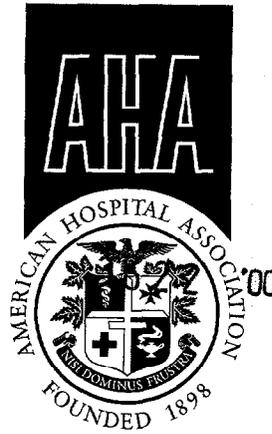


January 26, 2000

Jane Henney, M.D.
Food and Drug Administration Commissioner
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852



Ref: Proposed Rule for Surgeon's and Patient Examination Gloves; Reclassification (64 *Federal Register* 146), July 30, 1999

Dear Dr. Henney:

The American Hospital Association (AHA) represents nearly 5,000 hospitals, health care systems, networks, and other health care organizations, and more than 37,000 personal members employed in the health care field. On behalf of our members, the AHA is pleased to offer comments to the Food and Drug Administration (FDA) on its proposed rule to reclassify surgeons' and patient examination gloves as class II medical devices.

Medical gloves are properly viewed as medical devices and, as such, we believe FDA is charged with regulating their labeling, ingredients, manufacturing, testing and approval. We are pleased that some of the proposed FDA regulations may assist hospitals, health systems and health care workers in making more-informed choices about which type of medical glove to use. But we are concerned that certain provisions will add to the confusion surrounding natural rubber latex (NRL) allergies, and may discourage the use of medical gloves that protect our patients and employees from life-threatening diseases.

The AHA supports efforts to safeguard the health and safety of all workers in the health care delivery setting, including measures to ensure that medical gloves provide effective barrier protection against bloodborne pathogens, including the human immunodeficiency virus (HIV) and hepatitis B and C. Medical gloves are crucial not only to health care workers but to our patients as well. The integrity of medical gloves' barrier properties must be maintained whenever new regulations are proposed. The AHA strongly agrees with the FDA that the reduction of powder and protein levels in medical gloves must be accomplished by methods that do not compromise the availability of or barrier properties of surgeons' and patient examination gloves.

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There is a great deal of confusion surrounding NRL allergies and how to effectively reduce the risk of NRL exposure to those with NRL allergies. Hospitals and health systems are concerned about the cause of skin reactions under gloves (some are truly allergic reactions to NRL, while others are allergic reactions to chemicals used in the making of NRL and non-NRL gloves); the lack of availability or standardization of methods to diagnose NRL allergies; confusion over the barrier effectiveness of non-NRL gloves; the cost of non-NRL gloves; and the lack of conclusive clinical data on the efficacy of powder-free NRL gloves and glove liners in lowering the potential for allergic reaction to NRL.

More confusion arises over glove powder. Some health care professionals believe that skin reactions under gloves are due to glove powder. While skin reactions may be attributed to NRL proteins or chemical additives that are found in NRL and non-NRL gloves, there is no evidence that they are attributable to glove powder. For that reason, to put FDA's proposed statement: "Caution: Glove powder is associated with adverse reactions. FDA recommends that this product contain no more than 120 mg powder per glove. This product contains no more than [insert level] mg powder per glove" (p. 41715) as a warning on powdered synthetic gloves, but not on any other type of powdered glove, will add to the confusion over NRL allergies.

Powder used for lubricating patient examination gloves must meet the United States Pharmacopoeia (USP) specifications for absorbable dusting powder or be shown to be equivalent in terms of safety and effectiveness. Powder used for surgeons' gloves is a class III device and must be supplied by a manufacturer that has an approved FDA Premarket Approval Application (PMA) or New Drug Application (NDA). The majority of glove manufacturers use cornstarch as glove powder because it is a resorbable particle and it has been approved by the FDA for lubricating gloves. If new studies or data exist to indicate that cornstarch or its equivalent is causing harm to patients or health care workers, the FDA should address these concerns through the USP or its PMA and NDA authority. Requiring cautionary labels on some powdered gloves but not on others is inconsistent, confusing, misleading and may discourage the use of medical gloves. **AHA urges FDA not to mandate cautionary labels about glove powder on either synthetic or NRL medical gloves.**

Hospitals and health systems throughout the country have been taking steps to ensure that patients and health care workers who have a NRL allergy are protected from exposure. They do this through protocols that include health screenings of patients and health care workers; evaluating and managing personnel with a suspected or known NRL allergy; establishing surveillance for NRL reactions; purchasing medical gloves according to barrier effectiveness and worker acceptance; and measuring the impact of preventive measures. Educational materials and activities are provided to health care workers about

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appropriate glove use and the symptoms and potential risk of NRL allergy. Hospitals and health systems also provide alternative gloves to employees who have an allergy to NRL or to chemical additives that are found in NRL and non-NRL gloves. Some hospitals have made the decision to limit the use of NRL in their facilities. While we support such voluntary initiatives, we cannot, based on current scientific data, support governmental efforts that would limit the current availability of medical gloves.

The availability of different types of medical gloves is crucial to health care workers and patients in the fight against deadly bloodborne pathogens. It has been demonstrated that NRL has more-effective and durable barrier qualities when compared to synthetic materials, including vinyl. Powdered NRL gloves have additional qualities, such as tactile sensation, sensitivity, and ease of donning, that are currently unmatched by any other glove. While we acknowledge that powder may play a role in aerosolizing NRL proteins, it is important to consider, and maintain the availability of, the qualities that are unique to powdered NRL gloves. We urge the FDA to continue to balance the known risks of deadly bloodborne pathogens with the relative risk of developing an allergy to chemicals or NRL proteins when making decisions about what types of medical gloves may be marketed in the U.S. **The AHA urges FDA to reject establishing a future requirement that all medical gloves marketed in the United States be powder-free.** Such a requirement would be over-reaching and would make unavailable the powdered gloves that many caregivers depend on to deliver high-quality medical care.

The AHA also believes that the FDA acted appropriately in rejecting a requirement for special air handling systems at the point of use for health care facilities using powdered surgeons' and patient examination gloves with powder levels over 120 mg per glove. This requirement is not supported by scientific data. The use of special air handling systems to effectively reduce the amount of NRL proteins in health care facilities and prevent allergies to NRL is questionable at best. In the future, the FDA should continue to take into account the potential ramifications of this requirement, including the relative risks and benefits and the requirement's cost implications for hospitals and health systems.

The AHA supports FDA's efforts to enable medical providers to distinguish between powdered and non-powdered gloves and to choose the glove type appropriate for their needs. Safeguarding the health and safety of all patients and workers in hospitals and health systems is a profound responsibility that our members take very seriously. It is vital to recognize the benefits medical gloves offer health care workers and patients, and to not unnecessarily discourage the widely accepted use of medical gloves, including powdered and NRL gloves.

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We thank you for the opportunity to comment on FDA's proposed rule. Should you have any questions about our comments, please contact me, Carmela Coyle, senior vice president for policy (202-626-2266) or Robyn Cooke, state issues forum coordinator (202-626-2672).

Sincerely,

A handwritten signature in black ink that reads "Rick Pollack". The signature is written in a cursive, flowing style with a large initial "R".

Rick Pollack

Executive Vice President

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