

# FDA Initiates Stricter Medical Glove Standards

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The Food and Drug Administration has issued a final rule that would require medical glove makers to improve their products' ability to serve as a barrier against pathogens.

Manufacturers are being given 2 years to comply with the new regulations.

The goal is to reduce the risk of transmission of bloodborne pathogens such as

HIV and hepatitis B, according to the FDA. While the agency can't quantify how many cases might be prevented with better barriers, it estimated that approximately 2.4 HIV infections occur each year due to "problems with the barrier protection properties of gloves used in health-care settings."

The FDA estimates that 140 health care workers are infected with the hepatitis B virus (HBV) on the job each year, primarily from percutaneous injuries. About a third, or 40 cases, may be due to glove

defects, according to the agency.

There is less evidence that glove defects are associated with hepatitis C, said the agency, noting that most occupational exposures are from needle sticks.

The agency has inspected gloves—used for patient examinations and surgical procedures—since 1990. At that time, the International Organization for Standardization (ISO), ASTM International, and the FDA had the same standards for glove quality. A few years later, the ISO and

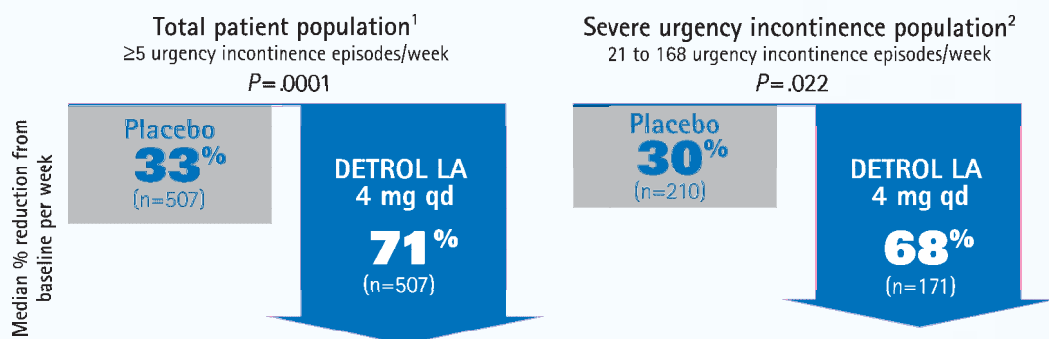
ASTM began requiring higher standards.

The agency has allowed a defect rate of 4% for gloves used during patient exams and 2.5% for gloves used in surgery.

With more and more brands of gloves being marketed and sold, the agency hopes to maintain that defect rate. To do so means increasing the quality standards, said the agency.

The FDA estimates that about 2% of the 39.2 billion gloves currently marketed are defective—some 940 million gloves. ■

DETROL LA is the #1 prescribed brand for OAB\*—  
with **BIG REDUCTIONS** in OAB symptoms<sup>1,2</sup>



Van Kerrebroeck et al. *Urology*. 2001;57:414-421.<sup>1</sup>  
A 12-week, placebo-controlled OAB study.  
See full study description on next page.

Landis et al. *J Urol*. 2004;171:752-756.<sup>2</sup>  
A post hoc subgroup analysis of Van Kerrebroeck et al.  
See full study description on next page.

DETROL LA is indicated for the treatment of overactive bladder with symptoms of urge incontinence, urgency, and frequency. DETROL LA is contraindicated in patients with urinary retention, gastric retention, or uncontrolled narrow-angle glaucoma and in patients who have demonstrated hypersensitivity to the drug or its ingredients. DETROL LA capsules should be used with caution in patients with clinically significant bladder outflow obstruction, gastrointestinal obstructive disorders, controlled narrow-angle glaucoma, and significantly reduced hepatic or renal function. Dry mouth was the most frequently reported adverse event (DETROL LA 23% vs placebo 8%); others (≥4%) included headache (DETROL LA 6% vs placebo 4%), constipation (DETROL LA 6% vs placebo 4%), and abdominal pain (DETROL LA 4% vs placebo 2%).

\* Source: IMS NPA, based on total US prescriptions of antimuscarinics for OAB from October 2001 to December 2005.

† Source: IMS Midas Global Sales Audit, Verispan longitudinal data, based on total prescriptions of DETROL and DETROL LA for OAB from April 1998 to December 2005.

74 million prescriptions<sup>†</sup>  **Detrol<sup>®</sup> LA**  
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