FDA SAFETY ALERT:

HEPATITIS B TRANSMISSION VIA SPRING-LOADED LANCET DEVICES

August 28, 1990

To hospital administrators, laboratory administrators, directors of nursing services, education coordinators, risk managers, and supervisors of infection control:

This is to alert you to the possibility of transmitting hepatitis B through the improper use of spring-loaded lancet devices (used for finger and heel sticks), and to provide guidance on reducing this risk.

FDA has learned from the Centers for Disease Control (CDC) of an outbreak of hepatitis B in a California hospital in which 27 cases occurred over a 10-month period. A common risk factor was the improper use of a spring-loaded lancet device. This device has a removable lancet and platform, which are intended to be discarded after each use. In the California cases, the platform was not removed between patients and was implicated as the most likely vehicle for transmission. As corroboration, similar cases have been reported in the medical literature and to FDA. (1, 2)

Although a single spring-loaded device was implicated in this outbreak, the potential for hepatitis B transmission exists with any spring-loaded lancet that is used on multiple patients if the lancet and platform are not removed and discard immediately after each stick. Concern about the improper use of these devices has been documented (3, 4). (There is also the possibility of transmitting other blood-borne pathogens, including HIV, although the risk is lower than for hepatitis B.)

To minimize the possibility of hepatitis B transmission, **FDA and CDC recommend the following precautions in using spring-loaded lancet devices:**

- As stated in the manufacturers' instructions, the lancet must be removed and discarded in the appropriate sharps containers between patients; likewise, the platform must be removed and discarded. The remaining device component should be cleaned and disinfected at the end of each day, and more frequently, if visibly contaminated with blood.

- Devices without a removable platform should only be used with one patient in the hospital or outpatient setting. After the patient is discharged, the device may be reused **only** if it is disinfected according to the manufacturer's instructions. If there are no instructions for disinfection, the device should be discarded.

- As with any procedures in which exposure to blood is possible, health care workers should observe universal blood and body fluid precautions to prevent the transmission of hepatitis B, HIV, and other blood-borne pathogens. (5)

I would appreciate your sharing this Safety Alert with those on your staff who might find it useful, particularly those caring for diabetics, and others who may be subjected to frequent finger and heel sticks.

If you have questions, please contact: J. Thomas Lowe, DDS, MPH, Deputy Director, Office of Health Affairs, Center for Devices and Radiological Health, FDA, at 301-427-1060.

Sincerely yours,

John C. Villforth
Director
Center for Devices
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Reference:

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2. Food and Drug Administration. Device Experience Network, access no.205114, July 21, 1990.
3. Drinka PJ. Spring-loaded lancets. N Engl J Med 1988; June 30:1762.
4. State of New York, Department of Health. Memorandum: Dafe use of capillary blood sampling devices. Series 90-22, May 23, 1990.
5. Centers for Disease Control. Recommendations for prevention HIV transmission in health-care settings. Morbidity and Mortality Weekly Report. Aug. 21, 1987;36(Suppl no. 2S):3S-18S.