



American Health Care Association

1201 L Street, NW, Washington, DC 20005-4014
Main Telephone: 202-842-4444
Main Fax: 202-842-3860 · 2nd Main Fax: 202-289-4253
Writer's Telephone: 202-898-2828
Writer's E-Mail: croadman@ahca.org
www.ahca.org

Mary Ousley
CHAIR

Steven Chies
FIRST VICE CHAIR

Angelo Rotella
SECRETARY

Philip Caldwell
TREASURER

Blaine Hendrickson
IMMEDIATE PAST CHAIR

Tom Reddy
INDEPENDENT OWNER
VICE CHAIR

John Elliot
REGIONAL MULTIFACILITY
VICE CHAIR

Michael Walker
NATIONAL MULTIFACILITY
VICE CHAIR

Lynn O'Connor
NONPROPRIETARY
VICE CHAIR

Jan Thayer
ASSISTED LIVING
VICE CHAIR

J. Robert Wilson
CHAIR/COUNCIL OF REGIONAL
VICE CHAIRS

Fred Watson
PRESIDENT OF ASHCAE

Charles H. Roadman II, M.D.
PRESIDENT & CHIEF EXECUTIVE OFFICER

September 12, 2002

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

Dear Docket Officer:

The American Health Care Association (AHCA) and its assisted living component, the National Center for Assisted Living (NCAL) welcome the opportunity to offer our views to the Food and Drug Administration (FDA) on its advance notice of proposed rulemaking relating to needlestick injuries to health care workers. AHCA, together with NCAL, is a federation of state affiliates representing more than 12,000 non-profit and for-profit assisted living, nursing facility, MR/DD residential services and subacute care providers. These health care providers, who employ more than 1.2 million workers, many of whom are direct front-line caregivers, are committed to the safety and health of their employees.

AHCA submits the following comments on the specific issues raised by the FDA in response to the petition submitted by Public Citizen's Health Research Group (HRG) and the Service Employees International Union (SEIU) (67 Fed. Reg. 119):

A. Banning Certain Devices as Identified in the Petition

AHCA believes that the risk of illness and injury from needlestick injuries by the devices identified in the petition¹ does not meet the established standard of "substantial deception or an unreasonable and substantial risk of illness or injury," which is required to ban devices.² As an example, IV lines that essentially connect a sterile line to a line already inserted in a patient provide only minimal risk to health care workers (HCW). If the needle on the sterile line punctures the HCW before insertion in the second line, the risk to the health care worker would be related to the nature of the solution/drug contained in the line and, therefore, minimal. If the HCW

01P-0120

C9

¹ IV catheters, blood collection devices (needles and tube holders) and blood collection needle sets ("butterfly syringes") that do not meet the criteria identified in FDA's April 16, 1992 safety alert, glass capillary tubes, and IV infusion equipment that does not use needleless technology or recessed needles.

² 21 U.S.C. 360f, section 516.

is injured when the needle exits from the patient tubing, then a possible risk is present.

In addition, the regulation requires that, in determining whether the risk of illness or injury is substantial, the FDA will need to consider risk in relation to benefit to the public health. In the case of blood collection needle sets (“butterfly syringes”) for example, the benefit outweighs any risk. These devices are extremely beneficial to patients, such as the elderly and infants, where it is extremely difficult to maintain open lines. Retractable needles, in these instances, could interfere with treatment and the capacity to infuse fluids and medications in the patient.

AHCA questions why the FDA should ban glass capillary tubes when, according to information provided by the petitioners making the request, glass capillary tubes accounted for less than 1 percent of sharp object injuries in 52 hospitals. Clearly, the risk is minimal.

Under OSHA’s amended bloodborne pathogens standard (BBP),³ employers must document the extent to which they use, or have considered using, products that will minimize workplace exposure to needlesticks and other percutaneous injuries. Therefore, long term care facilities are required to annually review and evaluate the devices used in their facilities and to remain diligent in considering potentially safer products brought to market. An employer’s annual update must reflect changes in technology and consider employee safety and patient treatment, when documenting the selection of devices being used.

AHCA does not support the banning of these devices because these devices, in and of themselves, have not been shown to be an unreasonable and substantial risk. These devices, with proper employer/employee precautions, can be used safely and effectively to provide necessary medical care. We believe such a ban of these devices would unnecessarily limit patient care options without significantly reducing employee risk.

B. Performance Standard

Not one of the five design criteria identified in the FDA safety alert relate to ensuring the delivery of medical fluids to the patient. AHCA believes that a performance standard must include, along with criteria to protect the safety of the HCW, criteria to ensure the safety of the patient. In this case, delivery of medical fluids without compromise from re-engineered systems must be addressed if a performance standard is developed.

C. Labeling

AHCA agrees with the FDA that the labeling statement⁴ requested by HRG and SEIU provides information that already is well known to HCWs who use

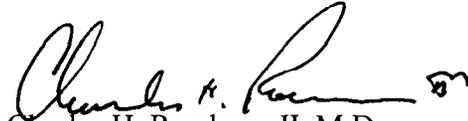
³ BBP standard, as amended on April 18, 2001.

⁴ “To prevent possible exposure to HIV and hepatitis, do not use for standard blood draws.”

conventional syringes. These medical devices are selected based on the need to preserve patient health and life. HCWs receive training to ensure their safety as they use these medical devices, as required by the Occupational Safety and Health Administration's (OSHA) BBP standard. Also in accordance with OSHA's BBP standard, all health care facilities have written infection control programs. The labeling is unnecessary and its costs unwarranted.

AHCA is concerned about significant health risks to direct care staff in long term care facilities, but we believe that the FDA should not take any of the actions requested by the petitioner. We note that HCWs are protected from needlestick injury through a number of actions that the FDA already has taken, e.g., safety alerts and guidance; through OSHA enforcement of its BBP standard; through the federal Needlestick Safety and Prevention Act and through state legislation in most states. OSHA's bloodborne pathogens standard, updated to comply with the Needlestick Safety and Prevention Act, already includes appropriate provisions for engineering and work practice controls, training, medical surveillance, hepatitis B vaccination, maintenance of a sharps injury log, signs and labels, as well as numerous other requirements to minimize the risk of disease transmission. Accordingly, for all of the above reasons, petitioners request should be rejected.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles H. Roadman II" with a stylized flourish at the end.

Charles H. Roadman II, M.D.
President & CEO

hca SCH
Health Care Association
Washington, DC 20005-4014

05/17/11

FIRST CLASS MAIL

Deekets Mgt Branch (HFA-305)
Fred & Ling John
5630 Fishers Lane, Rm 1061
Rockville, MD 20852