

FDA's Communication of Drug Safety Information Hearing

Drug Labeling for Limited English Proficiency (LEP)

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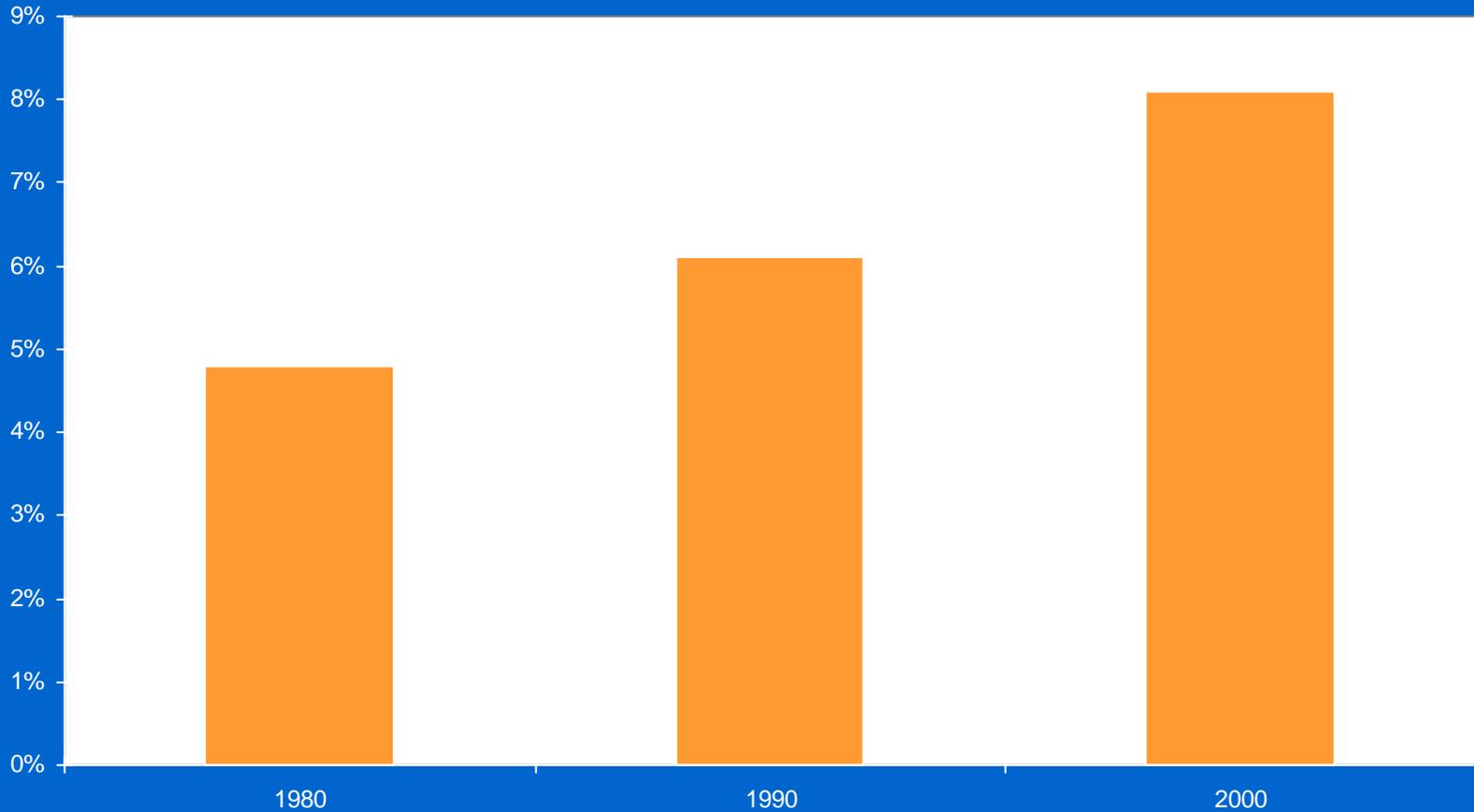
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“In 2000, 4.4 million households encompassing 11.9 million people were linguistically isolated. These numbers were significantly higher than in 1990, when 2.9 million households and 7.7 million people lived in those households.”

US Census Bureau, Language Use and English-Speaking Ability:
2000 (Oct. 2003)

LEP as a % of US Population



Source: US Census (2003)

Nexium[®]
(esomeprazole magnesium)



Cupon Gratis
Para 7 Dias

Mas informacion
sobre NEXIUM

F.A.Q.s

Cupon Gratis
Para 7 Dias



CONTRAINDICACIONES

NEXIUM está contraindicado en pacientes con hipersensibilidad conocida a algún componente de la fórmula o a los benzimidazoles sustituidos.

FDA Nexium Label

CONTRAINDICATIONS

NEXIUM is contraindicated in patients with known hypersensitivity to any component of the formulation or to substituted benzimidazoles.

Clarithromycin is contraindicated in patients with a known hypersensitivity to any macrolide antibiotic.

Concomitant administration of clarithromycin with pimozide is contraindicated. There have been post-marketing reports of drug interactions when clarithromycin and/or erythromycin are co-administered with pimozide resulting in cardiac arrhythmias (QT prolongation, ventricular

tachycardia, ventricular fibrillation, and torsade de pointes) most likely due to inhibition of hepatic metabolism of pimozide by erythromycin and clarithromycin. Fatalities have been reported. (Please refer to full prescribing information for clarithromycin.)

Amoxicillin is contraindicated in patients with a known hypersensitivity to any penicillin. (Please refer to full prescribing information for amoxicillin.)

LEP & Health

- LEP hinders access to care and prevention
- LEP compromises patient understanding of treatment advice
- LEP can lead to misdiagnosis and medical error

Sources: Woloshin, JGIM, 12:472-477 (Aug 1997); Woloshin & Bickell, JAMA 273:724-727 (1995); RWJ Foundation (Dec. 12, 2001); Anderson, et al., AmJPrevMed 24(3S):68-79 (2003); Ngo-Metzger, et al., JGIM, 18:44-51 (Jan. 2003).

LEP Rx

- More than 25% of LEP did not fully understand the prescription instructions (cmp. 2% control)
- Vietnamese and Chinese LEP patients value written health information and prescription medications in their native languages
- Provision of interpreters to LEP patients roughly triples scripts written and filled

LEP Rx

- Not mentioned in HHS LEP Guidance 68 Fed. Reg.47311-47323 (Aug. 8, 2003)
- Not mentioned in National Standards for Culturally and Linguistically Appropriate Services in Health Care (HHS OMH, March 2001)
- Dual-language Rx labeling permitted but not required under MAPP 6020.7 (CDER OND, July 9, 2004)

LEP and Rx Importation

“FDA remains concerned about...drugs obtained from foreign sources...

The labeling of the drug may not be in English and therefore important information regarding dosage and side effects may not be available to the consumer.”

FDA Border Seizures 2003

Top Countries of Origin

- Canada
- India
- Thailand
- Philippines
- Japan
- Netherlands
- Taiwan
- UK

Top 10 LEP Languages

- Spanish 7,931,848
- Chinese 571,123
- Vietnamese 326,971
- Korean 264,420
- Russian 192,294
- French 145,580
- Portuguese 118,723
- Polish 112,487
- Italian 111,249
- Japanese 89,677

Language spoken at home, speaks English 'not well' or 'not at all'

US Census 2003

LEP Languages 11-20

• French Creole	85,598
• Tagalog	85,217
• German	84,254
• Arabic	71,128
• Armenian	45,685
• Persian	43,135
• Greek	37,562
• Gujarathi	30,340
• Urdu	26,146
• Hindi	19,936

Language spoken at home, speaks English 'not well' or 'not at all'

US Census 2003

OCR Title VI Safe Harbor

< 100

Oral translation

<1000 or 5%

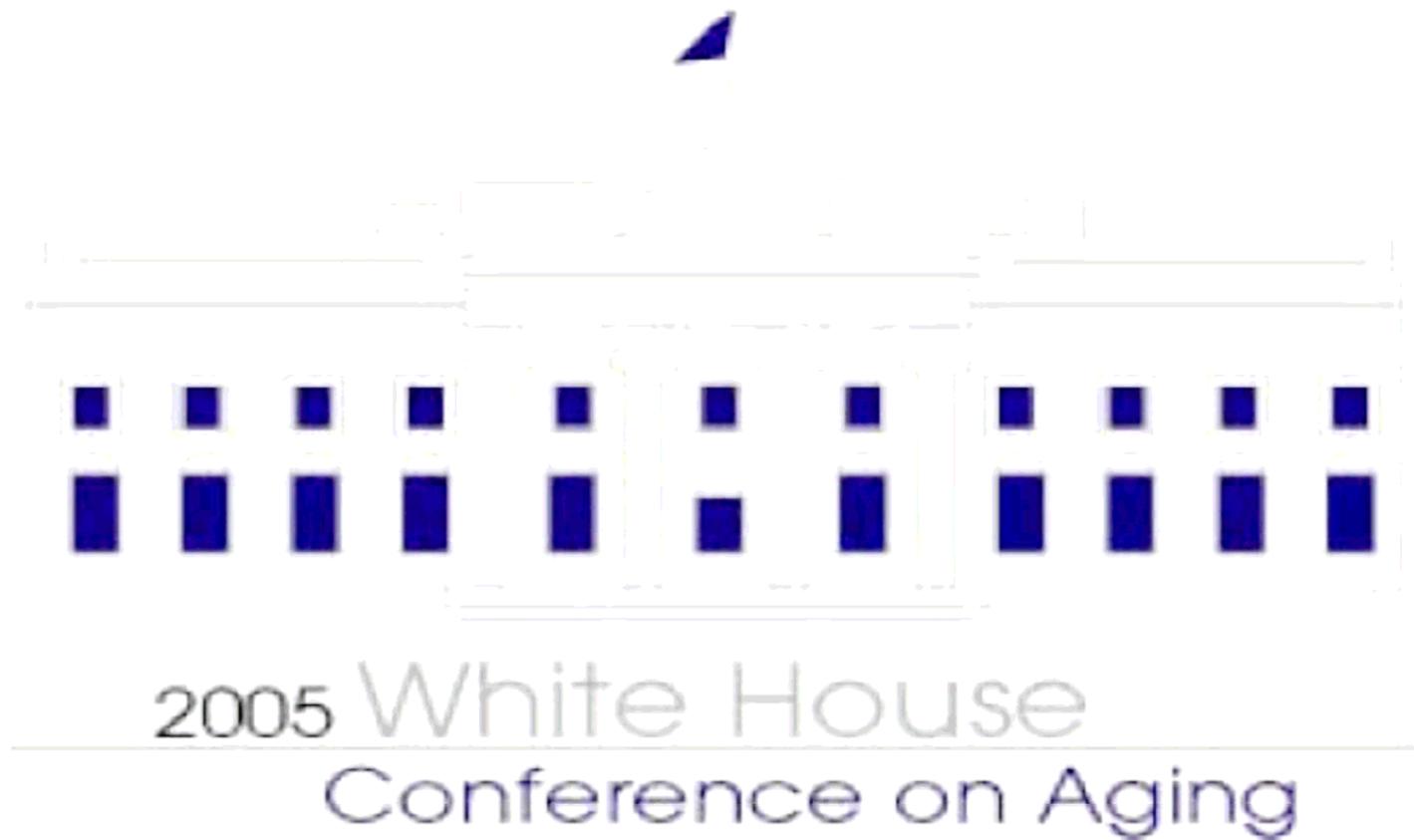
Translation of vital documents

<3000 or 10%

Translation of all documents

What Should PhRMA Companies Do?

Post-Event Summary & Recommendations



Mini-Conference on Health Literacy & Health Disparities

Post-Event Summary & Recommendations

Accurate translations in multiple languages should be available for all retail pharmacies to use as needed. Make side-by-side translations available

Patient leaflets should be translated under supervision of the pharmaceutical companies and reviewed by an FDA panel ... consumer focus groups should validate the leaflets

CMS should track ... the availability and accuracy of patient education materials (in multiple languages)...

2005 White House
Conference on Aging
Mini-Conference on Health Literacy & Health Disparities

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Patient Education

•Lansoprazole capsules ESPAÑOL

What are lansoprazole capsules?

LANSOPRAZOLE (Prevacid®) prevents the production of acid in the stomach. It reduces symptoms and prevents injury to the esophagus or stomach in patients with gastroesophageal reflux disease (GERD) or ulcers. Lansoprazole is also useful in conditions that produce too much stomach acid such as Zollinger-Ellison syndrome. Generic lansoprazole capsules are not yet available.

Options

1. Revise OCR/HHS LEP regulations to require compliance by all drug companies with Title VI
2. Revise MAPP 6020.7 to require distribution to LEP patients of appropriate FDA-approved or foreign NDRA-approved labels and patient educational materials in languages other than English

Options

3. Permit importation of personal use Rx by LEP patients
4. Monitor drug company use of foreign-language materials not approved by either FDA or an appropriate foreign NDRA
5. All of the above should be done in consultation with the LEP communities