ASTMH
AMERICAN SOCIETY OF TROPICAL MEDICINE & HYGIENE
ADVANCING GLOBAL HEALTH SINCE 1903

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Valerie E. Jensen, R.Ph.
Director for Drug Shortage Staff
Center for Drug Evaluation and Research
Food and Drug Administration
White Oak Complex, Building 51
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Captain Jensen:

I am writing on behalf of the members of the American Society of Tropical Medicine and Hygiene (ASTMH) to express our concern about the lack of an FDA approved drug for the treatment of severe malaria in the United States. The latest report from the Centers for Disease Control and Prevention (CDC) on malaria in the United States shows a continued increase in the number of malaria cases. As you know, the Lilly Corporation discontinued the production of quinidine in the United States, leaving the country with no FDA approved treatment for severe malaria.

The CDC recommends treatment with artesunate, the international standard for treatment of severe malaria, but the only way to obtain this drug in the US is through a request to the CDC, which will then arrange for shipment of the drug to the center requiring the treatment. There are concerns among the infectious disease and travel medicine clinician community that delays in provision of the drug could result in adverse outcomes for patients, particularly in areas further from metropolitan centers. In addition, the drug is released through an investigational new drug mechanism, which requires that the patient sign a consent form for use of the drug. This can lead to concerns from patients that the drug is experimental, and not the standard medication used for this condition. In some cases in the past, in which artesunate was requested from the CDC because of lack of availability of quinidine, patients or their parents or guardians have been reluctant to sign the consent form, because they believe the consent form signifies non-standard treatment and the absolution of the hospital and CDC from liability if adverse events occur with the treatment. Though the treatment is the international standard, the consent form and IND mechanism lead some to believe it is not. This can further delay provision of badly needed therapy.

ASTMH is strongly advocating for FDA approval of artesunate as standard therapy for severe malaria in the United States, and for general availability of this important drug. Numerous international clinical trials have demonstrated unequivocally that it is the current gold standard for therapy of severe malaria. We wish to offer support and partnership with the FDA in any way that would be helpful to move forward approval and availability of artesunate in the US. We know that this issue is also of concern to the FDA, and we look forward to hearing of progress in getting the best therapy for severe malaria approved by the FDA and generally and rapidly available to clinicians.

Sincerely,

Chandy C. John, MD, MS, FASTMH
President, American Society of Tropical Medicine and Hygiene