FDA SAFETY ALERT:
Potential Hazards With Restraint Devices

July 15, 1992

To: Hospital Administrators, Directors of Nursing, and Directors of Emergency Room Services:

The Food and Drug Administration (FDA) is warning healthcare providers of the potential hazards associated with the use of physical patient restraint devices, such as safety vests, lap and wheelchair belts, and body holders.

We are issuing this warning because reports of deaths and injuries related to the use of these devices have increased over the last year. It is probable that still many restraint related deaths and injuries go unreported. The reports received by FDA encompass all restraint types, patient populations, and types of facilities. The FDA estimates there may be at least 100 deaths or injuries annually associated with the use of restraints, many deaths occurring when the patient is trying to get out of the restraint or while attempting purposeful behavior such as going to the bathroom.

Many of the incidents (fractures, burns, strangulations) seem to be the result of incorrect use of these devices, including inappropriate patient selection, incorrect restraint selection, errors in correctly applying the devices, and inadequate monitoring of patients when restrained. We have consulted with facilities, users, clinicians, and manufacturers to determine what factors may be contributing to hazards with physical restraints. We have also reviewed related regulations such as OBRA ’87 and the HCFA Guidelines. The following FDA recommendation are designed to emphasize and complement the HCFA Guidelines and to help decrease the incidence of deaths and injuries with these devices.

- Assess the cause for which the restraint is being considered, develop alternatives to restraint use, and implement these alternatives before applying restraints.

- Allow the use of restraints ONLY under the supervision of a licensed healthcare provider and for a strictly defined period of time.

- Define and communicate a clear institutional policy on the use of restraints (alternatives to restraint use, appropriate conditions for restraint use, length of wear time, etc.). This written policy should also be available for any patient/resident or any family member.

- Obtain informed consent from patient/resident or guardian prior to use. Patients have the right to be free from restraint. However, if it is determined that a restraint is necessary, explain the reason for the device to the patient/resident and guardian to prevent misinterpretation and to ensure cooperation.

- Display instructions for use in a highly visible location and interpret in foreign languages as necessary.

- Provide in-service training staff as regularly as possible which should include a return demonstration of proper application of restraints.

- Prior to use, read and follow the manufacturers directions for use:
    - Select the types of restraint that is appropriate to the patient’s condition.
    - Use the correct size.
    - Note the “front” and “back” of the restraint and apply correctly.
    - Secure restraints designed for use in bed to the bed springs or frame, NEVER to the mattress or the bed rails. If the bed is adjustable, secure restraints to parts of the bed that would move with the patient (not constrict the patient).
    - Tie knots with appropriate hitches so that they may be released quickly.

- Emphasize good nursing, rehabilitative, and patient care practices:
    - observe patients in restraints frequently.
    - Remove the restraints at least every two hours, and more often if necessary, and allow for activities of daily living.
    - Carefully apply the device and adjust properly so that it maintains body alignment and ensures patient comfort.
    - Continue assessment even after a restraint is used and discontinue use as soon as feasible. Restraint use should be considered a temporary solution to a situation.

- Clearly document in the patient's record the medical reason for use of the restraint, the type selected, and the length of time for treatment.
- Follow local and State laws regarding the use of protective restraint devices.

Currently, manufacturers of physical patient restraints are being notified of regulatory changes with respect to restraint manufacturing and labeling. Improved device labeling will be required, including the label "prescription only", and should appear on newly marketed devices late 1992. Accompanying graphics, and visual aids will also be encouraged. These improvements should provide facilities with additional instructions and bridge some languages barriers.

The Safe Medical Devices Act of 1990, effective November 28, 1991, requires that all hospitals, nursing homes, and acute care facilities report deaths and injuries related to the use of any medical device to the FDA. Discuss with your staff and management your procedures for reporting any death or injury related to patient restraints.

On the attached page are important messages for patients/residents and family members, which you may copy and distribute (using your own letterhead or address stamp, if you wish).

If you have additional questions about the physical patient restraint issue, contact Carol Herman, Office if Training and Assistance (HFZ-250), Center for Devices and Radiological Health, Food and Drug Administration, Rockville, Maryland 20857.

Sincerely ours,

James S. Benson
Director
Center for Devices and
Radiological Health

IMPORTANT TIPS FOR THE USE OF PATIENT RESTRAINTS

Physical patient restraints can be useful in protecting the patients/residents from falls and from wandering or straying. However, restraints are not the only solution to these difficulties and in some cases may be more dangerous. The following are important tips that can make more aware of when and how restraints should be used. It will also help you identify problems which could have serious consequences if not responded to.

Patient Rights	Patients/residents have the right to be free from restraints. Restraint use should not be a first choice solution. Before allowing yourself or a loved one to be restrained, be sure to understand the reason for the restraint use, request a limited time frame for restraint use, and be sure that all other solutions to the problem have been exhausted.
Facility Policy	All health care facilities must have a written policy on use of patient restraints. Ask to see this document and be sure that you understand and are comfortable with the policy set forth by your facility.
Prescription Device	Restraints are prescription devices and may only be used if a physician, or orther healthcare professional licensed to prescribe in your State, has specifically ordered a restraint for an individual. The need for the restraint must be well document in the patient chart and assessment of the need should continue even after the device has been ordered.
Patient Criteria	Not all patients/residents are appropriate for restraint use. For example, an agitated or seriously confused patient may not be a good candidate for restraints. The use of restraints may only add to this agitation or confusion and place the patient in jeopardy as he/she may try to escape from the device. These medical symptoms combined with the use of a restraint may lead to a serious injury or death.
Appropriate Size	It is very important to be sure that the appropriate size o restraint is selected. A restraint that is too small will be uncomfortable for the patient and may cause agitation or constriction of bodily parts. A restraint that is too large or loose, where the patient can slide down or forward, may result in asphyxiation.
Good Labeling	Manufacturers of patient restraints are being required to develop better labeling. They are also being encouraged to use graphic in improved labels, sewn directly on the device, to help ensure proper application. Look for these labels and alert a healthcare provider if it appears a device is on incorrectly or a patient is uncomfortable in a restraint.
Proper Use	For wheelchair use, be sure that the patient is upright and securely seated in the chair before applying the restraint. See device directions for correct application. Incorrect applications is more likely to result in the patient sliding forward which may result in asphyxiation. For use in a bed, be sure the restraint is NEVER tied to the bed rails or mattress. The restraint should only be tied to the bed springs. Also, most restraint are not indicated for use with regular beds or regular chairs, including geri-chairs. Consult the manufacturer labeling for correct application of the restraint to any bed or chair.
Length of Wear	Any patient/resident in a restraint must be free of that restraint at frequent intervals to ensure good patient health. Long-term immobilization can contribute to various health problems including decubitus ulcers, nerve damage, incontinence, and sensory deprivation. Consult with the facility policy for the maximum length of each period of restraint use. During the time when the patient is free of restraint, be sure that exercise, such as walking, is available and encouraged.

Patient Monitoring	Patients/residents must be monitored frequently while wearing a restraint device. As with any other medical device, supervision and monitoring are critical to ensure the safety of the patient.

Ask your facility what alternatives exist or are being developed to reduce the use of restraints. Restraints should never be used a substitute for nursing care. They are an adjunct to proper care. In many cases, volunteers may be all a facility needs to help keep patients free from restraints. However, if you are aware of potential dangers of restraint use and know what to look for and what to do if you see a restraint being used incorrectly, it could save a patient from a serious injury or even death.