# Addressing Safe OTC Use Among Older Adults


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# Disclosures

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- Pfizer

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- Pfizer
- Sanofi


An Aging Perspective

# An Aging America

- Over 65 population experiencing a rate of growth 3-fold that of Under 65 population
  - from 2002 to 2018, adults over 65 grew from 36 to 52 million
  - 2060 projections estimate 95 million adults over 65 in the U.S.

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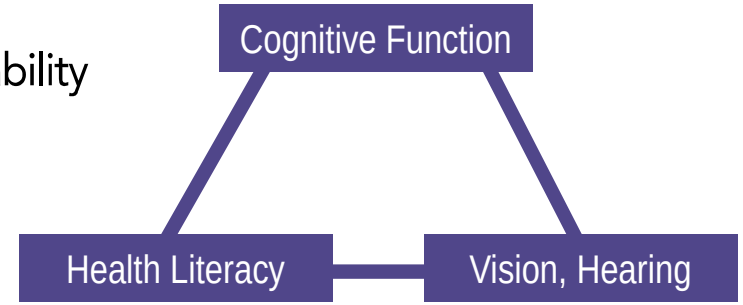
- Implications: an older America translates to increase needs for healthcare
  - 9 out of 10 adults over 65 have a chronic illness; 80% have multiple chronic conditions

# Challenges to Patients

- ✓ OTCs making 'guest appearances' among multi-drug Rx regimens
- ✓ Overall frequency of OTC use
- ✓ Poor medication reconciliation = High chance doctors don't know what patients are taking

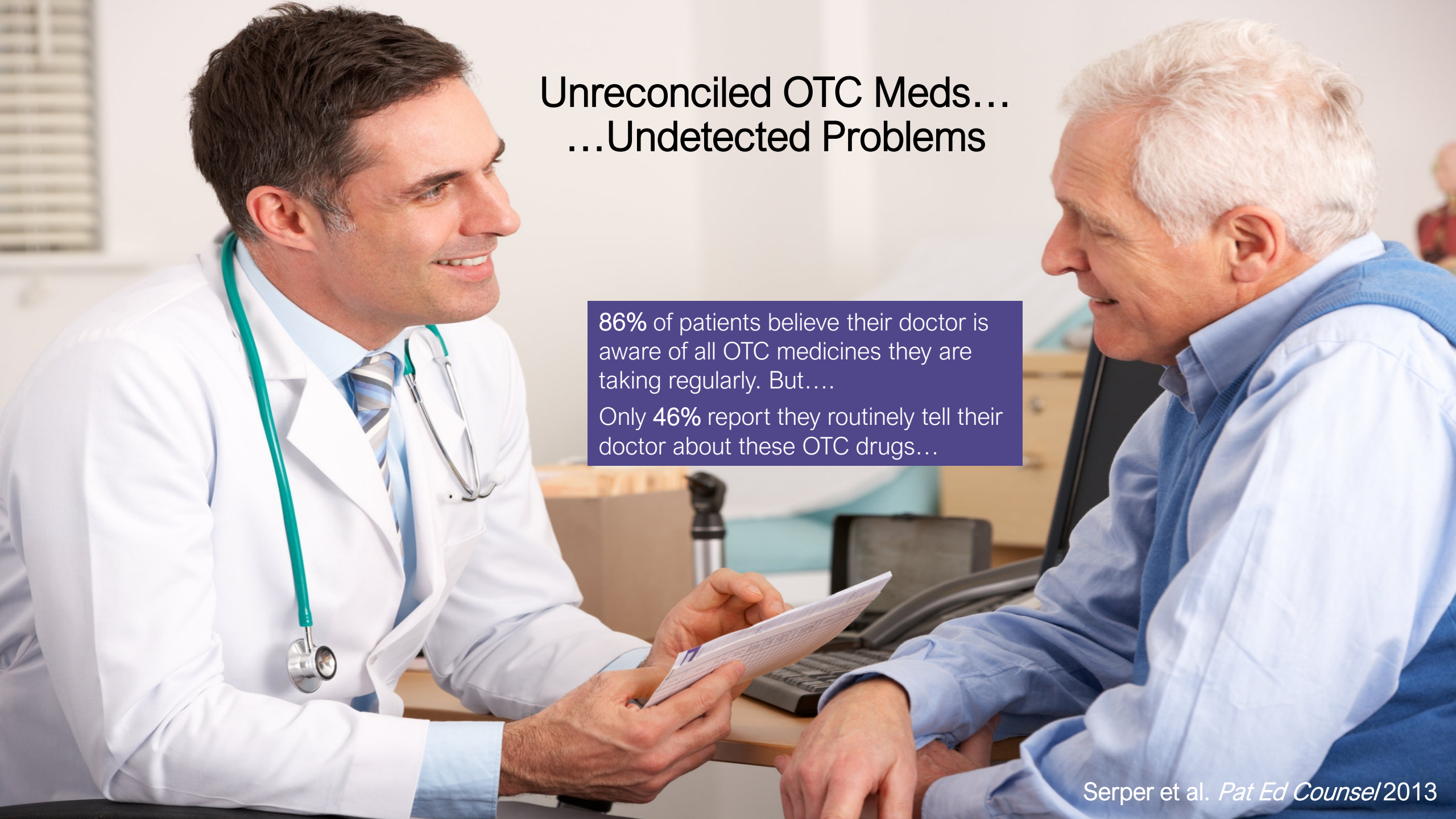
- ✓ Caregivers may also be involved with older adults' medications use, yet lack knowledge of full regimen

- Polypharmacy
- Multiple lifestyle behavior changes (i.e. diet, physical activity)
- Burdensome self-care tasks associated with monitoring conditions and managing symptoms (i.e. foot exam, blood pressure monitoring)
- High prevalence of functional limitations affecting self-care ability
- Requisite illness and treatment knowledge to problem solve around self-management
- Frequent healthcare provider visits with multiple prescribers
- Frequent pharmacy visits to collect typically unsynchronized prescriptions, and sometimes multiple involved pharmacies
- Financial costs
- Changes in cognition, caused either by age, illness, or treatment
- Co-existing behavioral health issues
- Unmet health-related social needs (i.e. housing instability, food insecurity, transportation)



# Low Visual Acuity and OTC Misuse

- Mullen et al. (Am J Health Sys Pharm, 2018) found low vision to significantly increase risk of OTC dosing errors and ‘double dipping’
- O’Conor et al. (J Aging Health, 2018) also found low vision to impact dosing accuracy, as well as overall poorer self-care task performance
- Bailey et al. (JAGS, 2020) found dosing accuracy declines over time among older adults, in line with poorer vision and worse cognitive function



# Unreconciled OTC Meds…
# …Undetected Problems

**86%** of patients believe their doctor is aware of all OTC medicines they are taking regularly. But….

Only **46%** report they routinely tell their doctor about these OTC drugs…

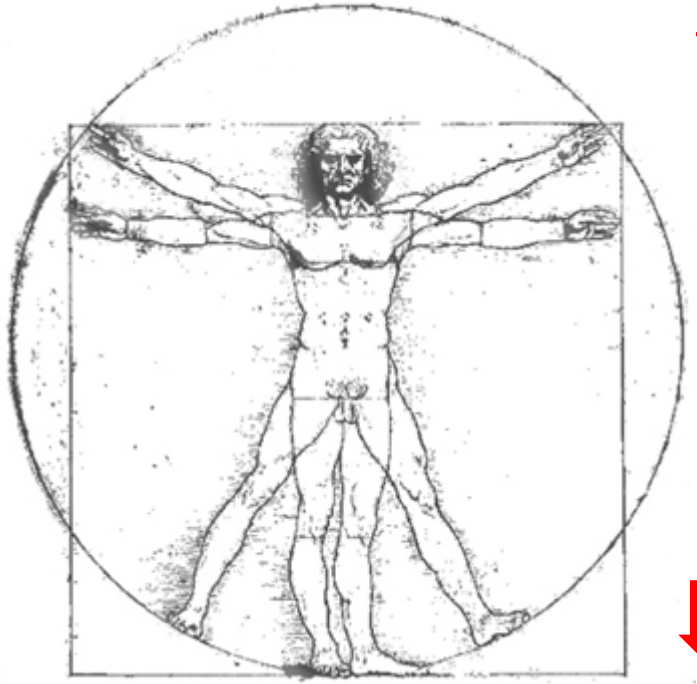
Serper et al. *Pat Ed Counsel* 2013


A Health Literacy Perspective

# Confluence of 2 Age-related Problems

**Body**

80% of adults over 65 live with ≥2 chronic conditions (vs. 18%; 18-44 years)



**Mind**

'Fluid' cognitive abilities necessary for self-care are known to decline with increased age.

↑ **Healthcare Demands**

↓ **Self-care Skills**

# Assumptions

1. A person's cognitive skills are a major determinant of health literacy skills

2. The requisite heath literacy skills needed to successfully manage health is determined by the design, accessibility of a healthcare system

3. Reducing the 'cognitive burden' of healthcare means…
   - ✓ better communication
   - ✓ simplified patient roles
   - ✓ proactive, learning healthcare systems

# Some Unique OTC DFL Challenges

- No ‘learned intermediary’

  - Consumer self-selection

- # of Product Choices

  - Brand + Generic Options

  - Single & Multi-Ingredient Products

- Labeling

  - Clarity, understandability (focus on symptoms, not AI)

  - Front-of-package indo, container vs. package

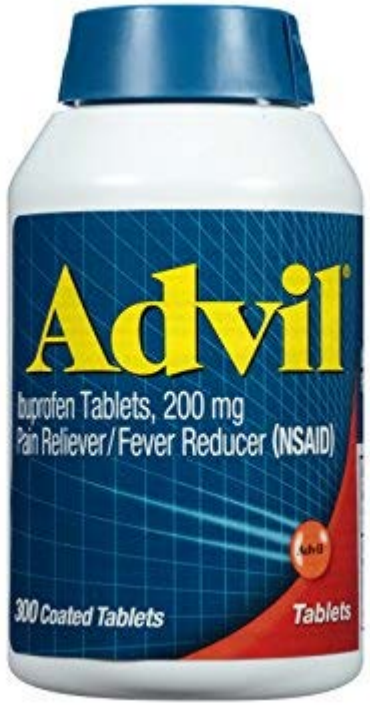
  - Size of font, information sequence

# Change to the DFL needed…

Our Prior FDA-Sponsored Study found –

- High recognition of product brand, matching to symptoms, but low AI recognition

# Adults' Understanding of OTC Products




Know Product 99.4%

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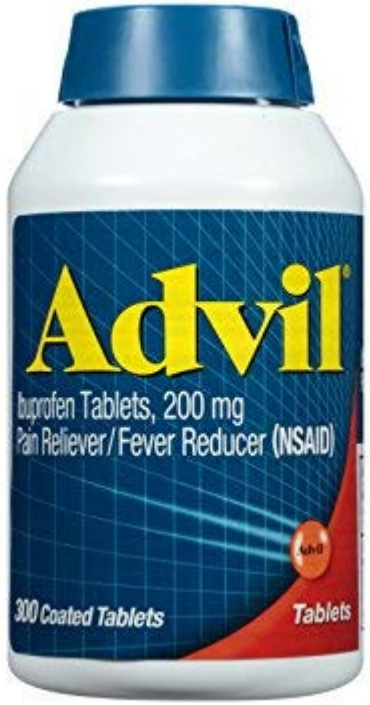


| | |
|---|---|
| Know Product | 99.4% |
| Know Symptom | 97.6% |

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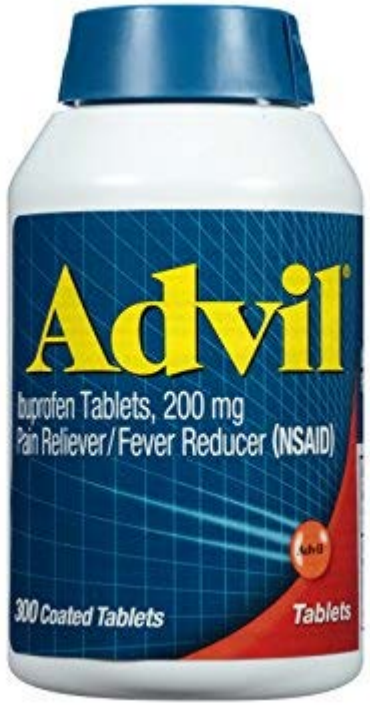


| | |
|---|---|
| Know Product | 99.4% |
| Know Symptom | 97.6% |
| Know AI | 32.1% |

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# Adults' Understanding of OTC Products


Know Product 98.5%

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# Adults' Understanding of OTC Products


| | |
|---|---|
| Know Product | 98.5% |
| Know Symptom | 86.1% |

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# Adults' Understanding of OTC Products


| | |
|---|---|
| Know Product | 98.5% |
| Know Symptom | 86.1% |
| Know AI | 4.9% |

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# Change to the DFL needed…

Our Prior FDA-Sponsored Study found –

- High recognition of product brand, matching to symptoms, but low AI recognition

- Rates of self-selection errors (due to contraindications, drug interactions) to widely range from 4-88%; confusion often around language used for symptoms treated (e.g. laxative vs. stool softener)

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- Problems with concomitant use due to multi-ingredient products high – 80%
- Older age a consistent risk factor for difficulty in OTC understanding

# Moving Forward

# Addressing Cognitive Load of Information

- Readability (e.g. font size, reading grade level)
- Incomplete or vague information & instructions
- Amount of content
- Format, organization
- Conflicting sources, nature of source
- Modality (spoken, print, multimedia)/opportunity for re-review
- Lack of coordinated 'system' of information
- Factual vs. procedural content
- Distraction (e.g. extraneous information, discordant imagery, environment)
- Communication speed (audio, visual)


Contents lists available at ScienceDirect

Patient Education and Counseling

journal homepage: www.elsevier.com/locate/pateducou

Working memory and the design of health materials:
A cognitive factors perspective

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# DFL Design Aging Considerations

- Involve older adult stakeholders to be patient-centered
- Re-prioritize sequence of information presented in DFL
- Consider font size requirements to address visual acuity concerns
- Reinforce learning of active ingredient
- Provide explicit language to support instructions for use
- Address abstract or similar language describing symptoms
- Promote sharing of any regular OTC use with healthcare provider
- Link DFL to other information sources; creating a ‘system’ of PMI
- Expand efforts to require ‘teach back’ at point of purchase for certain products

## III. INNOVATIVE APPROACHES FOR NONPRESCRIPTION DRUG PRODUCTS

### A. Labeling in Addition to the DFL for Nonprescription Drug Products

In addition to labeling created to satisfy the DFL requirements,[5] FDA may approve additional labeling for nonprescription drug products (see section 505(d) of the FD&C Act (21 U.S.C. 355(d)). Examples of nonprescription drug product labeling the Agency may consider approving in addition to the DFL include, but are not limited to, the following:

- Information leaflets or other documents contained inside the carton or container for the nonprescription drug product
- Text or images on a video display, including interactive displays for consumers to review
- Information displayed on websites
- Statements or questions in a mobile application

### B. Nonprescription Drug Products With Additional Conditions for Safe and Effective Use

Applicants may consider proposing one or more additional conditions that consumers must fulfill to ensure that the drug product is safe and effective for nonprescription use, when labeling alone is not sufficient for this purpose.

Examples of additional conditions for safe and effective use that the Agency may consider, particularly with regard to appropriate self-selection and actual use, include, but are not limited to, the following:

- Prior to purchase, the consumer is required to respond to a set of questions on a self-selection test in a mobile application, and the outcome of the self-selection test affirmatively indicates that the consumer is an appropriate candidate to use the nonprescription drug product.
- Prior to purchase, the consumer is required to view and affirm that they viewed text or images in a video that describes how to appropriately use the nonprescription drug product.

As part of the development process for a nonprescription drug product for which an additional condition for nonprescription use will be proposed, applicants should consider how to ensure proper implementation of any additional condition necessary for safe and effective use.

# A Senior Section?

- Gilson et al. (2021, JAPhA in press) AHRQ pilot study shows promise for highlighting potential OTC safety concerns to prevent misuse




**Figure 1.** Senior Section.

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# Questions, Comments?


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