



Advancing
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4325 '02 JUL 30 P1:31

July 26, 2002

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

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to comment on the Food and Drug Administration's (FDA's) June 20, 2002 advance notice of proposed rulemaking regarding the agency's efforts to reduce needlestick injuries involving medical devices. AACC appreciates your efforts in this area and encourages the FDA to continue to work with the private sector to improve the safety of medical devices.

In November 2000, then President Clinton signed into law the Needlestick Safety and Prevention Act, which obligates employers to consider safer needle devices when they annually review and update their exposure control plan. AACC supported this legislation and believes it is a good starting point for ensuring that health care workers have greater access to safer medical devices.

Currently, the agency is considering a petition submitted by Public Citizen and the Service Employees International Union, which requests that the FDA ban certain medical devices (i.e., IV catheters, blood collection devices and blood collection needle sets) that could pose safety risks to health care workers. As you stated, however, the studies submitted in support of this petition do not provide "sufficient information to conclude that there is a legal basis for banning the devices."

Given the FDA's description of the study data, we concur with the agency's decision not to ban these devices. We think any decisions banning medical devices must be based on specific credible evidence, not extrapolations from general data sets. Further, we think the focus on banning medical devices is misplaced. AACC recommends that more emphasis be placed on ensuring adequate staffing, and providing necessary training to health care employees, such as phlebotomists, rather than debating whether these particular devices should be banned or adding new labeling requirements.

OLP-0120

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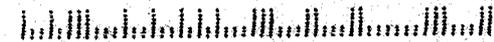
2101 L Street, NW, Suite 202
Washington, DC 20037-1526

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Dockets Management Branch (HFA-305)
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5630 Fishers Lane, Room 1061
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2101 L Street, NW
Suite 202
Washington, DC
20037-1558
Phone 202.857-0717
800.892.1400
Fax 202.887.5093
www.aacc.org

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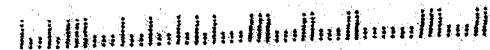
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FDA
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Page Two

By way of background, AACC is the principal association of professional laboratory scientists--including MDs, PhDs and medical technologists. AACC's members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and work in hospitals, independent laboratories and the diagnostics industry nationwide. The AACC provides national leadership in advancing the practice and profession of clinical laboratory science and its application to health care.

If you have any questions or we may be of any assistance, please call me at (302) 631-6870 or Vince Stine, Director, Government Affairs, at (202) 835-8721.

Sincerely,

A handwritten signature in cursive script that reads "Mary Lou Gantzer".

Mary Lou Gantzer, PhD
President

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