Department of
Ophthalmology

1653 West Congress Parkway
Suite 906 Prof. Bldg I
Chicago, Illinois 60612-3833

Tel 312.942.5570
Fax 312.942.2140
www.rush.edu

RUSH UNIVERSITY
COLLEGE OF NURSING
RUSH MEDICAL COLLEGE
COLLEGE OF HEALTH SCIENCES
THE GRADUATE COLLEGE

RUSH
RUSH-PRESBYTERIAN-ST. LUKE'S
MEDICAL CENTER

May 21, 2004

Comments in response to Docket # 2004N-0221; Study on Making Prescription Pharmaceutical Information Accessible for Blind and Visually Impaired Individuals.

Recent studies have indicated that by the year 2020, the number of blind citizens in this country is expected to increase by 70% (Congdon NG, Dejong PT, Klein BE et al. The Eye Disease Prevalence Research Group, AGS, March 2003). As medication errors are a significant cause of morbidity and mortality among all population segments, the importance of providing accessible and understandable medication use information to populations considered at greatest risk for medication error is of utmost importance.

Although CFR Title 21 Subpart C stipulates guidelines for print size concerning drug information on the "principal display panel" for OTC products, currently no such federal standards exist in regard to consumer labeling for legend drugs. Print size, font, contrast and effect of wrap-around are just a sample of factors that contribute to legibility of labels affixed to standard 10 dram vials, a common drug container size used in retail pharmacies.

Although numerous studies have examined medication dispensing practices within the hospital and health care setting, little is known concerning home medication management practices. Home medication management is particularly relevant considering the growing number of older individuals living independently at home without caregiver support. Although general loss of sensory function and physical impairment are well known correlates with aging, perhaps the best predictor for risk of home medication error is vision impairment.

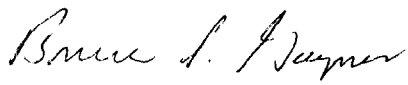
Our preliminary work in the area of medication use accessibility among the elderly and visually impaired has indicated significant variation in print size of consumer legend drug labeling. Moreover, our studies have indicated that despite assumptions by health care providers, many visually impaired individuals are required to manage their home medication use independently due to lack of caregiver support. We have also shown that various aspects of prescription drug labeling, such as the "auxiliary label" are markedly deficient in terms of accessibility of medication use information. A sample of recently published abstracts outlining our work is enclosed with this statement.

2004N-0221

C1

I applaud Congress for taking the initiative to study the problem of drug information accessibility within the various population segments. This mandate certainly supports our preliminary data demonstrating a need for continued study of current Rx labeling practices. In addition, I believe this mandate echoes our own study goals for the development of rational, cost-beneficial methodology easily adopted by community pharmacies for the purpose of providing accessible, population specific medication use information.

Sincerely,



Bruce I. Gaynes, OD, PharmD
Assistant Professor, Ophthalmology and Pharmacology
Rush University College of Medicine
Chicago, IL
Bgaynes@rush.edu

Home medication management by the visually impaired

BI. Gaynes[1], A Rosenbloom[1,2].

1. Rush University Medical Center, College of Medicine, Department of Ophthalmology
2. Chicago Lighthouse for the Blind and Visually Impaired

Purpose: To describe methodology visually impaired individuals utilize in home medication management. **Methods:** Survey assessment of consecutive individuals presenting for low vision evaluation at the Chicago Lighthouse for the Blind and Visually Impaired. The survey includes a subjective measure of compliance as well as medical and drug history, information regarding visual acuity, type of low vision aid used, role of a caregiver, and use of devices such as cassettes, audio devices or other patient specific mediation use aids. Data collection is ongoing. **Results:** 20 subjects have been enrolled to date with an age range of 41-97 years with a mean age of 72 and a median of 75. On average, each subject utilized 6 prescription drugs per day. Best-corrected near visual acuity with low vision aids ranged from 20/50 to 20/1600. 40% did not utilize a caregiver to assist in any form of medication management. Among the 40% who did not use a caregiver, best corrected vision with low vision devices ranged from 20/50 to 20/400. 16% of those who did not utilize a caregiver for medication management could not read prescription labeling, even with low vision aids. 63% of the individuals who did not rely on a caregiver for medication management did not use any form of medication management aid. However, the most commonly used medication aid among all subjects was a weekly medication cassette. **Conclusions:** A high proportion of our study sample did not utilize a caregiver for medication management. Furthermore, low vision aids play a valuable role in medication management, particularly in those without caregivers. Visually impaired patients may not have access to caregiver support for medication management despite assumptions by health care providers. Validity is limited by small sample size. Data collection is ongoing. Supported in part by the Louise C. Norton Trust, Chicago, IL.

Print size and readability of consumer prescription drug labeling based on near visual acuity among older adults.

Bruce I. Gaynes, OD, PharmD[1] Martin J. Gorbien, MD[2] Joyce Cramer BS[3] David M. Yasutake, PhD[4] Marlos Viana, PhD[5] Elaine Chen, BS[3] Denise Voskuil-Marre BS[3]

1. **Rush University College of Medicine, Departments of Ophthalmology and Pharmacology, Chicago, IL**
2. **Rush University College of Medicine, Section of Geriatric Medicine, Chicago, IL**
3. **Rush University College of Medicine, Department of Ophthalmology, Chicago, IL**
4. **Northeastern Illinois University, Department of Special Education, Chicago, IL**
5. **University of Illinois, Eye and Ear Infirmary, Section of Biostatistics, Chicago, IL**

Purpose: To describe typical print sizes and readability of prescription drug (Rx) labeling among older adult individuals. **Methods:** Descriptive, cross-sectional assessment of ambulatory adults 59 years of age or greater. One prescription drug was obtained from each of five randomly selected community retail pharmacies. All medications were dispensed in round 5-10 dram vials. The size of the lettering components on each label was measured with a 7X handheld-lighted magnifier with a reticule of 0.5-mm. Following cognitive screening and measure of best corrected near visual acuity, subjects were asked to identify and read various elements of the Rx labeling on 5 randomly presented prescription vials at 50-75 foot-candle illumination. Subjects were encouraged to hold the vial at any distance that allowed them to read the labeling confidently. **Results:** 153 subjects were studied. Mean age was 74 years. Mean best corrected near visual acuity was 20/50. 39% of participants had a best-corrected near vision of worse than 20/50, 16% measured 20/100 or worse. Print size on Rx labels ranged from 1.0 mm to 3.25 mm on the main label and from 1.0 mm to 5.0 mm on auxiliary labels. Approximately 30% of those with 20/50 or worse corrected near vision could not see the print of one or more Rx label components. **Conclusions:** Various Rx label elements are inaccessible to older adults with 20/50 or less visual acuity due to inadequate print size. There is a direct correlation between declining visual acuity and readability of print size between 1.0-1.7 mm in height. Print size > 1.74 mm in height offered sustained readability up to visual acuity levels of 20/100. Relative distance magnification likely accounted for discrepancies between lowers levels of visual acuity and print readability.
Supported in part by the Louise C. Norton Trust and Envision America.

Poster No. 208

DEMOGRAPHIC ATTRIBUTES CONTRIBUTING TO PRESCRIPTION DRUG LABEL READING ACCURACY WITHIN AN OLDER ADULT POPULATION

Ying Cao MEng, Bruce I Gaynes OD, PharmD, Joyce Cramer, Martin Gorbien MD, Marlos Viana PhD, David Yasutake PhD
Ophthalmology
RUSH

PURPOSE: To describe demographic features that contribute to accuracy in reading prescription drug (Rx) labels among adults' age 59 or older

METHODS: 153 subjects, average age 74 years, were asked to read pharmacy names, addresses, instructions for medication use, and drug names from 5 different drug vials varying in size from 5-10 drams. Gender, level of education, daily reading habits, native language, use of reading spectacles and medical, drug, and ocular histories were analyzed against ability to correctly read drug labels All prescriptions were obtained from community retail pharmacies.

RESULTS: The most significant determinants in demonstrating accurate reading of Rx labels were patients' educational level, daily reading practices and habits regarding use of reading glasses. Compared to individuals with less than an 8th grade education, the number of subjects who correctly read drug labels was 9.4% and 12.7% higher in those with an 8th grade or high school education respectively The number of subjects who correctly read Rx labels was 9.86% higher among subjects who were read items such as a newspaper on a daily basis compared to those who read infrequently Individuals who ordinarily utilized reading glasses read Rx labels 16 4% more accurately than those who did not require reading glasses or normally did not use them. Subjects with fewer medical diagnoses read labels slightly more successfully than individuals with a more complex medical history Remaining factors such as number of daily prescription drugs used, presence of ocular disease, gender or whether or not English was their native language did not show consistent correlation with ability to correctly read drug labels.

CONCLUSION: This study confirms presumptions that older individuals who lack an 8th grade education and/or those who read infrequently would be at most risk for reading Rx labels incorrectly. Diversity in terms of native language does not appear to influence accuracy in terms of reading an Rx label. Older adults who simply wear a required near spectacle correction for reading Rx labels may benefit from greater reading accuracy and perhaps avoid a costly medication error. Supported in part by the Louise C. Norton Trust and Envision America.