



SEE MISSION STATEMENT JANUARY 2010

AMERICAN ASSOCIATION OF EYE & EAR CENTERS OF EXCELLENCE

January 11, 2010

The Honorable Margaret Hamburg
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 21244

Dear Commissioner Hamburg:

On behalf of the American Association of Eye and Ear Centers of Excellence (AAEECE), formerly the American Association of Eye and Ear Hospitals (AAEEH), and the patients we serve, I am writing to ask your assistance with an issue that continues to threaten patient safety in our facilities and for many ophthalmic patients. The issue relates to look-alike sound-alike (LASA) ophthalmic medication errors.

Background

The AAEECE is comprised of the world's premier centers for specialized eye and ear procedures. Eye and ear specialty hospitals have led the way as providers of high-quality, cost-effective outpatient health care services. The mission of these specialty institutions requires that they maintain leading edge technologies, enabling them to provide highly specialized services not available in general hospitals. AAEECE member facilities serve as models of cost efficiency and high-quality care when surgery and services are rendered by specialty hospitals on an outpatient basis. Association members are major nation-wide referral centers with a commitment to teaching, research and hands-on patient care of the highest level of quality. These specialty hospitals routinely treat the most severely ill eye and ear patients.

The LASA Issue

In an operating room a nurse mistakenly selects a cyclopentolate 1% 2mL ophthalmic solution instead of a tropicamide ophthalmic solution 3mL from a standardized dilation tray. A pharmacist dispenses a 5mL tobramycin and dexamethasone ophthalmic suspension instead of a 5mL 1% prednisolone acetate ophthalmic suspension from his supply of ophthalmic medications. A physician dispenses a 2.5 mL diclofenac 0.1% solution instead of a flurbiprofen 0.03% 2.5mL solution to her patient in her medical office. At a Veterans Administration Center eardrops were dispensed as eye drops following cataract surgery¹. An elderly patient with glaucoma incorrectly

¹ "And the 'Eyes' have it": Eardrops, that is..." ISMP Medication Safety Alert!. The Institute of Safe Medication Practices. 11/19/06; Vol 11:Issue 21, pg 1-2

self-administers his glaucoma eye drops instead of his anti-inflammatory eye drops because “the letters and bottles all look the same to me”. These are just some examples of ophthalmic medication related LASA medication errors that occur on a daily basis here in the United States and worldwide in hospitals, pharmacies, physician offices, ambulatory clinics or in a patient’s home.

Medication errors due to LASA drugs are unfortunately common in the United States and are responsible for thousands of injuries, deaths, and millions of dollars in cost each year. Up to 25% of all medication errors are attributed to product name confusion, while 33% have been attributed to packaging and or labeling confusion². According to the MEDMARX Data Report published by the United States Pharmacopoeia (USP) in 2008, 26,000 records were reviewed and a list of 3,170 look-alike sound-alike drug names were identified that may have contributed to healthcare practitioner related medication errors. In this study, records were collected from 670 healthcare facilities participating in the USP’s Medmarx program and from 512 records that were collected from the Institute of Safe Medication Practice’s Medication Error Reporting Program. Of the 25,000 errors that were identified, 64.4% originated in the dispensing phase of the medication process. It was also determined that 1.4% of the total errors identified resulted in patient harm³.

Dispensing or administering, ophthalmic solutions or suspensions are especially problematic when one considers existing manufacturer specific color-coding of bottles and the repetitive use of similar lettering and company symbols. In 1996 the problem was unintentionally exacerbated for hospitals and other providers, when the Academy of Ophthalmology (AAO) endorsed a color-code scheme system of identifying eye drops by therapeutic class in an effort to minimize ophthalmologist drugs selection errors. This system was later approved by the FDA and manufacturers on a voluntary basis. Examples of this system include: anti-infectives ophthalmic containers and caps have tan caps and backgrounds, mydriatics and cycloplegics containers use a red cap and background, miotics use green, beta-blockers use yellow or blue, and so on. According to an AAO spokesperson, “The system results in a time saver for the physician who can read the label on the drugs once- at the beginning of the day” (www.fda.gov/cder/meeting/part15_3_2005/Transcript.pdf).

The Institute of Safe Medication Practices (ISMP) later observed “that despite the Academy’s intention to reduce errors, the downside of color coding products in this manner is that items within each class become more difficult to differentiate. Also when similar corporate logos, fonts, package sizes, and color combinations are factored in, what may work well in an office setting or in a patient’s home does not necessarily work well in the hospital setting, pharmacies or on the nursing units.”⁴ In 2005, despite the ISMP’s effort to convince to change their color coding system on the basis of improving medication and public safety, no changes were made to any ophthalmic bottles, labeling, colored caps, or containers.

In 2009, as part of the new National Patient Safety Goals, The Joint Commission, which grants accreditation to healthcare organizations, in conjunction with the Centers for Medicare and

² Berman, Adrienne. Reducing Medication Errors Through Naming, Labeling, and Packaging. February 2004; Journal of Medical Systems, Vol 28, Number 1, pgs 9-29

³ Thompson, Cheryl A. USP Says Thousands of Drug Names Looks or Sound alike”. AJHP News. American Society of Health System Pharmacists. March 1, 2008; www.ashp.org/import/news/HealthSystemPharmacyNews/newsarticle.

⁴ “Caution regarding color-coded eye meds. ISMP Medication Safety Alert!. April 21, 2008, Vol 13.Issue 8;pg 1-2

Medicaid Services (CMS), advocated that all healthcare systems, at minimum, on an annual basis review a list of look-alike sound-alike medications and takes actions to prevent errors involving the interchange of these medications⁵. In addition other organizations such as the American Society of Health-System Pharmacists (ASHP), The Institute for Safe Medication Practices (ISMP), The American Pharmaceutical Association (APhA), The Institute of Medicine (IOM), the United States Pharmacopoeia (USP), The National Coordinating Council for the Prevention of Medical Error Reporting and Prevention (NCCMERP), The Massachusetts Coalition for the Prevention of Medical Errors, The American Medical Association (AMA), the American Nurses Association (ANA), and countless other healthcare organizations have published prevention Strategies for Hospital Care and the elimination of such look-alike sound-alike medication related errors. In fact, if one were to Google the terms “look alike eye drop errors” one would find a listing for 33,600 related articles of which a multitude of articles and examples of LASA errors are included. Last, it is also of interest that law firms have also posted ophthalmic drug safety tips on their websites that address how potential clients can avoid eye drop related LASA errors after they receive their medication(s) from a pharmacy, physician’s office or hospital.

Regulatory Policy Recommendation

In an effort to directly address these medication safety issues that affect our hospitals, physicians, nurses, pharmacists, and patients on a daily basis, the AAEECE strongly recommends that the FDA and pharmaceutical manufacturers of ophthalmic solutions and suspensions consider abandoning the color coded system that was implemented in 1996, ensuring that all ophthalmic drugs are provided in clearly labeled containers that are easily distinguishable in the clinical practice setting as well as in the homes of our patients. We will invite the American Academy of Ophthalmology to join us in working together with the pharmaceutical companies, nationally and internationally, to address and correct this ongoing patient safety issue.

Packaging and drug labeling must differ based on the volumes of the medications to further distinguish one product from the other (an example of such a problem is seen with pilocarpine 15ml from Falcon where the 1% bottle and the 4% bottle look identical). In addition we would like to advocate new patient safety strategies that have already been successfully implemented in hospitals throughout the United States. These include the use of tall men lettering systems on product labels to minimize LASA reading errors (ex. Tobrex® and Tobradex®).

We ask the FDA to work with manufacturers to be more sensitive to the visual limitations of their patients who are at the greater risk for selecting an incorrect ophthalmic solution, especially when multiple eye drops have been prescribed by their physicians for treatment. Manufacturers must be urged to review existing policies and practices of packaging drugs which include a review of color schemes, fonts, plastic wrapping designs and logo placement on external boxes as well as on the actual bottle which holds the medications. We also ask that the pharmaceutical manufacturers take these concerns seriously and adopt new and innovative safety practices when naming and manufacturing new ophthalmic solutions and containers (ex. Cosopt® and Azopt®). Risk assessments programs should also be performed prior to the marketing of new drugs, which take “front line” healthcare feedback, including risks associated with the administration, storing, and distribution of potential LASA meds, into consideration.

⁵ National Patient Safety Goal 3.03.01; The Joint Commission Accreditation Standards 2009 E-dition; <http://e-dition.jcrinc.com/Frame.aspx>.

We have included photos of 16 groupings of ophthalmic solutions and suspensions which we consider LASA drugs groupings that have resulted in patient medication errors due to their similarities. These photos have been printed both clearly and blurry to further emphasize how easy it is for healthcare practitioners and patients alike, with or without visual disturbances, to be involved in medication errors which may ultimately result in patient harm.

There are immediate steps that could help reduce these LASA errors. We recommend the FDA urge all healthcare systems and the public to remain vigilant when handling or using these products to avoid medication errors. We advocate the storing of LASA drugs in separate areas (not next to each other) to further minimize risk. We advocate the use of LASA stickers as utilized in healthcare systems to alert healthcare professionals when using LASA ophthalmic medications. All healthcare practitioners must be urged to communicate these potential risks with their patients as well as with the caregivers of those patients who may be visually impaired themselves.

We urge the FDA to bring attention to this problem by addressing these issues with wholesalers and the pharmaceutical companies who label these medications. We strongly recommend that labeling practices for otic products also be reviewed so as to avoid the potential for selecting an ophthalmic drug instead of an otic drug or vice versa. A 2006 report from the VA National Center for Patient Safety stated that one-third of VA facilities, which employed bar coded drug administration for additional safety, had documented cases in which eardrops had been placed in patient eyes.⁶

As advocates for the patients we serve, the AAEECE will work with our members in Congress calling their attention to this patient safety issue. Likewise we will contact other healthcare professional advocates inviting them to champion this cause which affects constituents and citizens who require ophthalmic medications nationally.

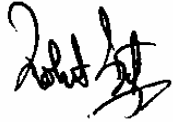
In conclusion, we strongly urge the FDA to address these issues and specifically for the FDA's Drug Safety and Risk Management Advisory Committee to take a leadership role in reviewing these serious problems which endanger public safety, and increase the medical, legal, and financial burden of our national healthcare system.

The AAEECE looks forward to working with you in addressing and resolving these serious hospital and public safety issues.

We thank you in advance for your consideration. Please contact the AAEECE if we can provide you with any additional information or assistance.

Sincerely,

⁶ "And the 'Eyes' have it": Eardrops, that is..." ISMP Medication Safety Alert!. The Institute of Safe Medication Practices. 11/19/06; Vol 11: Issue 21, pg 1.



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AAEECE ATTACHMENT

LOOK-ALIKE OPHTHALMIC MEDICATIONS

***Note – For demonstration purposes, products on left are clearly presented while products on the right are intentionally blurred to show how a patient with slight vision impairment might see the products.**









LOOK-ALIKE OPHTHALMIC/OTIC MEDICATIONS



For the Worldwide Patient Safety Initiative Mission Statement,
as of January 2010, please click [here](#).

Thank you