OTC Drug Monograph Reform

FDLI Annual Conference

May 4, 2018

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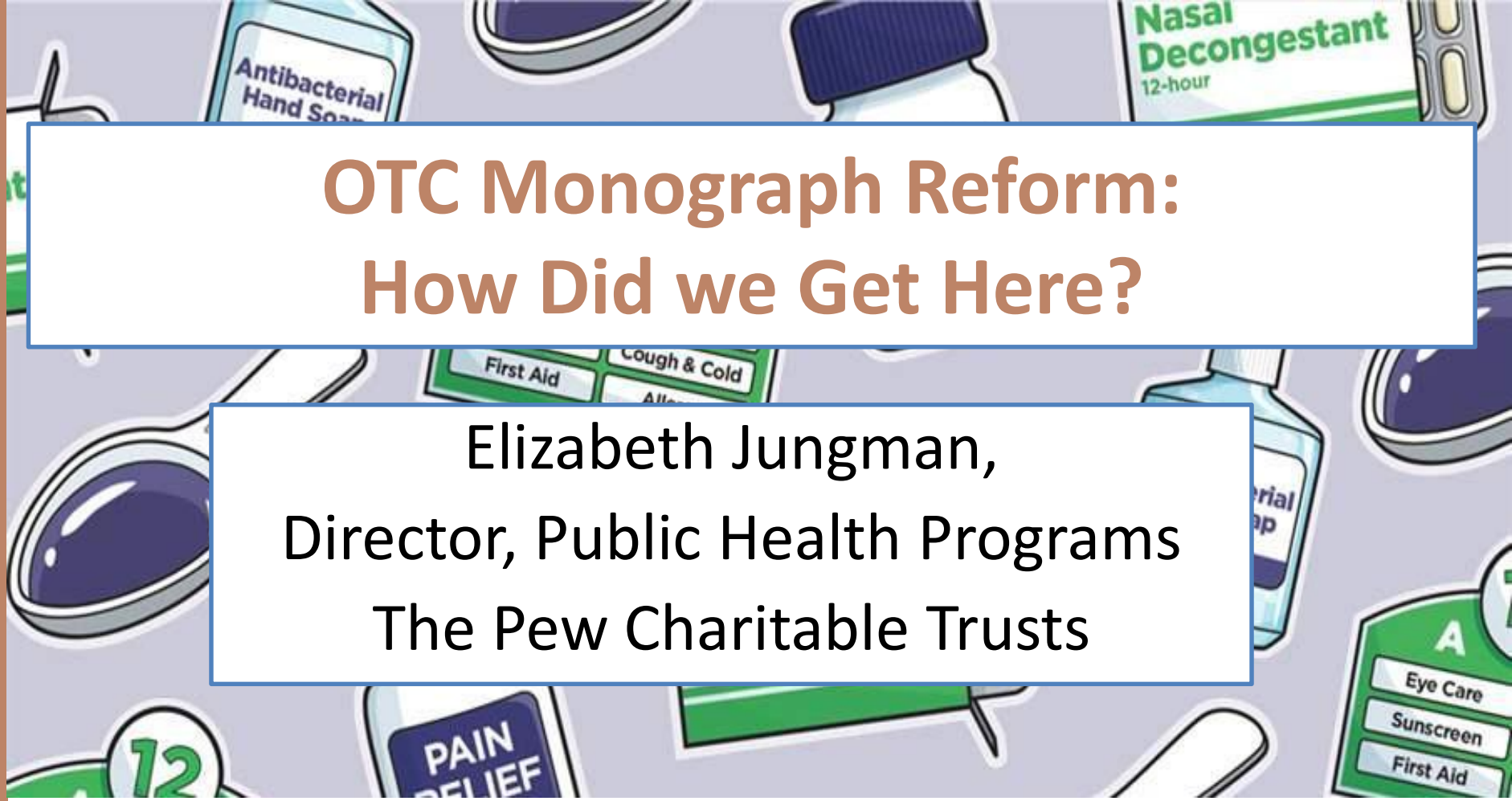


OTC Monograph Reform: How Did we Get Here?

Elizabeth Jungman,
Director, Public Health Programs
The Pew Charitable Trusts

OTC Oversight

- Americans routinely reach for OTC products
- Regulatory system dates from 1972
- Industry has grown: 100K+ products, $32B sales

Quick Review: What is a Monograph?

- Organized by therapeutic class or product categories, published in CFR
- Includes active ingredients, dosage form, doses/concentration, mandatory labeling
- Ingredient categories:
  - I: GRASE
  - II: Not GRASE
  - III: Inadequate evidence

Updating a Monograph

- Process: Rulemaking

- Input: HHS, often OMB, public comment

- Evidence: not standardized, not complete

Example: Topical Antimicrobials

What's the Problem?

- Expertise: FDA should make decisions about drug safety/ effectiveness
- Efficiency: FDA should be able to react quickly
- Evidence: FDA needs tools to obtain evidence
- Funding: FDA needs FTEs/resources

Example: Cough and Cold Products

- Monograph: 2 & Older
- Concerns re young children
- Voluntary updates: children under 4

Path to Legislation

FDA-Industry Negotiations Completed: July 2016

Stakeholder Involvement [November 2016]

S. 2315 introduced January 2018

Senate HELP Committee Markup April 24, 2018

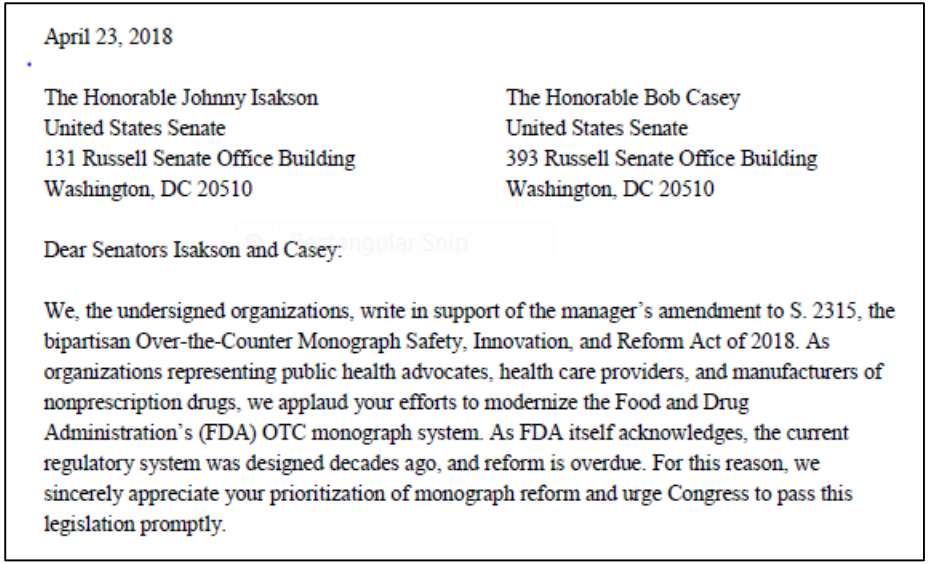
House Hearing September 2017

House Health Subcommittee Discussion Draft Markup January 2018

H.R. 5333 introduced March 2018

Stakeholder Engagement

- FDA/CHPA
- Patient/Public Health
  - AAP
  - AAAAI
  - APHA
  - NACCHO
  - SMFM



April 23, 2018

The Honorable Johnny Isakson
United States Senate
131 Russell Senate Office Building
Washington, DC 20510

The Honorable Bob Casey
United States Senate
393 Russell Senate Office Building
Washington, DC 20510

Dear Senators Isakson and Casey:

We, the undersigned organizations, write in support of the manager's amendment to S. 2315, the bipartisan Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018. As organizations representing public health advocates, health care providers, and manufacturers of nonprescription drugs, we applaud your efforts to modernize the Food and Drug Administration's (FDA) OTC monograph system. As FDA itself acknowledges, the current regulatory system was designed decades ago, and reform is overdue. For this reason, we sincerely appreciate your prioritization of monograph reform and urge Congress to pass this legislation promptly.

OTC Monograph Reform: What would S.2315 or H.R.5333 do?

David Spangler, Consumer Healthcare Products Association

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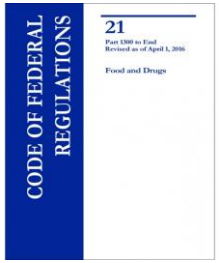
Rulemaking Replaced by Administrative Orders

Rulemaking



- Many iterations
- Years to finalize, no timeline
- Gov't reviews outside CDER

Administrative Orders

- Signed off in CDER
- Keeps scientific decisions with scientists
- Less than 2 years to finalize

Accelerated Safety Labeling Changes

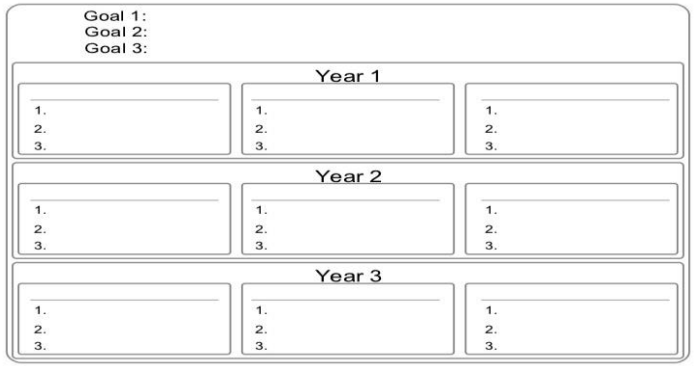
- FDA may issue an interim final order when safety issues demand quick action
- Stakeholders may comment, but interim order is effective when issued

INNOVATION

- Need to update monographs as technology advances
- Companies may submit an order request to amend a monograph (fee required)
- Two innovation tiers:
  - Tier 1: Human data (and exclusivity eligible)
  - Tier 2: New interchangeable term, standardizing dose directions, nomenclature, adding to “Other Information” within Drug Facts

Dashboard = Increased Predictability

- At least once a year, FDA will inform stakeholders what actions it is planning in next 3 years
- Will enable generation or assembly of data for GRAS/E determinations



User Fee Package Summary

- FDA message: no new mandates without resources
- Goals letter outlines FDA commitments under reforms at $22-34M/yr in fees over 5 years
  - FDA original estimates ≈ $100 million/yr for a program
- Fee revenue will come primarily from facility fees
  - Supplemented with minimal amounts from fees for innovation submissions
- FDA will increase base funding from $8M to $12M/yr

Key FDA Activities – First 5 Years

- Hiring and training scientific, technical, and leadership staff
- Ongoing safety activities
- Dashboard development
- IT implementation
- Guidance document development

Goals Letter – What's Measured?

- Hiring and training
  - ~20 FTEs/yr
- IT infrastructure
- Guidance documents
- GRAS/E determinations
- Meetings management
- Public dashboard
  - 1st one Oct 2019
- Innovations
- Dispute resolution
- Timelines for OTC monograph order requests
  - Years #4-5

Implementation Challenges and Priorities Prognostication

Deborah Livornese, Arnall Golden Gregory LLP

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CHALLENGES
KEY FDA ACTIVITIES

- Hiring and training
- IT Implementation
- Guidances
- Ongoing work

PRIORITIES

- Commitments under OMUFA
- FDA's safety priorities
- Other obligations

FDA's SAFETY PRIORITIES

- Drug safety communications (DSC)
- Advisory committees
- Actions on NDA labeling
- Category II Ingredients

DRUG SAFETY COMMUNICATIONS

- OTC Antacid products containing Aspirin (2016) (see NDAC)
- OTC Sodium Phosphate Laxative (2014)
- Acetaminophen SJS Warning (2013)
- Risk of Burns from OTC Topical Muscle & Joint Pain Relievers (Menthol, Methyl, Salicylate or Capsaicin)(2012)
- Limited Strength of Acetaminophen (≤ 325 mg) (2011)
- OTC Benzocaine Gels & Liquids for Teething Pain (2011)
- Different Concentrations of Liquid Acetaminophen for Infants (2011) (2009 NDAC)
- Non-Aspirin Nonsteroidal Anti-Inflammatory (NSAIDs) Risk of Heart Attack and Stroke (2015)

NDACs

- Combination analgesic & antacid (hangover) – 2017
- Codeine in children (Pulmonary-Allergy AC) - 2015
- Bronchodilators administered by hand-held bulb nebulizer – 2014
- Acetaminophen dosing information for children 6-24 months- 2011

Action on Rx Formulation

- Acetaminophen – Rx dose limited to ≤ 325 mg (2011)

Other and Related Monographs

- Pediatric Cough/Cold
- Internal Analgesic (Acetaminophen)
- Teething pain (Benzocaine)

Other Obligations

- Antiseptics – consent decree

- Sunscreen Innovation Act Rulemaking

QUESTIONS?

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Backup Slides

Example: phenylpropanolamine

- Risk of hemorrhagic stroke
- FDA proposed as Cat. II in 2005
- Manufacturers voluntarily halted sale

Example: acetaminophen

Dosing for Young Children

- Data to support dosing ages 6-24 months

High Doses

- > 325mg
- Compare to Rx