Guidance for the use of Over-the-Counter Products & Dietary Supplements

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Speaker Disclosures

Dr. Ally is on faculty
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She is the Senior Partner of BBfN,
a health and safety consulting company

Her conflict statement follows:

Faculty Disclosure Statement

I do not have a vested interest in nor an affiliation with any corporate organization offering financial support or any grant monies for this continuing education activity, nor any affiliation with an organization whose philosophy could potentially bias my presentation.

I do not speak for nor consult with any pharmaceutical manufacturer.

Any products shown in this presentation have been altered to avoid promotion of any manufacturer.
Learning Objectives

At the completion of this activity, the attentive learner should be able to:

- Describe the difference between OTC drugs and dietary supplements
- Cite scientific research into appropriate indications for self-care use of OTC products and dietary supplements
- Design a therapeutic plan, incorporating OTC products or dietary supplements, when appropriate
- Educate patients when self-care is appropriate, when pharmacist consultation is appropriate, and when a medical visit is appropriate

The Durham – Humphrey Amendment to the FDCA

Most important item –
Explicitly defined Prescription Drug and Over-the-Counter Drug

Codified the thought that legend drugs needed medical supervision, but OTC could be safely labeled for self-care
Legend Drugs v OTC

It’s not actually safety - - it’s the ability to use the product safely

OTC Products are safe for self-care, when used as directed on the FDA approved label

7 Point Label
- Drug Facts – including active ingredients and purpose of ingredient
- Uses
- Warnings
- Directions
- Other Information
- Inactive Ingredients
- Contact Information

OTC Purpose v OTC Use

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antifungal</td>
<td>Jock-itch</td>
</tr>
<tr>
<td>Antihistamine</td>
<td>Itch</td>
</tr>
</tbody>
</table>
OTC Warnings
If it’s an external product – that MUST be the first warning listed

Other mandated warnings:
- allergies
- Reye’s Syndrome
- Alcohol content
- Flammability

THEN comes contraindications - - heading is “Do Not Use”

Recommending OTC Products
OTC Products have labeled doses and ages

There are times when the labels don’t fit - - write a prescription!!

You can recommend anything, I can only go beyond/outside the OTC label with a prescription
Pharmacists

We’re actually really good people, once you learn to tolerate us

We are the health care team’s drug experts

If you are unsure we’ll help you decide - - we know the doses, we know the contraindications, we know the drug interactions, we (our technicians) know the insurance

diphenhydramine

Evidence
- allergic conjunctivitis
- urticaria
- dermatographism
- motion sickness (tx and prophy)
- Parkinsonian movements
- sleep aid (not <12 years)

No evidence
- no known inappropriate uses*
  * MANY known inappropriate doses or durations
Diphenhydramine don’ts

**Contraindications**
- Neonates & Premature infants
- Lactation

**Warnings**
- narrow angle glaucoma
- stenosing peptic ulcer
- pyloroduodenal obstruction
- prostatic hypertrophy
- bladder-neck obstruction
- excitation in pediatrics
- geriatrics

Diphenhydramine Dosing

**OTC Label**
- Pediatrics
  - do not use under 6 years
  - 6 – 12 years
    - 25mg q 4-6 hrs
    - max 150mg/day
- Adults
  - 25-50mg q 4-6 hrs

**Prescription Use**
- Pediatrics
  - max of 5mg/kg/24 hours
- Adults
  - 25-50mg qid
  - sleep 50mg

**Covered OTC under Nebraska Medicaid**
aspirin

Evidence
  Pain
  Fever
  Inflammation

2\textsuperscript{nd}ary stroke prevention

Reyes Syndrome!

NSAIDs other than aspirin

I can’t tell the patient to take more than the OTC label

Most folks can figure out that 4 x 200mg = 800mg, but I can’t tell them that!!

OTC label for ibuprofen 200mg tablets
  Children <12-years do not use
  Adults and children >12-years
    1 q 4-6hours
    if pain doesn’t respond take 2 tablets
Find those OTC directions I dare you....

Front of package: Ibuprofen 200mg tablets
Next panels: Active Ingredients
Warnings

Visible label: Do not use
Ask a doctor before use if

Give up and peel: Reasons to call your doctor (!)
Ask a doctor or pharmacist if
When using this product
STOP and ask a doctor if

I just want to know how many to take!!!

Keep peeling, hope the label doesn’t fall off the bottle...

If pregnant or breast-feeding

Directions TA DAH!!
Finally found them

Other information
DSHEA 1994
Dietary Supplement Health & Education Act

Defines dietary supplements and defines how they may be regulated

It’s not what you think!!

What is a “dietary supplement”? 
A product {other than tobacco} intended to supplement the diet, that contains 1 or more dietary ingredients including:
- a vitamin,
- a mineral,
- an herb or other botanical,
- an amino acid,
- a dietary substance for use by man to supplement the diet by increasing total dietary intake, or
- a concentrate, metabolite, constituent, extract, or combination of any of these
What can the FDA do?

They can restrict a substance if it poses a “significant and unreasonable risk” to the public.

They cannot –
- Ask for proof of safety
- Ask for proof of efficacy
- Ask for proof of purity
- Ask for warning labels
- Ask for any truth on the labels

OTC Product or Supplement?

If you want to claim to diagnose, treat, cure, or prevent some human condition – then you need go to the FDA and be an OTC product. Otherwise, you may be able to market a supplement.
Recommendation supplements

Is there a deficiency?
- Scurvy
- Beriberi
- Anemia

Is there an evidence basis for the recommendation?

Melatonin

Evidence
- Put your face in the sun for 10 minutes
- Prepare for sleep 2 hours in advance

No evidence
- improved sleep by supplementing
- may help with adolescent psychiatric conditions
Fish Oil

Evidence

- People who eat seafood 1-4 x weekly are less likely to die of heart disease
- Allergy to shellfish is a real contraindication
- Mercury has not proven to be a problem
- Very high doses lower triglycerides

No evidence

- decrease in heart disease
- improvement in age-related macular degeneration

cranberry

Evidence

- Yummy!
- was used by Native Americans to treat lower UTI
- may be useful in prophylaxis of recurrent UTI in young women not as effective as “headboard SMZ/TMP” but no resistance
- Drug to drug interaction with warfarin ↑ bleeding

No evidence

- Treatment of UTI
Co-Q-10

Evidence
supplementation increased coenzyme Q10 levels in patients on statins who have coronary artery disease

Increased risk of clotting when on warfarin

No evidence
cancer treatment or prevention
heart failure
muscle pain from statins
hypertension
Parkinson’s symptoms

placebo

Evidence
Pain
Insomnia
Anxiety
Weight loss
Depression
Irritable Bowel

*** See the work of Ted Kaptchuk, MD; Harvard Medical School
How to make this work

How to make this work for you & your office

How to make this work for the pharmacist

How to make this work for our patients

“Treat yourself”

When to tell the patients to treat themselves

Simple diagnosis
Recurrent condition
Condition amenable to OTC therapy

Patient able to determine a problem
“Go ask the pharmacist”
Probable viral infection - - you can’t be forced to write an antibiotic if the patient isn’t in your office
GI discomfort with no risk of dehydration
Simple sprains, strains, aches & pains

“Come on in to the office”
Set thresholds, for your patients, for your office staff, for your pharmacist colleagues

Body Temperature
Adults >102°F
Children >101°F
>100°F after 2 hours appropriate antipyretic
Other Thresholds

Significant difficulty breathing
Failure of OTC therapy
Respiratory rate >25 breaths per minute
Hypotension <100mmHg systolic
Change in mental status
Significant pain
Changes in sleep patterns
Unplanned weight loss in adults
Any weight loss in children without intentional change in diet or activity

More specialized thresholds

Oxygenation <90%
Peak flow meter in red following albuterol
INR > goal +1
Professional Consultation

Need for diphenhydramine in a 4-year old (2nd generation antihistamines are labeled for little ones)

First vaginal yeast infection

Super-labeled dose of an NSAID

Bring on the Questions
Partial Bibliography

Frankos, VH; Street, DA; O'Neill RK; FDA Regulation of Dietary Supplements and Requirements Regarding Adverse Event Reporting; *Clinical Pharmacology and Therapeutics*; 87 (2): 239-244.

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Bor-Jen Lee, Yu-Fen Tseng, Chi-Hua Yen, Ping-Ting Lin; Effects of coenzyme Q10 supplementation on antioxidation and antiinflammation in coronary artery disease patients during statin therapy: a randomized, placebo-controlled trial; *Nutrition Journal* 2013; 12:142

All supplements checked with the National Center for Complementary and Integrative Health: NCCIH.NIH.GOV

21 USC Federal Food, Drug, and Cosmetic Act; Ch 9; 301 et seq. 26 Oct 1951


Contribution of the Pharmaceutical Profession toward Controlling the Quality of Drugs in the Nineteenth Century. Safeguarding the Public: Historical Aspects 1970.