The Familiar OTC Drug Facts Label: Obstacles and Opportunities

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Background

- Specialize in consumer behavior research for OTC Drug Facts Labels (over 30 years)

- Label comprehension, self-selection, actual use and other studies

- We conduct **4000 - 5000** individual, DFL-oriented consumer interviews every year across a wide range of prospective OTC products

- That experience yields insights about strengths and weaknesses of the OTC DFL that can't be obtained in any other way

- Note:

Nearly all my comments today will focus on one special class of nonprescription labels – <u>Rx-to-OTC Switch DFLs</u>

The Familiar Drug Facts Label

To achieve its intended purpose, the standardized DFL has:

- Consistent format and appearance

- Standardized headings

- Straightforward, consumer-friendly language

Consequently, the DFL is generally best suited to OTC conditions that are:

1. Symptomatic, self-recognizable

2. Episodic or self-limiting

3. Have straightforward contraindications

The Familiar Drug Facts Label

- However, the current, familiar DFL has clear limitations:
  - Flat and static (meant to be printed on a physical package)
  - One-directional, single medium
  - Highly regulated headings and content → minimal flexibility

- That rigidity creates obstacles for:
  - Conditions that are:
    1. Difficult to self-recognize
    2. Chronic
    3. Require external testing or validation
  - Medications that are:
    1. Preventative
    2. Have complex or difficult-to-recognize contraindications

What the DFL Needs to Do

- To achieve its intended purpose, the DFL needs to communicate and mediate across a chain of steps and behaviors:

Look at Label or Ignore? → Read Carefully or Skim? → Compre-hend? → Right for Me to Use? → Warnings Apply to Me? → Ask a Doctor or Pharm? → Follow Directions for Use? → Modify or Stop Use? → Health Outcomes (Benefit and Risk)

- Things can go wrong at any point in this chain:
  - Consumers may choose not to read, or may default to other sources
  - May read but not understand
  - May understand but not apply (intentional over-ride)
  - May initially comply but fail to adapt to changing circumstances or symptoms

New OTC-Switch DFLs

- According to FDA's count, there have been 41 new Rx-to-OTC switches approved since 2001

New Rx to OTC Switch Approvals
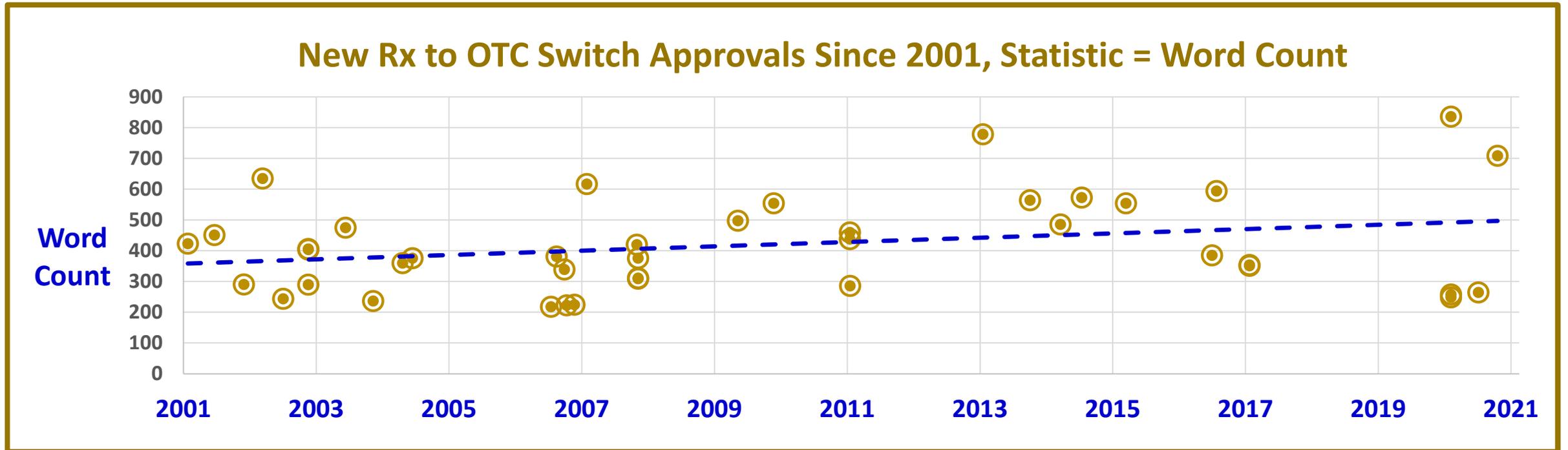**Prescription to Over-the-Counter (OTC) Switch List | FDA**
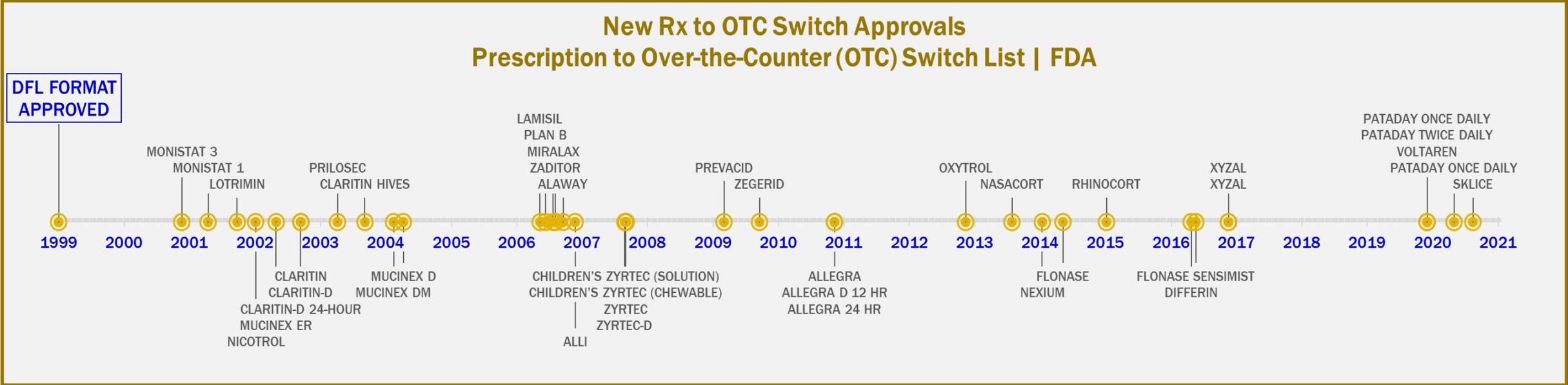
- Most are to treat symptomatic, self-recognizable and episodic or self-limiting conditions

Are New DFLs Changing Over Time?

- We first looked at the <u>length</u> of new OTC-switch DFLs over time (simple word count)

New Rx to OTC Switch Approvals Since 2001, Statistic = Word Count

- Range 217-835 words (Mean = 418.6, SD = 155.0)
- General increasing trend for quantity of label information over time

Are New DFLs Changing Over Time?

- Next, we looked at <u>readability</u> of new OTC-switch DFLs over time (Flesch-Kincaid Grade Level)

New Rx to OTC Switch Approvals Since 2001, Statistic = Reading Grade Level
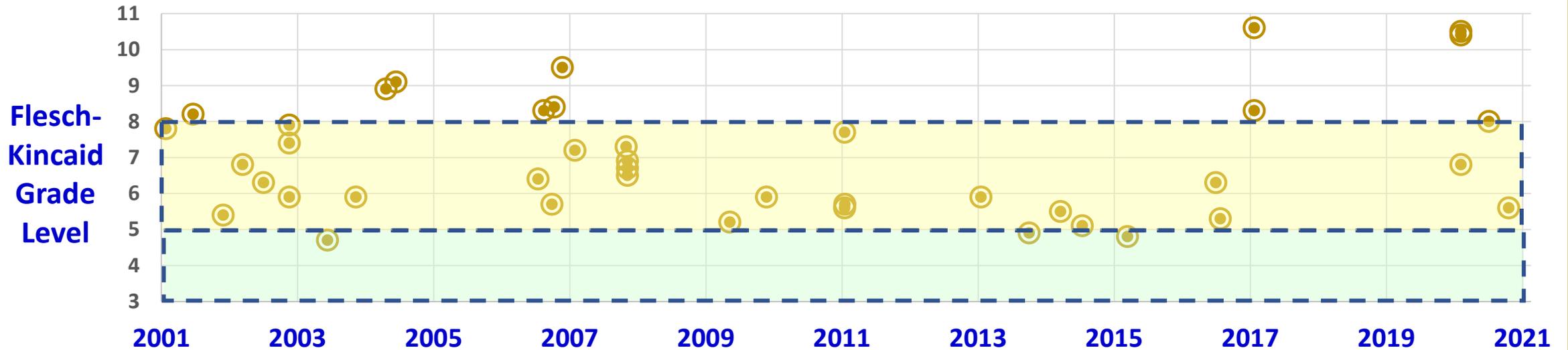
- No clear pattern or change in reading grade level over time
- Range: grade level 4.7 - 10.6 (Mean = 7.0, SD = 1.6)

Are New DFLs Changing Over Time?

- Key Points:
    1. New OTC switch DFLs may be getting longer on average (simple word count)

    2. Many new OTC switch DFLs are written to an 8th grade level or lower

    3. About one-quarter have reading grade levels 9th or higher (up to 10.6)

    4. Findings suggest we are already <u>stretching the boundaries of the DFL</u> in its current format

Other OTC Candidates/Categories

- Additional OTC categories that could provide a public health benefit, fill unmet needs, increase access to safe and effective medicines:
  - Cholesterol lowering drugs
  - Naloxone
  - Oral contraceptives
  - Erectile dysfunction drugs (PDE-5 inhibitors)
  - Migraine drugs, etc.

- Some of these have been carefully developed and tested, but encounter challenges or obstacles when attempting to portray <u>all</u> needed information within the confines of the standard DFL

- Note:

  Some sponsors and programs are significantly ahead of what I will describe in terms of OTC labeling innovation, but information is not yet in the public domain

Case Studies - Statins

- Clear public health case to expand access to safe and effective medications for dyslipidemia
- Merck Mevacor: 3 separate OTC applications and advisory committee meetings (in 2000, 2005, 2007)
- In each case, panels expressed concern about whether consumers can:
  - Understand the indication (cholesterol) well enough
  - Correctly diagnose themselves
  - Make appropriate decisions about whether to take the drug
  - Avoid adding a statin to, or replacing, their current Rx therapies
- Merck made valiant efforts to innovate with labeling, but constrained by limitations of DFL

DFL Obstacles or Challenges

- DFL offers only limited standard headings to help consumers to *self-diagnose* and *decide if a drug is appropriate* to use:

Case Studies – Statins

- Specifically, Merck added new panels or elements around the traditional DFL

- Even with these enhancements, FDA noted:

  consumers simply <u>could not select correctly</u>

Case Studies – Oral Contraceptives

- Clear potential public health benefits,
  But also labeling challenges…

- For example, the USPI breaks patient instructions into chronological pieces:
  - Before use
  - When to start
  - How to use, with directions for how to handle dosing errors

- OTC label must convey multiple messages about **bleeding** at different timepoints, each with a specific action:
  - Unexplained bleeding <u>before use</u> (ask a doctor)
  - Expected changes in bleeding <u>during use</u> (continue taking)
  - Unexpected changes in bleeding <u>during use</u> (<u>keep taking</u> and talk to a doctor)

DFL Obstacles or Challenges

- How to portray what to do if **bleeding occurs** at different time points. Messages could apply to multiple DFL sections:

Drug Facts

Active ingredient(s)   **Purpose**

Use(s)

Warnings

Do not use

Ask a doctor before use if you have

Ask a doctor or pharmacist before use if you are

When using this product

Stop use and ask a doctor if

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

- Messages to communicate a consumer should *talk to a doctor while* **continuing** *use* simply have no logical place in this DFL structure

Case Studies – PDE-5 Inhibitors (ED)

- Significant demand for a drug to provide true symptomatic relief to men with erectile dysfunction

- But, a key **contraindication** in the USPI is to avoid concurrent use with **nitrate drugs**

- Key **warning** about using with **heart disease**

- These must be clearly portrayed on an OTC DFL to ensure correct self-selection and safe ongoing use
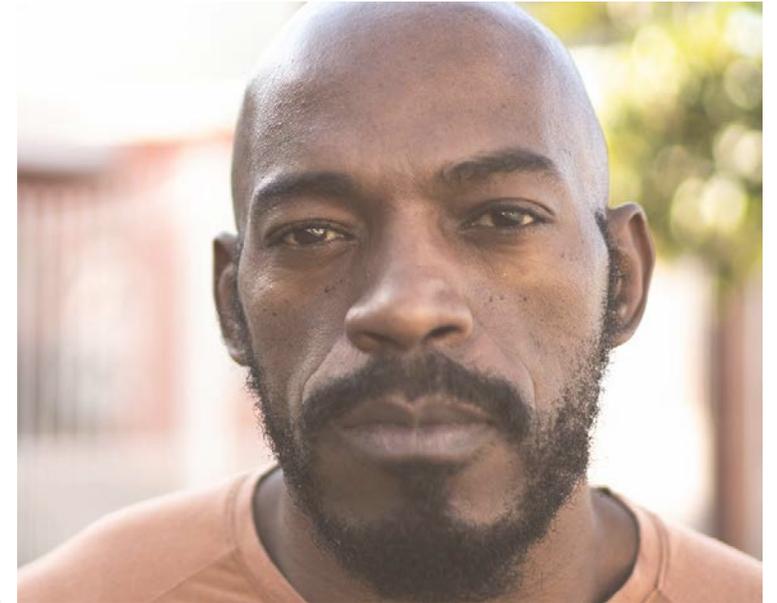
DFL Obstacles or Challenges

Drug Facts	
Active ingredient(s)	**Purpose**
....	
Use(s)	
Warnings	
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Ask a doctor before use if you have	
Ask a doctor or pharmacist before use if you are	
When using this product	
Stop use and ask a doctor if	
If pregnant or breast-feeding, ask a health professional before use.	

Challenges:

- Warnings must not only:
  1) **identify** "nitrate medications" but also
  2) **educate** about what "nitrates" are

- Standard "**Do not use**" warning may not be strong enough

- DFL must direct potential users who:
  1) Are **diagnosed** with **heart disease**, or
  2) **Not diagnosed** but have signs and symptoms of heart disease

  To "ask a doctor before use"

Familiar DFL "Work-Arounds"

- Colored text highlighting **<u>inside</u>** the DFL can be used to draw attention to important messages

- However, format and headings of the DFL cannot be altered, so sponsors routinely try adding elements **<u>outside or around</u>** the DFL to supplement understanding:

  - Principal Display Panels (PDPs) with graphics, claims or warnings
  - Icons
  - Pictograms (as in FDA's model naloxone label)
  - Colored text

- These techniques can help improve comprehension or self-selection, but often simply aren't enough on their own
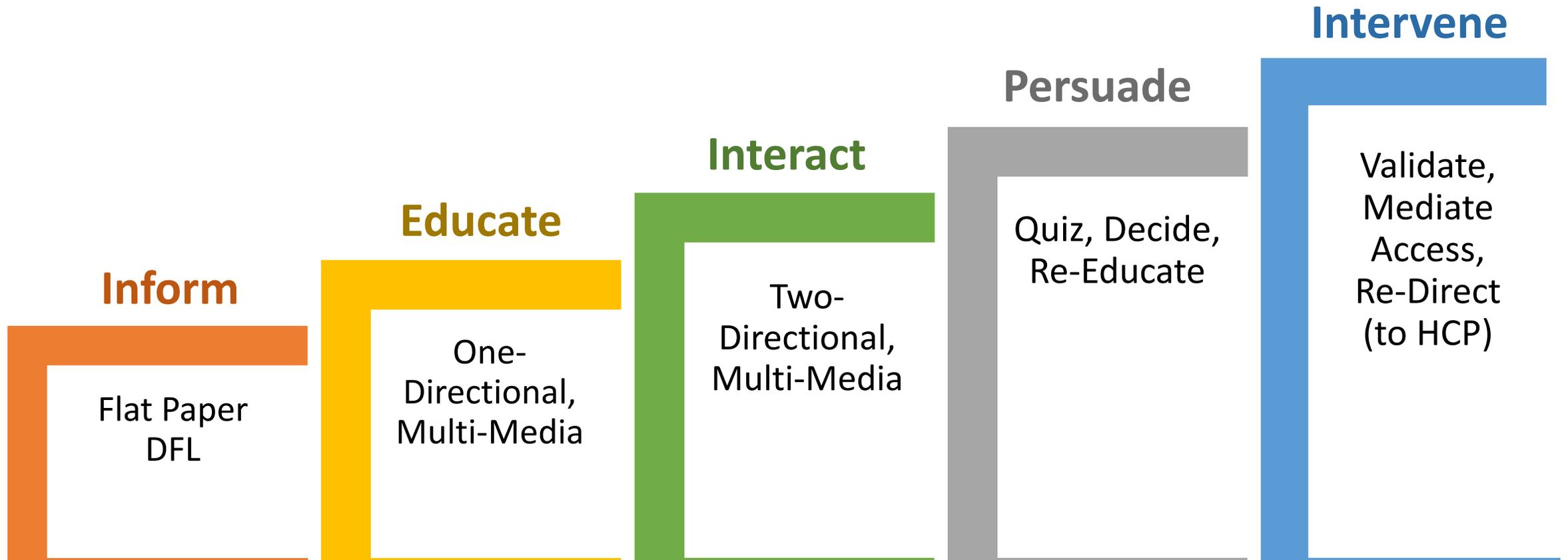
OTC Label Opportunities

- We have been focusing on extracting every drop of communication utility out of the flat, static DFL

- But available media for delivering health information have been evolving rapidly

- These tools and media are already all around us:
  - Websites, apps
  - Pictures, diagrams
  - Sound, narration
  - Automated, algorithmic support for decision-making
  - Quizzes to test knowledge
  - Interconnectedness to other existing health records and data

Think of all the things OTC labeling _could_ do…

- Hierarchy of possible actions
- Where are we with the DFL today?

Inform

Flat Paper DFL

Educate

One-Directional, Multi-Media

Interact

Two-Directional, Multi-Media

Persuade

Quiz, Decide, Re-Educate

Intervene

Validate, Mediate Access, Re-Direct (to HCP)

To achieve higher possibilities, we need to set the rigid, flat DFL aside

Question:
What is the state of the art in interactive, public-facing, self-directed education and decision-making tools?

- Think of the US federal tax code. The rules are vast and complicated.
- How can that volume of information be presented to intelligently assist average taxpayers in correct filing a return?
  - Hire a professional advisor (learned intermediary), OR
  - Create an application so intelligent and flexible that it accurately walks taxpayers through myriad individualized situations and requirements
- Online tax services have been doing this kind of "**guided-tour**" process for years and are getting very good at it

Why Do These "Guided Tour" Services Work?

- Reduce complex tasks to simple, distinct steps driven by an algorithm in the background
- At every step, there is a simple question, usually yes or no, but sometimes multi-select or enter-a-value
  - Every question comes with brief explanation about what the question means
  - Readily-available additional education for those who need to dig deeper or feel they are on the wrong pathway
- Users can ask for external help at any point, including linking out to a professional
- The process is designed to be so flexible, so simple and so robust that users essentially cannot fail <u>if they enter honest values</u>
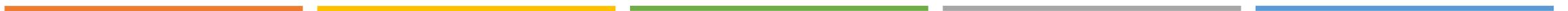
Key Take Away Points

- The current DFL has been a good tool to standardize and inform

- However, it cannot accommodate the more complex, less-traditional OTC candidate drugs of the future – DFL has been "stretched" to its limits

- Examples of technology to make complex education and decision tasks simple, reliable, and safe are all around us

- These intelligent tools provide a model for what "OTC labeling" could be, and must become, to keep up with the changing needs of the OTC consumer marketplace
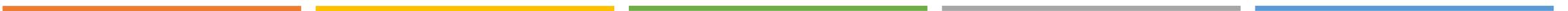
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