



CONSUMER  
HEALTHCARE  
PRODUCTS  
ASSOCIATION

# The Drug Facts Label – Looking to the Future with the Consumer in Mind

Barbara A. Kochanowski, Ph.D.

Senior Vice President, Regulatory & Scientific Affairs, CHPA



“ You have to start with  
the customer experience  
and work back to the  
technology. ”

- Steve Jobs, Co-founder of Apple

## DFL – What we believe

- Important tool to help consumers use OTC medicines safely and effectively
- Must keep pace with profound changes in consumer self-care environment

# Optimization Opportunity #1

## *Font size*



# Optimization Opportunity #2

## *Pull-outs*







CONSUMER  
HEALTHCARE  
PRODUCTS  
ASSOCIATION

# Optimization Opportunity #3

## *Amount of non-prioritized information*



# Regulations – Practical limitations to optimizing DFL

- Very specific language must be used in all sections
- Specific order of information
- Precise font size

# Future improvements require a strategic, scientific, and holistic approach

- Packaging
- Principal display panel
- Dosing device
- DFL



# Prioritizing the consumer voice

- Publicizing the opened docket
- Holding open forums with consumer groups



We make  
progress when  
FDA, industry,  
and consumers  
come together

## Drug Facts

### Active ingredient (in each caplet) Purpose

Acetaminophen 500 mg.....Pain reliever/fever reducer

### Uses

- temporarily relieves minor aches and pains due to:
  - the common cold    ■ headache
  - backache            ■ minor pain of arthritis
  - toothache           ■ muscular aches
  - premenstrual and menstrual cramps
- temporarily reduces fever

### Warnings

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Allergy alert:** acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening    ■ blisters    ■ rash

If a skin reaction occurs, stop use and seek medical help right away.

### Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are allergic to acetaminophen or any of the inactive ingredients in this product

**Ask a doctor before use if you have** liver disease

**Ask a doctor or pharmacist before use if you are** taking the blood thinning drug warfarin

### Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
  - fever gets worse or lasts more than 3 days
  - new symptoms occur    ■ redness or swelling is present
- These could be signs of a serious condition. ➔

## Drug Facts (continued)

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.**

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

### Directions

■ **do not take more than directed (see overdose warning)**

adults and children 12 years and over	<ul style="list-style-type: none"> <li>■ take 2 caplets every 6 hours while symptoms last</li> <li>■ do not take more than 6 caplets in 24 hours, unless directed by a doctor</li> <li>■ do not use for more than 10 days unless directed by a doctor</li> </ul>
children under 12 years	ask a doctor

### Other information

- store between 20-25°C (68-77°F)
- **do not use if carton is opened or neck wrap or foil inner seal imprinted with "TYLENOL" is broken or missing**

### Inactive ingredients





carnauba wax\*, corn starch, FD&C red no. 40 aluminum lake, hypromellose, magnesium stearate, polyethylene glycol\*, powdered cellulose, pregelatinized starch, propylene glycol, shellac, sodium starch glycolate, titanium dioxide

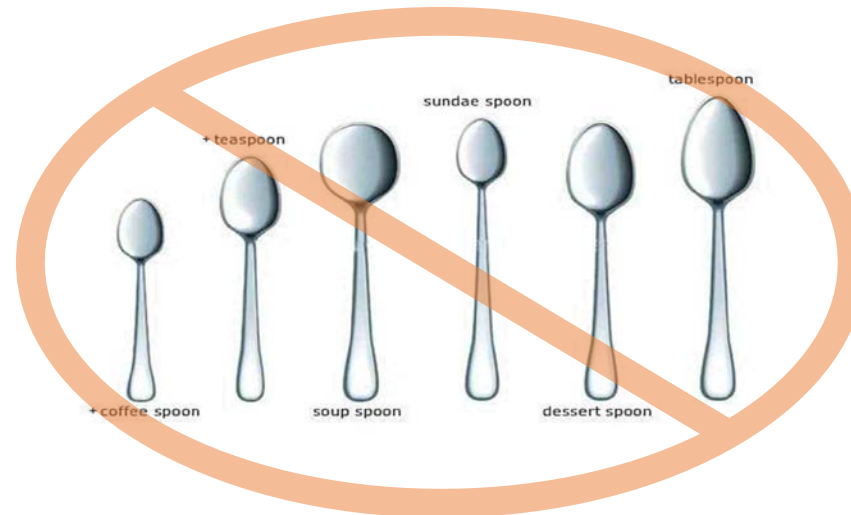
\*contains one or more of these ingredients

### Questions or comments?

call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)

We've made  
great strides in  
simplifying  
information to  
help consumers  
properly dose

Age (yr)	Dose (mL)*
Under 2 years	Ask a doctor
2-3 years	 5 mL
4-5 years	 7.5 mL
6-8 years	 10 mL
9-10 years	 12.5 mL



**Drug Facts (continued)**

**Directions**

- use only with enclosed dosing cup

adults 65 years of age and older	■ ask a doctor
adults and children 12-64 years of age	■ take 5 mL or 10 mL once daily in the evening depending upon severity of symptoms ■ do not take more than 10 mL in 24 hours
children 6-11 years of age	■ take 5 mL once daily in the evening ■ do not take more than 5 mL in 24 hours
children 2-5 years of age	■ take 2.5 mL once daily in the evening ■ do not take more than 2.5 mL in 24 hours
children under 2 years of age	■ do not use
consumers with kidney disease	■ do not use

Note: mL=milliliters

**Other information**

- each 5 mL contains: sodium 3 mg
- store between 20° and 25°C (68° and 77°F)
- safety sealed: do not use if carton was opened or if printed foil inner seal on bottle is torn or missing

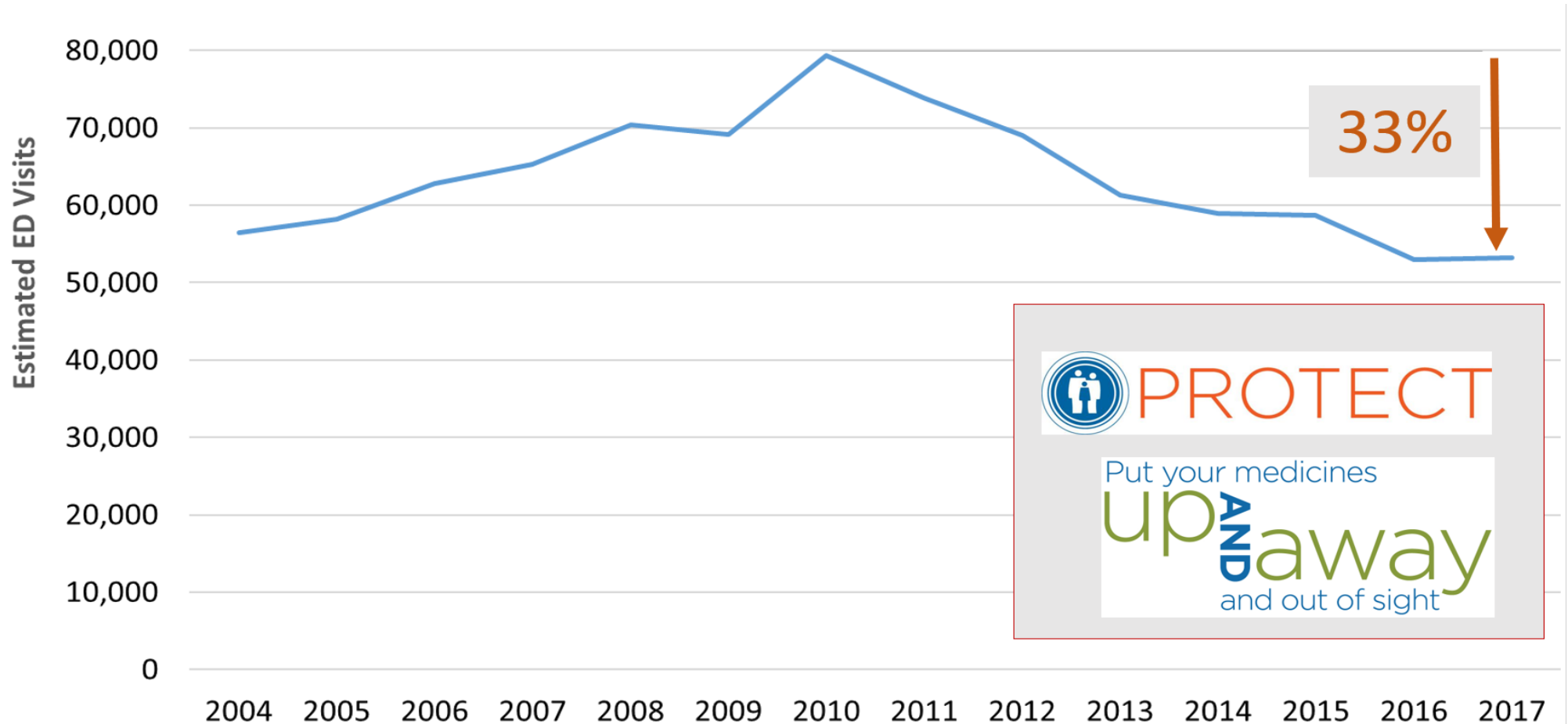
**Inactive ingredients**

flavor, glacial acetic acid, glycerin, maltitol solution, methylparaben, propylparaben, purified water, saccharin sodium, sodium acetate trihydrate

**Questions or comments?**  
call 1-800-633-1610

The trade dress of this Xyzal® package is subject to trademark protection.  
Dist. By: Chatterm, Inc., a Sanofi Company,  
Chattanooga, TN 37409-0219  
©2017, Origin: Canada

# We've had highly productive partnerships



# 20 years later, major shifts provide challenges – and opportunities

- Demographics have changed – older, multi-lingual
- Demand for more environmentally friendly processes and packaging
- We're “plugged in” – consumer comfort with technology

## Consideration – QR codes may be a consumer-friendly way to optimize label

- On Product: Simplified label, easier to read
- On Website: Expanded language, larger font, in native language





# Consideration – Leveraging smart phones and the Internet

- 85% of Americans use smart phones
- 93% of adults use the Internet
- Percentage consistently growing over last decade



# Considerations that are complex and often at odds *require a holistic approach*

- Technology advancing quickly; tools must be practical and effective
- Requires diverse group of experts – healthcare, regulatory, technology, environmental
- Need to understand benefits and how to execute
- Consumers at the center of the conversation and decisions

CHPA

CONSUMER  
HEALTHCARE  
PRODUCTS  
ASSOCIATION



PROTECT

Preventing Overdoses and Treatment Errors in Children Taskforce

*A model of public-private partnership*



UPSTATE  
MEDICAL UNIVERSITY



GeorgiaPoisonCenter



American Pharmacists Association®  
Improving medication use. Advancing patient care.



DFL continues to help consumers take products safely and effectively – in a consumer-friendly way





CONSUMER  
HEALTHCARE  
PRODUCTS  
ASSOCIATION

# THANK YOU

**Barbara A. Kochanowski, Ph.D.**

Senior Vice President, Regulatory & Scientific Affairs  
Consumer Healthcare Products Association

Email: [bkochanowski@chpa.org](mailto:bkochanowski@chpa.org) | [chpa.org](http://chpa.org) | [KnowYourOTCs.org](http://KnowYourOTCs.org)