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In Reply:—Astra attempts to diligently monitor the safety and effectiveness of its products and, in this effort, carefully evaluates all spontaneous reports from health professionals throughout the United States. Reports such as Mr. Jackson's enable us to become aware of problems, and allow us to take expeditious corrective action.

Review of our files indicates that a total of 12 similar complaints from seven reporting sources have been received since 1983. There have been no reports of patient injury associated with any of these reports.

Astra receives tubes and lined tube caps preassembled from a supplier. The individual cap liners are produced by a punch-out process from a large sheet of mylar liner bound to a pulp backing. We believe that rare detachment of the mylar liner from the pulp backing may be the result of occasional small areas of incomplete bonding between these two materials.

Accordingly, we have contacted the supplier of tubes and tube caps used for Xylocaine® Ointment and Xylocaine® Jelly, and are seeking implementation of additional measures to assure that the pulp-plastic laminating step in preparing the cap liner is performed such that the lamination is always uniform and complete.

Other measures being investigated include the introduction of a new closure system which would not require a mylar liner bound to pulp for effective tube closure.

In addition, we have applied to the Food and Drug Administration for use of an easily visualized black rubber liner in the tube caps of Xylocain® 2% Jelly. This would allow immediate detection, by the practitioner, of improper liner detachment from the cap, should it occur.

Astra continues to actively pursue this matter in order to assure correction of the problem. We thank Mr. Jackson and Dr. Welch for notifying us of their concerns, and encourage all practitioners who encounter similar situations to do the same.

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