



Society of Infectious Diseases Pharmacists

July 24, 2006

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

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SIDP
823 Congress Avenue
Suite 230
Austin, TX 78701
Phone: 512-479-0425
Fax: 512-479-9031
www.SIDP.org

Tax ID # 76-0338459

RE: Docket Item #2006P-0271/CP1 (filed 26 June 2006)

Dear Sirs:

This letter is in full support of the above mentioned citizen's petition submitted by the Clinical and Laboratory Standards Institute (CLSI) requesting that applications for approval of medical devices used to determine *in vitro* antimicrobial susceptibility of bacterial and fungal pathogens give positive consideration to the use of new or revised susceptibility interpretive criteria ("breakpoints") advocated by the CLSI, as well as the interpretive criteria in the FDA-approved labels, for antimicrobial agents that can be tested by the medical device.

The Society of Infectious Diseases Pharmacists (SIDP) is a dynamic association of over 450 clinical pharmacists and other health professionals dedicated to excellence in infectious diseases pharmacotherapy and the appropriate use of antimicrobials. Our members are active across the country in the development of new knowledge through antimicrobial research from the bench to the bedside, the provision of quality patient care services in individual health care settings and for large health services organizations, and the education of patients and clinicians aimed at optimal antimicrobial use. In the performance of these important activities, we work closely with physicians, microbiologists, epidemiologists, nurses, and administrators to ensure that the critical aspects of infectious diseases pharmacotherapy are addressed in a timely and efficient manner.

An obvious key responsibility of many SIDP members is active participation on antimicrobial management teams and the critical interpretation of antimicrobial susceptibilities to ensure that patient care is optimal. To this end, SIDP members are keenly aware of the ongoing need to critically assess the *in vitro* antimicrobial susceptibility data provided by our microbiology colleagues in light of the pharmacokinetic and pharmacodynamic profiles of individual antimicrobial agents and the nature of the infectious process in a particular patient. For years, the CLSI (formerly NCCLS) has provided vitally important interpretive guidelines and criteria for *in vitro* antimicrobial susceptibility testing that have aided the clinician in the selection of appropriate antimicrobial therapy for individual patients, determination of appropriate dosing of antimicrobials, selection of empiric antimicrobial regimens for standardized indications, and the ability to monitor critical trends in pathogen susceptibilities within institutions and for defined geographical areas.

It is understood that the FDA establishes interpretive breakpoints for susceptibility testing as part of the label approval process for antimicrobials and various medical devices used for *in vitro* susceptibility testing based on the data provided to the FDA by the industry sponsor requesting the approval. Often, these FDA breakpoints are identical to the breakpoints advocated by the CLSI. However, on occasion, the CLSI breakpoints differ from the FDA-approved label, possibly related to the emergence of resistance to a drug previously approved by the FDA. As clinicians, we strongly believe that the ongoing vigilance of the CLSI to ensure that the interpretive criteria for *in vitro* antimicrobial susceptibility testing contributes positively to quality patient care. Additionally, the CLSI provides annual guidance updates for the conduct and interpretation of *in vitro* antimicrobial susceptibility testing that serves to maintain a high standard for this diagnostic testing.

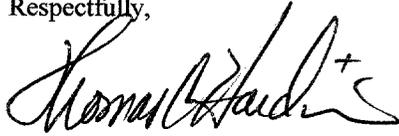
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Therefore, the SIDP is in full support of the CLSI-submitted citizen's petition to have the FDA Center for Devices and Radiological Health clear susceptibility test devices, especially those with software providing interpretive criteria, that would permit clinical laboratory directors and their associated medical staff to choose to apply either the FDA or the latest CLSI interpretive criteria for reporting their susceptibility results.

Thank you for the opportunity to offer our support of this petition and for your consideration of our request.

Respectfully,

A handwritten signature in black ink, appearing to read "Thomas C. Hardin", with a small plus sign above the "n". The signature is written in a cursive style.

Thomas C. Hardin, Pharm.D., MBA, FCCP
President
Society of Infectious Diseases Pharmacists

Cc: SIDP Board of Directors