2021 L Street, NW, Suite 900, Washington, DC 20036 ph 202.776.0544 fax 202.776.0545 e-mail ASH@hematology.org

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2012 President

Armand Keating, MD Princess Margaret Hospital 610 University Avenue, Suite 5-303 Toronto, ON M5G 2M9 CANADA

phone 416-946-4595 fax 416-946-4530 armand.keating@uhn.on.ca

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Janis L. Abkowitz, MD University of Washington Box 357710 Seattle, WA 98195-0001 phone 906-685-7877 206-543-3560 janabk@u.washington.edu

Vice President

Linda J. Burns, MD Division of Hematology, Oncology, and Transplantation 420 Delaware Street, SE MMC 480/Room 14-154A Moos Tower Minneapolis, MN 55455-0341

phone 612-624-8144 612-625-9988 burns019@umn.edu

Secretary

Charles S. Abrams, MD University of Pennsylvania School of Medicine 421 Curie Boulevard, #912 Philadelphia, PA 19104-6140

phone 915-573-3988 fax 215-573-7400 abrams@mail.med.upenn.edu

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Richard A. Larson, MD University of Chicago 5841 S. Maryland Avenue, MC-9115 Chicago, IL 60637-1470

phone 773-702-6783 773-702-3002 rlarson@medicine.bsd.uchicago.edu

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Martha L. Liggett, Esq. mliggett@hematology.org National Heart, Lung, and Blood Institute 31 Center Drive, Bldg. 31, Room 5A48 Bethesda, MD 20892-2486

RE: Draft "Expert Panel Report on the Management of Sickle Cell Disease"

To Whom It May Concern:

The American Society of Hematology (ASH) appreciates the opportunity to provide comments on the National Heart, Lung, and Blood Institute's (NHLBI) draft Expert Panel Report on the Management of Sickle Cell Disease (SCD). ASH is the world's largest professional society concerned with the causes and treatment of blood and blood-related disorders, representing more than 14,000 members. Consequently, the Society includes hematologists who treat children and adults with SCD and researchers who seek ways to prevent, treat, and cure this disease.

ASH applauds the NHLBI on completing the draft of the guidelines, using a systematic evidence-based review process and developing specific graded recommendations. The guidelines have the ability to significantly improve the treatment of patients; however, the Society would like to share the following concerns and recommendations to strengthen the guidelines, in order to provide the most high quality and comprehensive product possible. ASH's comments focus on the need for a second review by additional stakeholders. In addition, we have included information that will be important to the dissemination of the guidelines.

Public Review Process and Review by Additional Stakeholders

ASH appreciates the high-quality process the NHLBI used to develop the draft guidelines and recommends that the NHLBI continue to use the same comprehensive process to finalize the document. The Society is concerned, however, that the short public comment period for the draft guidelines is prohibiting several key constituencies from providing the feedback necessary to ensure that the guidelines meet the needs of the health care providers who are at the epicenter of care for patients with sickle cell disease. For example, it would be helpful to incorporate feedback from neurologists, pulmonologists, and cardiologists who often deal with complications of sickle cell disease and can provide practical guidance for primary care physicians treating these patients. Additionally, the short comment period did not provide ASH with enough time for a comprehensive review of the guidelines by those hematology experts who did not participate in the NHLBI Expert Panel. Since the open comment period includes a parallel review by sickle cell experts and other stakeholders, the next version of the guidelines is likely to include significant revisions. Once the draft document is updated by the Expert Panel, ASH strongly recommends that NHLBI implement a longer secondary open comment and review period to ensure that all stakeholders have an opportunity to provide comprehensive feedback on the guidelines. The NHLBI should specifically solicit feedback from key constituencies, including: primary care physicians, pediatricians, family physicians, emergency room physicians, cardiologists, pulmonologists, neurologists, nurses, nurse practitioners and physician assistants. It is imperative that all stakeholders have a chance

to provide the NHLBI with feedback from their perspective on how the guidelines can be improved to ensure the appropriate and widespread use of the final guidelines by all health care providers who treat patients with sickle cell disease.

Guideline Dissemination and Training Plan

ASH recognizes the importance of widely disseminating the final guidelines to a variety of audiences in a range of formats. The length of the document may be a barrier to its implementation. ASH recommends distilling the clinical directives from the guidelines and developing tools and resources to assist health care providers in translating the recommendations into practice. As the NHLBI develops a distribution strategy and corresponding resources, it is imperative to include input from a broad cross section of hematologists (many of whom may not regularly render services to SCD patients and would particularly benefit from these guidelines) as well as a number of health care providers who treat patients with SCD, including: primary care physicians, pediatricians, family physicians, emergency room physicians, cardiologists, pulmonologists, neurologists, nurses, nurse practitioners and physician assistants.

ASH welcomes the opportunity to work closely with the NHLBI on developing an effective and innovative dissemination plan for the guidelines. The Society recommends developing an article for submission to *Blood* focused on what the sickle cell guidelines mean for hematologists with a series of follow-up articles specific to the clinical implications for hematology. These articles can also be used as a mechanism to identify where the Expert Panel found gaps in existing high-quality evidence, highlighting where there is additional need for further sickle cell disease research. The Society also recommends that NHLBI develop similar articles and marketing pieces for other key constituency groups to increase awareness about and utilization of the guidelines.

Furthermore, ASH will plan on condensing the key recommendations from the guidelines into practical user-friendly tools such as quick reference or "pocket" guides, corresponding mobile downloads and educational webinars. For example, previously, ASH worked with the NHLBI in converting the Institute's 2008 von Willebrand disease (VWD): evidence-based diagnosis and management guidelines into an <u>ASH pocket guide</u>, which has been widely utilized by health care providers. Additional examples of similar tools the Society has developed can be found on the ASH Website: <u>pocket guides and mobile downloads</u> / <u>webinars</u>. The Society hopes to coordinate and work with the NHLBI as this moves forward.

The guidelines will be extremely valuable to clinicians and sickle cell patients; however, it will be critically important to establish a method for physicians to have access to SCD resources for care coordination and consultative services in their communities. ASH would like to, for example, take the lead in developing a "resource bureau" of SCD experts modeled after the Society's successful Consult A Colleague program that could help provide training on the guidelines as well as ongoing consultative assistance. The "resource bureau" could also present the guidelines in a grand rounds format at continuing medical education (CME) sessions and at annual meetings for the primary care groups.

The Society appreciates the opportunity to submit our concerns and recommendations regarding the SCD guidelines. ASH is committed to working with the NHLBI to pursue the common goal of improving the care of patients with SCD. If you have any questions or would like additional information, please feel free to contact ASH Government Relations and Practice Manager Stephanie Kaplan at skaplan@hematology.org or 202-776-0544.

Sincerely yours,

Armand Keating, MD

Lew Kesting

President