

# Increasing Awareness of Acetaminophen via Pharmacy-Generated Prescription Labeling

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# Disclosure

Dan Ramirez is a paid consultant for McNeil. The conflict of interest was resolved by peer review of slide content. He declares no other conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

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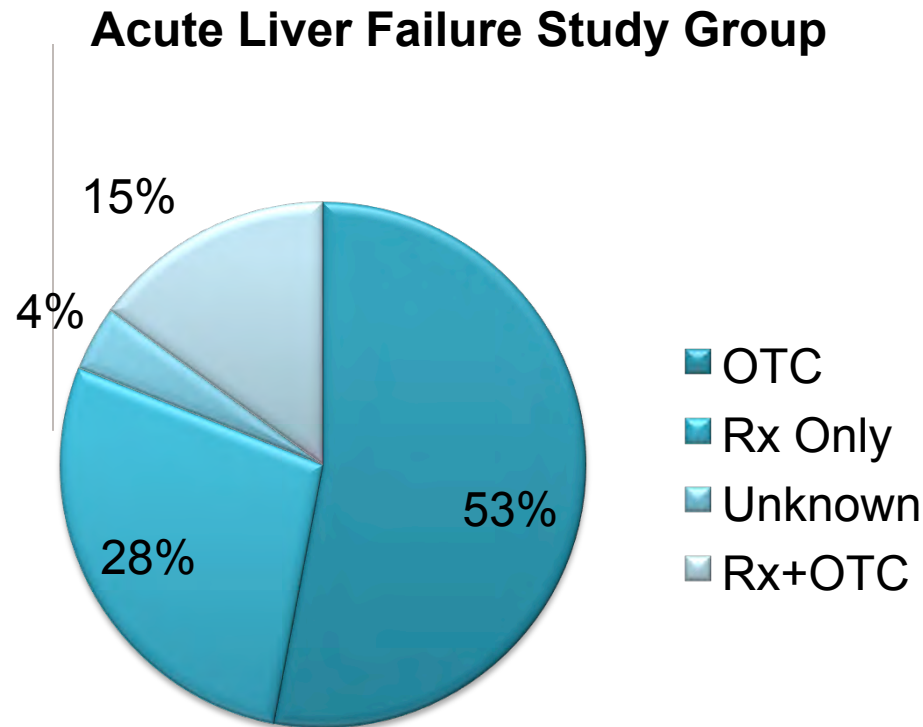
# Acetaminophen: Important Ingredient in OTC + Rx Medicines

- One of the most widely used and most important medicines in the United States.
- When used according to the label directions has well-established record of safety and efficacy.
- Although very rare in the context of its broad usage, overdose can be toxic and lead to acute liver failure.

Presented at FDA Safe use Initiative: Public Workshop Nov 16-16, 2010:  
<http://www.fda.gov/downloads/Drugs/NewsEvents/UCM234181.pdf>

74 Fed. Reg. 18731 (Apr. 24, 2009); "FDA Final Rule".

# Prescription Medicines Containing Acetaminophen are a Significant Root Cause of Overdose and Liver Injury



**Larson 2005**

**Adults=275**

**Larson AM, et al. Acetaminophen-Induced Acute Liver Failure: Results of a United States Multicenter, Prospective Study. Hepatology 2005; 42(6):1364-1372  
American Society for Automation in Pharmacy • Midyear Conference 2011**

# Gaps in Awareness

- Patients may not recognize that acetaminophen:
  - is the active ingredient
  - is commonly abbreviated (ex. “APAP”) on Rx pharmacy generated labels<sup>1,2</sup>
  - common to many over-the-counter (OTC) and prescription (Rx) medicines<sup>3,4</sup>
  - use from multiple acetaminophen-containing medicines places them at risk for overdose<sup>5</sup>
  - overdose places them at risk for liver injury

1. Institute for Safe Medicines Practices. “PA State Board of Pharmacy Newsletter Winter 2007-2008 (page 4-5)

2. National Association Boards of Pharmacy July 15 2010

<http://www.nabp.net/news/nabp-recommends-boards-of-pharmacy-prohibit-use-of-acetaminophen-abbreviation> (accessed 11/2/10)

3. Fosnocht D. et al. Emerg. Med. J.2008;25:213-216

4. Stumpf JL, et al. Journal of the American Pharmacist Association. 2007;47:1:35-41

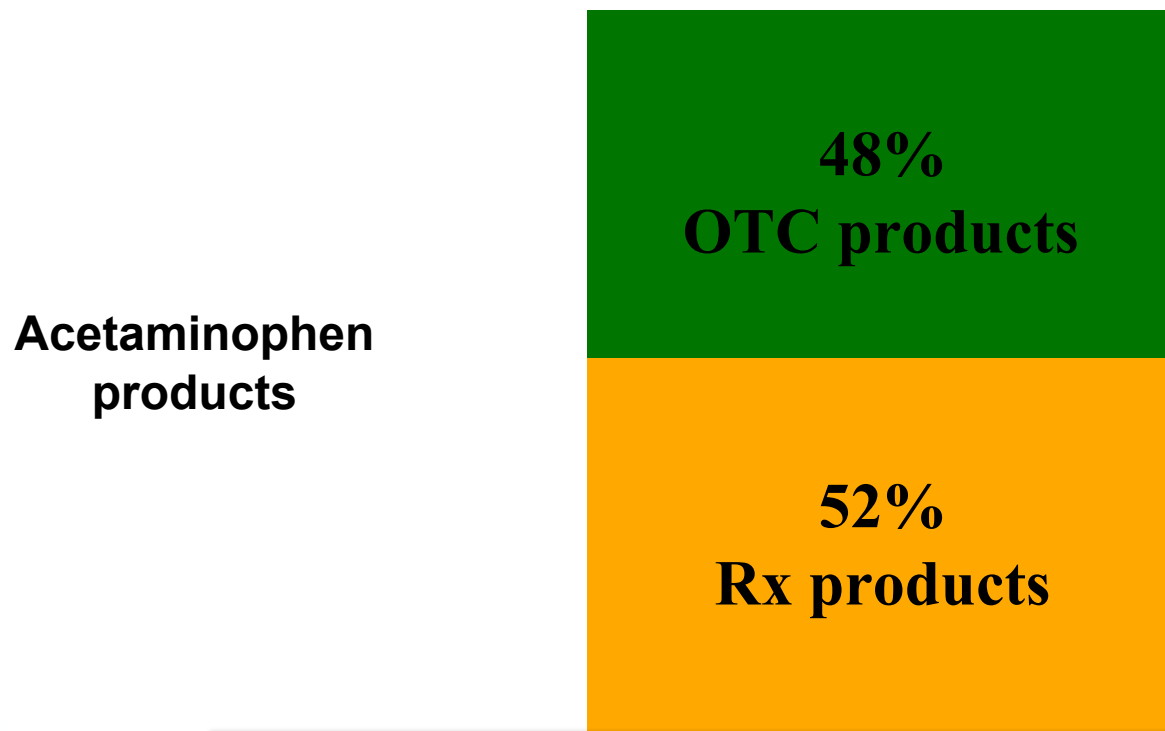
5. Letter from S. Galson to State Boards of Pharmacy, 2004;

<http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM171903.pdf>

Presented at FDA Safe use Initiative: Public Workshop Nov 16-16, 2010:

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# Increasing Acetaminophen Ingredient Awareness Needs to Involve Multiple Stakeholders



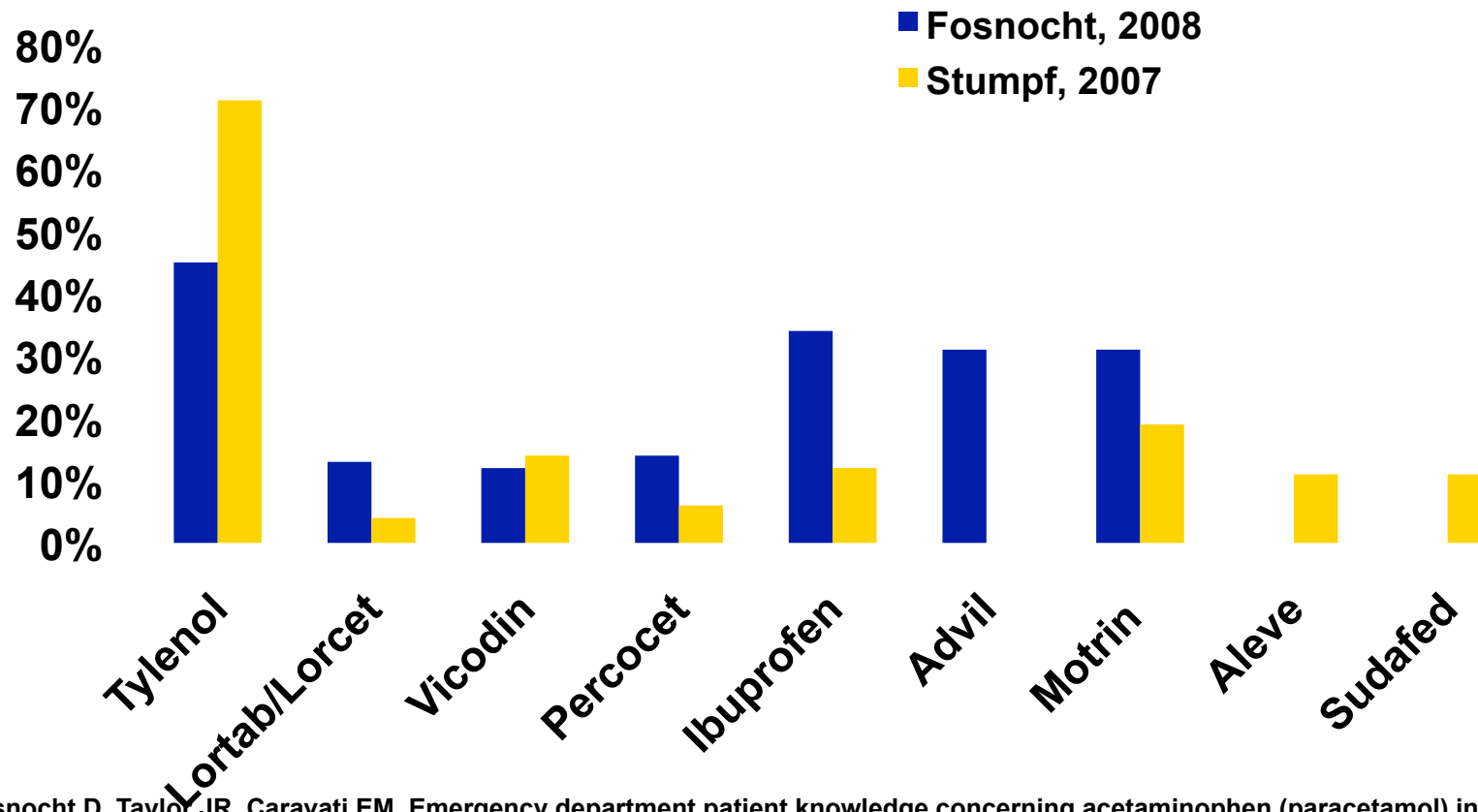
Presented at FDA Safe use Initiative: Public Workshop Nov 16-16, 2010:

<http://www.fda.gov/downloads/Drugs/NewsEvents/UCM234181.pdf>

IMS Health, MIDAS Feb 2011; 24 billion dosage units of adult acetaminophen-containing medicines sold in 2010

# Variable Awareness of Analgesic / Antipyretic Ingredients in OTC and Rx Products

Does this product contain acetaminophen? – “Yes”



1. Fosnocht D, Taylor JR, Caravati EM. Emergency department patient knowledge concerning acetaminophen (paracetamol) in over-the-counter and prescription analgesics. *Emerg. Med. J.* 2008;25:213-216
2. Stumpf JL, Skyles AJ, Alaniz C, et al. Knowledge of appropriate acetaminophen doses and potential toxicities in an adult clinical population. *Journal of the American Pharmacist Association.* 2007;47:1:35-41
3. Chen L, Schneider S, Wax P. Knowledge about acetaminophen toxicity among emergency department visitors. *Vet Human Toxicology.* 2002; 44: 370-373.

# "APAP" Appears on Pharmacy-Generated Rx Container Labels

RXDC EPS TRAIN 01 001 (817)-246-6760  
9560 CLIFFORD STREET FORT WORTH TX 76109

6601235 null Smith, Rance MD

Hill, Tray 05/28/09  
**TAKE ONE TABLET BY MOUTH EVERY  
FOUR HOURS AS NEEDED FOR PAIN.**

Ultracet Tab Mcne

NO REFILLS 28 TAB Drug Exp 5/28/2010

CAUTION: FEDERAL LAW PROHIBITS TRANSFER OF THIS DRUG TO  
ANY PERSON OTHER THAN THE PATIENT FOR WHOM PRESCRIBED.

RXDC EPS TRAIN 01 001 (817)-246-6760  
9560 CLIFFORD STREET FORT WORTH TX 76109

6601236 null Smith, Rance MD

Hill, Tray 05/28/09  
**TAKE ONE TABLET BY MOUTH EVERY  
FOUR HOURS AS NEEDED FOR PAIN.**

Tramadl/Apap Tab Par  
PAR GENERIC DISPENSED  
NO REFILLS 28 TAB Drug Exp 5/28/2010

CAUTION: FEDERAL LAW PROHIBITS TRANSFER OF THIS DRUG TO  
ANY PERSON OTHER THAN THE PATIENT FOR WHOM PRESCRIBED.

RXDC EPS TRAIN 01 001 (817)-246-6760  
9560 CLIFFORD STREET FORT WORTH TX 76109

4401051 null Smith, Rance MD

Hill, Tray 05/28/09  
**TAKE ONE TABLET BY MOUTH EVERY  
FOUR HOURS**

Hydroco/Apap 10-325 Tab Wats  
WATSON LAB GENERIC DISPENSED  
NO REFILLS 28 TAB Drug Exp 5/28/2010

CAUTION: FEDERAL LAW PROHIBITS TRANSFER OF THIS DRUG TO  
ANY PERSON OTHER THAN THE PATIENT FOR WHOM PRESCRIBED.

RXDC EPS TRAIN 01 001 (817)-246-6760  
9560 CLIFFORD STREET FORT WORTH TX 76109

4401050 null Smith, Rance MD

Hill, Tray 05/28/09  
**TAKE ONE TABLET BY MOUTH EVERY  
FOUR HOURS AS NEEDED FOR PAIN.**

Hydroco/Apap 7.5-65 Tab Mall  
MALLINCKRO GENERIC DISPENSED  
NO REFILLS 28 TAB Drug Exp 5/28/2010

CAUTION: FEDERAL LAW PROHIBITS TRANSFER OF THIS DRUG TO  
ANY PERSON OTHER THAN THE PATIENT FOR WHOM PRESCRIBED.

RXDC EPS TRAIN 01 001 (817)-246-6760  
9560 CLIFFORD STREET FORT WORTH TX 76109

4401052 null Smith, Rance MD

Hill, Tray 05/28/09  
**TAKE ONE TABLET BY MOUTH EVERY  
FOUR HOURS AS NEEDED FOR PAIN.**

Propo-N/Apap 100-65 Tab Teva  
TEVA PHARM GENERIC DISPENSED  
NO REFILLS 28 TAB Drug Exp 5/28/2010

CAUTION: FEDERAL LAW PROHIBITS TRANSFER OF THIS DRUG TO  
ANY PERSON OTHER THAN THE PATIENT FOR WHOM PRESCRIBED.

RXDC EPS TRAIN 01 001 (817)-246-6760  
9560 CLIFFORD STREET FORT WORTH TX 76109

6601237 null Smith, Rance MD

Hill, Tray 05/28/09  
**TAKE ONE TABLET BY MOUTH EVERY  
FOUR HOURS AS NEEDED FOR PAIN.**

But/Apap/Caf Tab West  
WEST-WARD GENERIC DISPENSED  
NO REFILLS 28 TAB Drug Exp 5/28/2010

CAUTION: FEDERAL LAW PROHIBITS TRANSFER OF THIS DRUG TO  
ANY PERSON OTHER THAN THE PATIENT FOR WHOM PRESCRIBED.

## Acetaminophen is Commonly Abbreviated as “APAP” on Pharmacy-Generated Rx Container Labels

- Standards lacking for completely spelling out “acetaminophen”
- Limited space in drug name fields of pharmacy labeling systems and on the Rx container label often prevent the use of complete generic drug names on the prescription generated Rx container label<sup>1</sup>
- If only a Rx Brand name or branded generic name is used, the container label may not list acetaminophen or “APAP” at all
- Standard practice unclear for content, selection, and prioritization of auxiliary warning labels

Institute for Safe Medicines Practices. “Pennsylvania State Board of Pharmacy Newsletter Winter 2007-2008 (page 4-5): “ Don’t Hide the Acetaminophen” Letter from Steven Galson to State Boards of Pharmacy, Acetaminophen Hepatotoxicity and Nonsteroidal Anti-inflammatory Drug (NSAID)-related Gastrointestinal and Renal Toxicity (Jan 22, 2004) available at

<http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM171903.pdf>

Chen L, et al. Knowledge about acetaminophen toxicity among emergency department visitors. *Vet Human Toxicology*. 2002; 44: 370-373.

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## FDA Safe Use Initiative

### “Reducing Unintended Acetaminophen Overdose”

- “ The FDA Safe Use Initiative is Working with the National Association of Boards of Pharmacy (NABP) to encourage pharmacies to stop using the abbreviation APAP and instead spell out acetaminophen on prescription container labels. Removing the abbreviation APAP and spelling out acetaminophen should make it easier for consumers to: 1) identify that their prescription pain reliever contains acetaminophen, 2) compare active ingredients on their prescription and over-the-counter labels, and 3) avoid taking two medicines with acetaminophen, which can lead to an overdose.”

FDA Safe Use Initiative: Acetaminophen Toxicity. Available at: <http://www.fda.gov/Drugs/DrugSafety/ucm230396.htm>

# National Association of Boards of Pharmacy

## July 15<sup>th</sup> 2010

- “...recommending that the state boards of pharmacy prohibit the use of the abbreviation “APAP” on prescription labels, and require that “acetaminophen” be spelled out ...
- “...understands that pharmacies may not be able to immediately implement new labeling requirements or recommendations and acknowledges that an implementation period may be necessary. The FDA Safe Use Initiative and NABP will work with interested pharmacy organizations to identify best processes to eliminate the use of “APAP,” and use, in its place, the word “acetaminophen,” and will work with pharmacy organizations to incorporate a reasonable implementation period for new requirements or recommendations related to this issue. “

# Recommendations to Help Patients Recognize Acetaminophen as an Ingredient in Rx Products

- The complete name of “acetaminophen “ is already required on OTC drug labels and principal display panel<sup>1</sup>
- Require only FDA-approved complete generic drug name in Rx drug name databases, pharmacy labeling systems, and on the pharmacy-generated prescription container label dispensed to patients
  - “Don’t Hide the Acetaminophen”<sup>2</sup>
  - Spell out using complete drug name; avoid all abbreviations.<sup>3</sup>
  - Don’t use drug name abbreviations, such as APAP for acetaminophen, to avoid consumer confusion.<sup>4</sup>
    - Replace “APAP” with “acetaminophen”

1.FDA Organ Specific Warnings; OTC IAAA Drug Products. 74 FR 19385 (April 29, 2009)

2.Institute for Safe Medicines Practices. “Pennsylvania State Board of Pharmacy Newsletter Winter 2007-2008 “ Don’t Hide the Acetaminophen”

3.USP Quality Review “Abbreviations Can Lead to Medication Errors” 2004;80:1-7

4.Letter: Steven Galson to State Boards of Pharmacy, Acetaminophen Hepatotoxicity and Non-steroidal Antiinflammatory Drug (NSAID)-related Gastrointestinal and Renal Toxicity (Jan 22, 2004) <http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM171903.pdf>

# Improving Pharmacy-Generated Rx Container Labels to Increase Acetaminophen Awareness

- Support expressed from multiple stakeholders for removing “APAP”
  - FDA , National Association Boards of Pharmacy (NABP), healthcare providers, retailers, pharmacy label system companies, etc.
- Completely spell out “acetaminophen” (Rx branded and unbranded medicines)
- Auxiliary warning label
  - **Content:** consistent with OTC drug facts concomitant use and liver warning
    - Example: Contains acetaminophen. Do not use with any other drug that contains acetaminophen (prescription or nonprescription). Too much can cause liver damage.
  - **Selection:** a single acetaminophen use warning (see above)
  - **Prioritization:** use warning within top 3 hierarchy
  - **Icon:** add research based acetaminophen ingredient icon

# Increasing Awareness of Acetaminophen via Pharmacy-Generated Rx Container Labeling

(555)321-4567

# 123456 04/26/2011 Dr. John Smith

JOHN DOE  
TAKE 1 PILL WITH FOOD  
TWICE DAILY

PERCOCET 20 DOSE Qty 20 pills  
Acetaminophen/Oxycodone

Contains acetaminophen. Do not use with any other drug containing acetaminophen (prescription or nonprescription).

Rinse mouth thoroughly after each use

Read The Patient Information Leaflet That Came With This Medicine

IT IS VERY IMPORTANT THAT YOU TAKE OR USE THIS EXACTLY AS DIRECTED. DO NOT SKIP DOSES OR DISCONTINUE UNLESS DIRECTED BY YOUR DOCTOR.

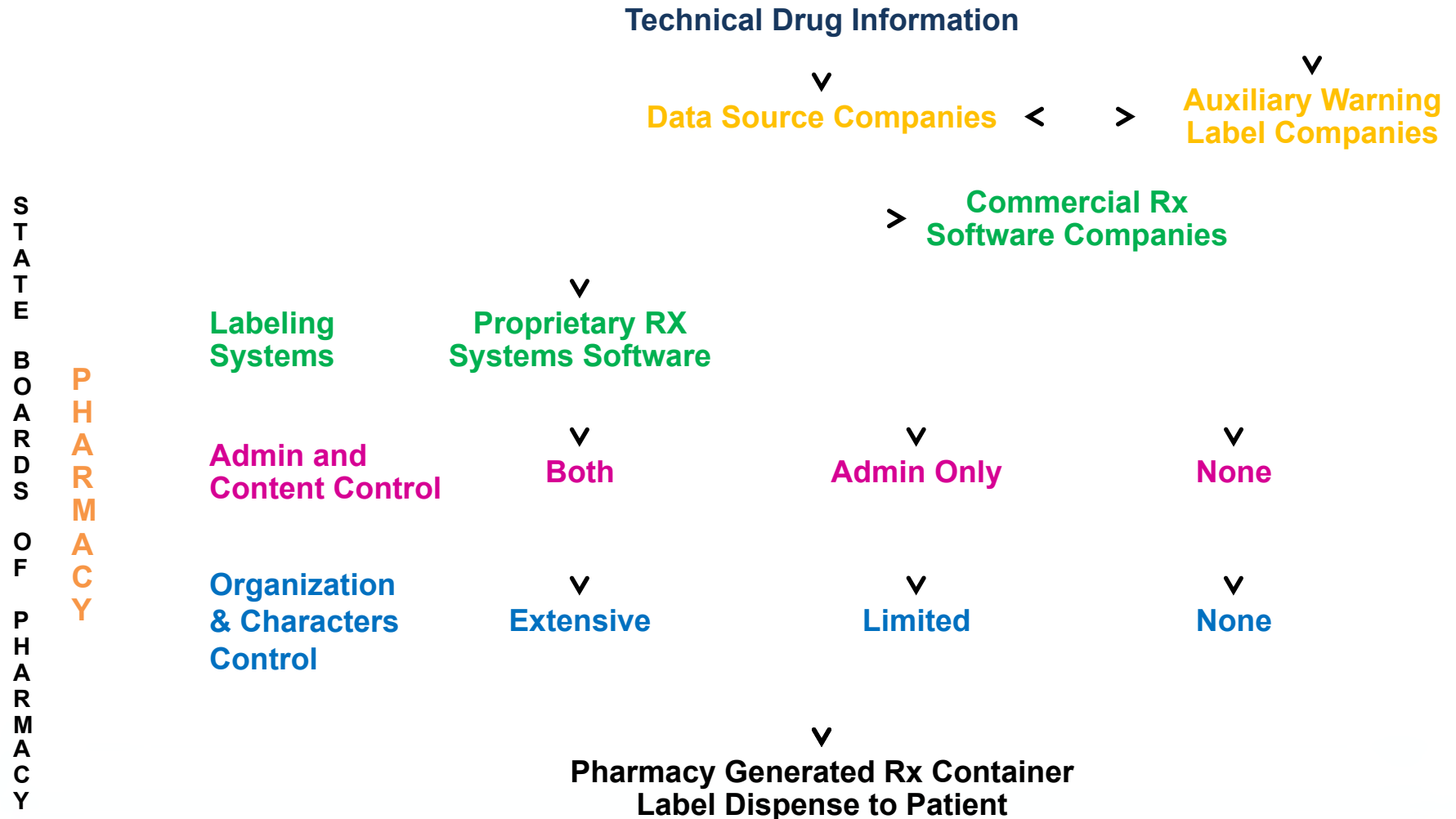


Contains acetaminophen. Don't use with other drugs that contain acetaminophen (prescription or nonprescription) unless doctor approves. Too much can cause liver damage.



Note: for demonstration purposes only.

# Key Elements Pharmacy-Generated Rx Container Label



## **First DataBank: “APAP” Revision (Oct 2010) Standard acetaminophen Warning Label (Apr 2011)**

- Will replace “APAP” in the Brand Name and Label Name of such products with:
  - Acetaminophen
  - Or alternate abbreviations:
    - Acetaminophn, Acetaminoph, Acetaminop, Acetamin, Acetam
- Implemented standard acetaminophen warning label on all acetaminophen-containing medicines in FDB data files:
  - Includes messages: Content, concomitant use, liver warning
  - Prints among top 3 of warning labels

# National Council for Prescription Drug Programs (NCPDP) Guidance

- Guidance (white paper) on new labeling standard for pharmacy generated labels for Rx acetaminophen-containing medicines:
  - Multi-disciplinary task group
- Anticipate approval of new guidance June 2011
  - Always completely spell out acetaminophen
  - Standard practice for content, selection, and prioritization of auxiliary warning labels
- Stakeholder call to action in 2011:
  - adopt, implement, adhere to recommended label improvements
  - optimize patient and consumer communication and education

# **Increasing Awareness of Acetaminophen via Pharmacy-Generated Prescription (Rx) Container Labeling**

## Continued Progress and Stakeholder Support

- Ensure support of state boards of pharmacy
- Encourage continued removal of “APAP” from data sources
- Promote change to completely spell out acetaminophen
- Establish standard practice for content, selection, and prioritization of acetaminophen auxiliary warning label
- Evaluate acetaminophen ingredient icon for all OTC and Rx labels
- Sustain stakeholder engagement