cannot be "killed" using current methods for virus destruction.

A new threat has also emerged – Creutzfeldt-Jakob Disease (CJD) and variant Creutzfeldt-Jakob Disease (vCJD). NHF encourages the FDA to work with the National Institutes of Health (NIH) and industry to move forward with efforts to develop a diagnostic tool for prions. While the FDA has taken steps to reduce the

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possibility of CJD and vCJD infection through its recently enhanced recommendations for donor deferral, the development of an accurate test for CJD and vCJD is extremely important to ensure the continued safety of the world's blood supply from the ravages of this terrible disease.

NHF was encouraged to learn of the FDA's recent global workshop on the application of NAT in December 2001. We believe that the hemophilia community would benefit by efforts to develop a consensus with the international community on such issues on standardization and quality assurance, emerging pathogens, and new technologies.

One such technology that deserves additional attention and holds great interest for the hemophilia community is pathogen inactivation, sometimes referred to as blood cleansing, of all blood products. Despite all recent improvements in NAT, rigorous donor screening programs, and strict quality control measures, the risk of transmission of a virus or other pathogen remains a small but continued threat. The development of a safe and efficacious technology to remove pathogens from plasma, platelets, red cells and other blood products would be a valuable public health asset. The FDA should again work with the NIH and industry to realize the development of a variety of blood-cleansing methodologies.

In conclusion, NHF wishes to commend the FDA for this draft guidance document and for its efforts to further technological advances to ensure the integrity and safety of the nation's and the world's blood supply.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark W. Skinner". The signature is fluid and cursive, with a long horizontal stroke at the end.

Mark W. Skinner
President

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2 Your Internal Billing Reference 136-109-5305-00

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