SELF-CARE: A COMPREHENSIVE APPROACH

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DISCLAIMERS

Loren Kirk, PharmD: Nothing to disclose
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The views expressed in this presentation are solely those of its presenters, and do not reflect those of the presenters’ employer.
OBJECTIVES

• Examine the impact of prescription to over the counter (OTC) switches on public perception of efficacy and safety

• Describe how the incorporation of self-care into comprehensive therapy plans improve patient adherence and outcomes

• Distinguish appropriate practice-based scenarios in which higher level treatment beyond that of self-care is necessary
Self Care
Well being

Non-Prescription
Legal/Regulatory

Over the Counter
Clinical
Self-diagnose
Self-treat
Self-manage
THE STATISTICS

1.3 to 2.1 billion people have no access to essential medicines

Elderly person travels about 9 miles for routine doctor’s visit in rural communities

26 trips/year to purchase OTCs vs. 3 visits/year to see doctor(s)

About 54,000 pharmacies in the U.S. and more than 750,000 retail settings that sell OTCs
THE STATISTICS

Factors that influence consumer’s choice to use OTC:

• Will work
• As effective as Rx
• Minor side effects
• Recommended by doctor

More than 2/3 consumers prefer using OTC vs. Rx

61% consumers visited a practitioner 1-2 times a year, but average U.S. household reports 4 to 5 episodes of cold/flu and 3 to 4 episodes of heartburn each year

Most consumers are knowledgeable
OVER THE COUNTER: THE BASICS

Benefits outweigh risks
Potential for abuse is low
Self-diagnosed conditions
Adequately labeled
OVER THE COUNTER: THE BASICS

Safe and appropriate for use without supervision of a healthcare professional

Can be purchased without a prescription

Can be approved like new prescription drugs

Marketed with OTC drug monograph
  • Ingredients, dose, instructions for use

Regulated by their active ingredient
OTC REGULATORY

OTC Drug Monographs
• Ingredient specific
• No application to FDA required
• E.g. acetaminophen, diphenhydramine

Prescription Switch Drug Products
• Drug product specific
• New Drug Application required
• E.g. omeprazole, nicotine replacement, orlistat
• Rx to OTC switches
More than 700 OTC products currently on the market use ingredients available only by prescription less than 30 years ago.

RX to OTC HISTORY

1951
Durham-Humphrey Amendment

1962
Kefauver-Harris Amendments to the FDCA

1972
FDA scientific reviews

September 9, 1976
First six OTC conversions occurred
## RX to OTC SWITCH LIST

<table>
<thead>
<tr>
<th>Medication</th>
<th>Class</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cetirizine/Pseudoephedrine</td>
<td>Antihistamine/Decongestant</td>
<td>November 6, 2007</td>
</tr>
<tr>
<td>Cetirizine</td>
<td>Antihistamine</td>
<td>November 16, 2007</td>
</tr>
<tr>
<td>Lansoprazole</td>
<td>Acid Reducer</td>
<td>May 18, 2009</td>
</tr>
<tr>
<td>Omeprazole</td>
<td>Acid Reducer</td>
<td>July 10, 2009</td>
</tr>
<tr>
<td>Ibuprofen/Phenylephrine</td>
<td>Analgesic/Decongestant</td>
<td>January 24, 2011</td>
</tr>
<tr>
<td>Fexofenadine/Pseudoephedrine</td>
<td>Antihistamine/Decongestant</td>
<td>January 24, 2011</td>
</tr>
<tr>
<td>Oxybutynin</td>
<td>Overactive Bladder</td>
<td>January 25, 2013</td>
</tr>
<tr>
<td>Triamcinolone Suspension</td>
<td>Allergic Rhinitis</td>
<td>October 11, 2013</td>
</tr>
<tr>
<td>Esomeprazole</td>
<td>Acid Reducer</td>
<td>March 28, 2014</td>
</tr>
<tr>
<td>Fluticasone Propionate</td>
<td>Upper Respiratory Allergies</td>
<td>July 23, 2014</td>
</tr>
<tr>
<td>Budesonide</td>
<td>Allergic Rhinitis</td>
<td>March 23, 2015</td>
</tr>
<tr>
<td>Adapalene</td>
<td>Allergic Rhinitis</td>
<td>July 8, 2016</td>
</tr>
<tr>
<td>Fluticasone Furoate</td>
<td>Upper Respiratory Allergies</td>
<td>August 2, 2016</td>
</tr>
</tbody>
</table>
NSURE

Convoked in 2012

Address the under treatment of common diseases or common conditions

Exploration of the regulatory expansion of the nonprescription drug class
MARKET FACTORS

Traditional drivers for switching came from manufacturers and the impetus to pursue OTC conversion was motivated by patent expirations.

- Generic Competition
- Increased availability of FSAs
- Managed Care Organizations
- Consumer Trends

OTC Conversion
RX to OTC MISCONCEPTIONS

Medications became safer
- Only 43% of patients consult a pharmacist when purchasing nonprescription medication

Medications became less expensive
- Insurance deductible
- Volume/Amount

Medications formulation is novel
- Ibuprofen
81% adults use OTC as first response
Additional 56,000 full-time medical professionals needed if OTCs not available
Consumers/taxpayers could save $5.2 billion/year
Overall savings of $102 billion/year
  • $77 billion from avoiding doctor’s visits and diagnostics
  • $25 billion from drug costs savings

$1 spent on OTC
  =
  $6 – $7 savings for U.S. health system
RX to OTC BENEFITS

Improved access and use
- Nicotine replacement therapies

Improved empowerment
- Yeast infection treatments

Cost savings
- Heartburn medicines
RX to OTC RISKS

Combination products
  • Acetaminophen

Repeated use
  • Vaginal Antifungal Products

Understanding of appropriate self-care
  • Histamine (H2)-receptor Antagonists

Cost burden
  • $200 billion in unnecessary ED visits and hospitalizations associated with high-risk and older patients
### WHAT’S NEXT?

<table>
<thead>
<tr>
<th>Class to Consider</th>
<th>Claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statins</td>
<td>More than 3000 patients <strong>appropriately selected cholesterol lowering therapy.</strong></td>
</tr>
<tr>
<td>Contraceptives</td>
<td>Women have been shown to <strong>correctly self-identify contraindications</strong> to use when using a standardized check-list.</td>
</tr>
<tr>
<td>Urinary Incontinence</td>
<td>An estimated 50-70% <strong>of women with overactive bladder fail to seek medical evaluation</strong> due to social stigma</td>
</tr>
<tr>
<td>Erectile Dysfunction</td>
<td>Treatment seekers turn to online pharmacies <strong>where &gt;75% of sildenafil purchases were counterfeit</strong> or contained varying levels of the prescription molecule</td>
</tr>
<tr>
<td>Migraine</td>
<td>Potential to <strong>limit the over use of acetaminophen</strong> and reduce the instance of stomach erosion due to high dose NSAIDs</td>
</tr>
</tbody>
</table>
DISCUSSION

Are the aforementioned classes appropriate to consider for a switch? (Statins, Contraceptives, Urinary Incontinence, Erectile Dysfunction, Migraine)

From your practice, what other classes/categories should be considered?
LEGAL FACTORS TO CONSIDER

TRADITIONAL

*No duty to warn*

Learned Intermediary Doctrine

Drug manufacturers have duty to warn doctors

Doctors have duty to warn patients

Pharmacists should not come between doctor and patient

EXPANDED

*Duty to warn*

State-by-state, case-by-case

Counseling Voluntarily

Certain situations

- Harmful on its face
- Known contraindications
- Other special knowledge
OTC DUTY TO WARN?

Code of Virginia §54.1-3319 states that a drug review shall include “serious interactions with nonprescription or over-the-counter drugs…”

Case Proceedings

Facts: Plaintiff’s wife called major pharmacy to ask about husband taking a pseudoephedrine product and after reviewing PMH, pharmacist approved use

- Catheters → Surgery → Nerve damage → Bladder distention → Death
- **Issue**: Does a pharmacist have a duty to warn with OTCs?
- **Holding**: Yes!
  - Did the pharmacist have a duty of care and breach that duty?
  - Was that breach a proximate cause of the harm/injury to the patient?
  - Did that injury result in damages (monetary loss)?
COURT DECISION

Learned intermediary doctrine protects pharmacists from liability for failure to warn prescription drugs only

Service provider vs. Seller

- “Service provider” is limited to selling only what the prescriber ordered → pharmacist = intermediary servicer
- “Seller” is not limited by a Rx, and can help a customer shop for a particular OTC product → pharmacist = direct seller

Duty existed → Duty was breached → Breach was a proximate cause of plaintiff’s injury → Injury resulted in damages
## 5 CATEGORIES TO CONSIDER

<table>
<thead>
<tr>
<th>PEDiATRIC ANALGESICS</th>
<th>PROTON PUMP INHIBITORS</th>
<th>SLEEP MEDICATIONS IN THE ELDERLY</th>
<th>TOPICAL ANALGESICS</th>
<th>PSUEDO-EphEDRINE PRODUCTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight Based Dosing difficult for parents</td>
<td>Associated with an increased risk of MI and kidney disease</td>
<td>Diphenhydramine is mentioned in the Beers Criteria as a medication to avoid.</td>
<td>Patches are considered common topical analgesics for pain.</td>
<td>Most patients first choice when it comes to a head cold or allergies.</td>
</tr>
<tr>
<td>Correct use of measuring device</td>
<td>Assess if the patient is truly a candidate for PPI therapy, or if a histamine receptor antagonist would suffice</td>
<td>Counsel on sleep hygiene or restrict use</td>
<td>Counsel on the fact that patches should not be cut, as to avoid potential overdose</td>
<td>Ask the patient whether they have uncontrolled blood pressure, DM, or BPH</td>
</tr>
<tr>
<td>Mark the exact dose on the measuring device in order to avoid confusion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CLINICAL FACTORS TO CONSIDER

Dosage strength variations
  • Hydrocortisone

Indication variations
  • Ibuprofen

Age distinctions
  • Nicotine replacement products

Cosmetic and drug claims on the same product
  • Antidandruff shampoos

The whole patient
CASE EXAMPLE

38-year-old man comes to the pharmacy looking for a recommendation for an OTC medication to treat the fever. Presented with fever (101.1°F) and reported night sweats that started two days ago.

He cannot remember what OTC agent is safe for him to use.

Past medical history:

- Crohns Disease

Current Medications:

- Immune-modifying medication (Name and dose unknown)
- Last IV treatment 7 days ago
RECOMMENDATION

Crohns Disease

Fever could be indicative of:

• A disease flare
• A reaction to the parenteral immune-modifying medication
• An infectious disease process secondary to the immune suppression

Be conservative

Patient is not eligible for self-care.

Patient should be referred to his primary care provider or gastroenterologist for further evaluation.
LOOKING AHEAD

e-OTC products
Integration into advanced clinical models
  • Point of Care Testing
  • Washington State
QUESTIONS?
ACKNOWLEDGEMENTS

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CITATIONS


• 2013 Summary and Recommendations from GSA and CHPA National Summit on Over-the-Counter Medication Behaviors of Older Adults: Research is Needed to Better Understand and Promote Safe and Effective Use. 2013 Apr 10; Washington, D.C.

• http://www.yourhealthathand.org/images/uploads/The_Value_of_OTC_Medicine_to_the_United_States_BoozCo.pdf

• Additional citations included in speakers notes