

The Future of the Drug Facts Label: Thinking Outside of the Box

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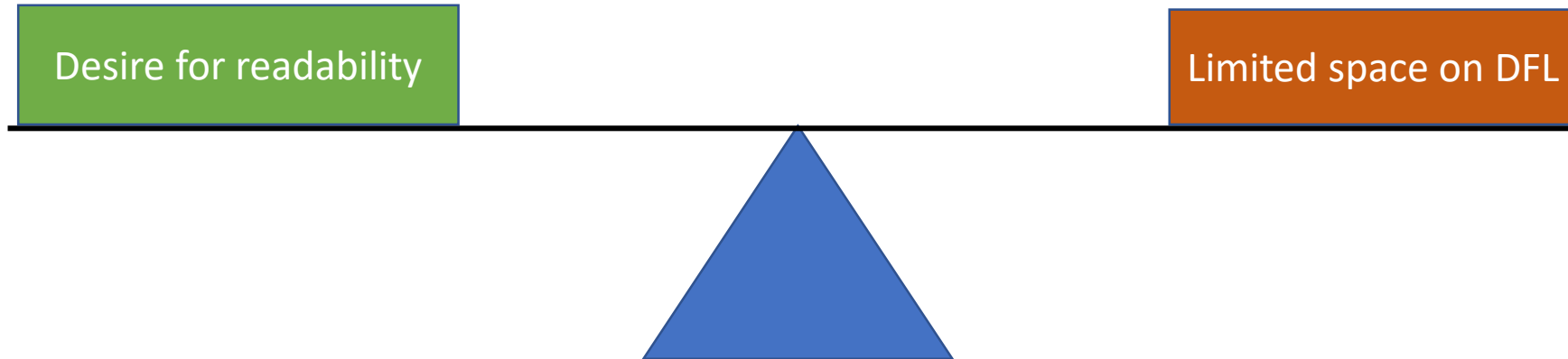
The DFL provided enormous improvements and advantages in OTC drug labeling

BUT

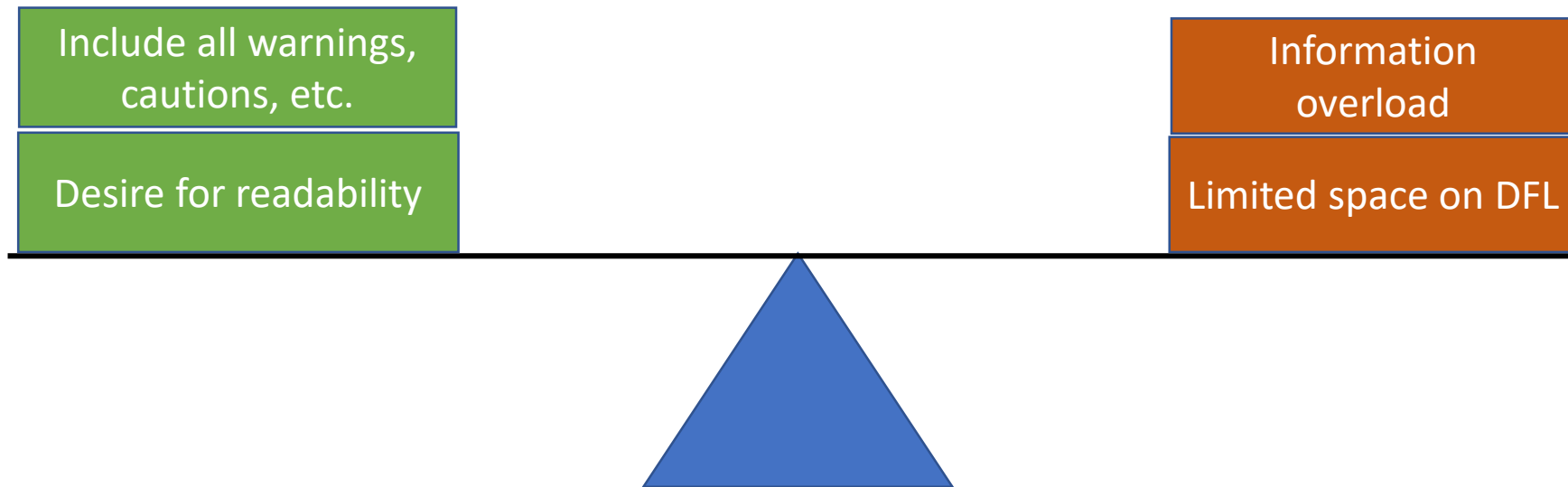
over the years the limitations of the current regulations have become clear.

<p>Drug Facts Active ingredient (in each tablet) Purpose Famotidine 10 mg.....Acid reducer</p>	<p>Drug Facts (continued) Stop use and ask a doctor if ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days</p>
<p>Uses ■ relieves heartburn associated with acid indigestion and sour stomach ■ prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages</p>	<p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>
<p>Warnings Allergy alert: Do not use if you are allergic to famotidine or other acid reducers Do not use ■ if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. ■ with other acid reducers</p>	<p>Directions ■ adults and children 12 years and over: ■ to relieve symptoms, swallow 1 tablet with a glass of water. Do not chew. ■ to prevent symptoms, swallow 1 tablet with a glass of water 60 minutes before eating food or drinking beverages that cause heartburn ■ do not use more than 2 tablets in 24 hours ■ children under 12 years: ask a doctor</p>
<p>Ask a doctor before use if you have ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ heartburn with lightheadedness, sweating, or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain ▶</p>	<p>Other information ■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store at 20°-25°C (68°-77°F) ■ protect from moisture and light</p> <p>Inactive ingredients carnauba wax, hypromellose, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, pregelatinized starch, talc, titanium dioxide, triacetin</p> <p>Questions or comments? 1-800-719-9260</p>

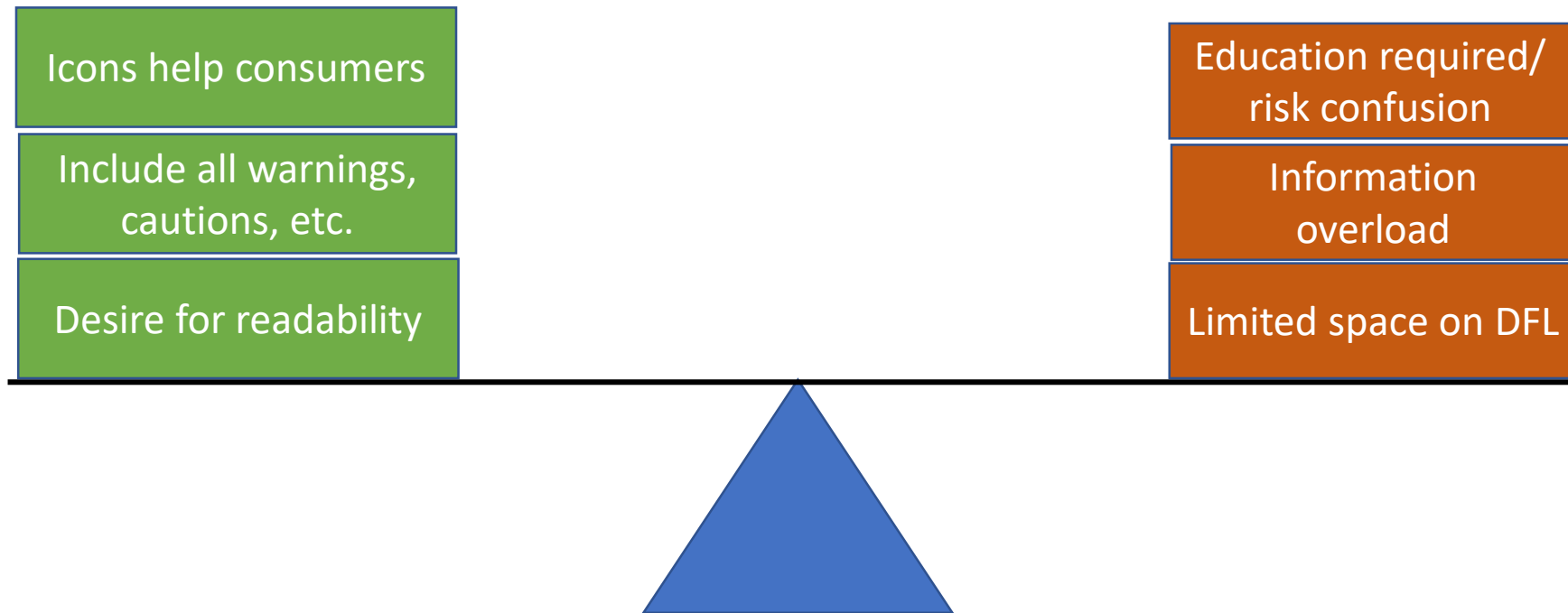
DFL construction becomes balancing act



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“Tweaking” of DFL yields only limited benefits

- “Information overload” from efforts to place too many messages on DFL – thus, adding information may decrease communication and decrease safety
 - How to reduce text burden?
 - Not all messages on the DFL are equally important – some can be omitted?
 - Use Consumer Information Leaflet to supplement DFL
 - Other adjunctive communication tools

Heretical proposal # 1: Not all information on the Rx label need appear on the DFL

- Prescription label intended for healthcare professional
 - Healthcare professional better able to filter information of minimal relevance
 - Less risk of information overload or incorrect decision making if information included of only theoretical concern or rare relevance

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- Prescription label may include outdated information – especially warnings
 - Post-approval studies and scientific advances may supersede label information
 - Often limited incentives for formal updating of prescription label


Should consumer bear the burden of irrelevant and/or outdated information?

No magic bullets: Icons and pictograms

- Accessible format to provide information to varied consumers, including groups for whom text DFL less effective
- Shown to improve communication in research setting
- Consumer must understand the pictogram!

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- Shown to be improve communication in research setting
- Consumer must understand the pictogram!
-  = Do not use if pregnant vs prevents pregnancy
- Research supports the need for education on icon to ensure proper interpretation
- Impact on communication of non-icon messages on DFL?

The DFL is not the complete reference but the *starting* point for the consumer-product interface

- Past 20 years make clear:
 - Limits on what the existing DFL can do, even with tweaks
 - Untapped opportunities to increase consumer access to safe and effective drugs and improve efficiency of healthcare system if product-related message delivery optimized
- Do not lose sight that the DFL must meet the consumer's needs for safe and effective use

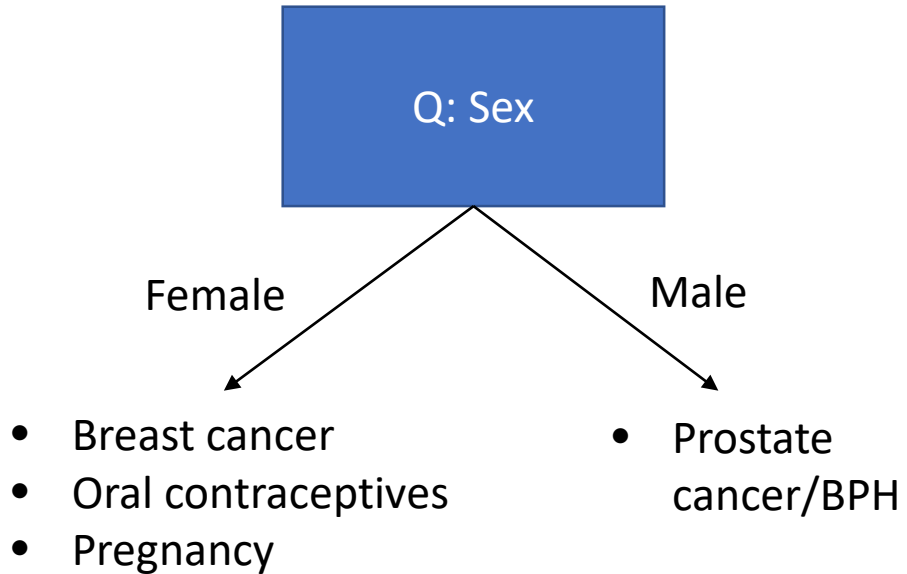
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- Heretical proposal #2: Potential future framework for the DFL
 - DFL *must* continue to provide the most critical information and, while if needed, effectively guide the consumer to *adjunctive* resources that ensure safe and effective use of the nonprescription drug

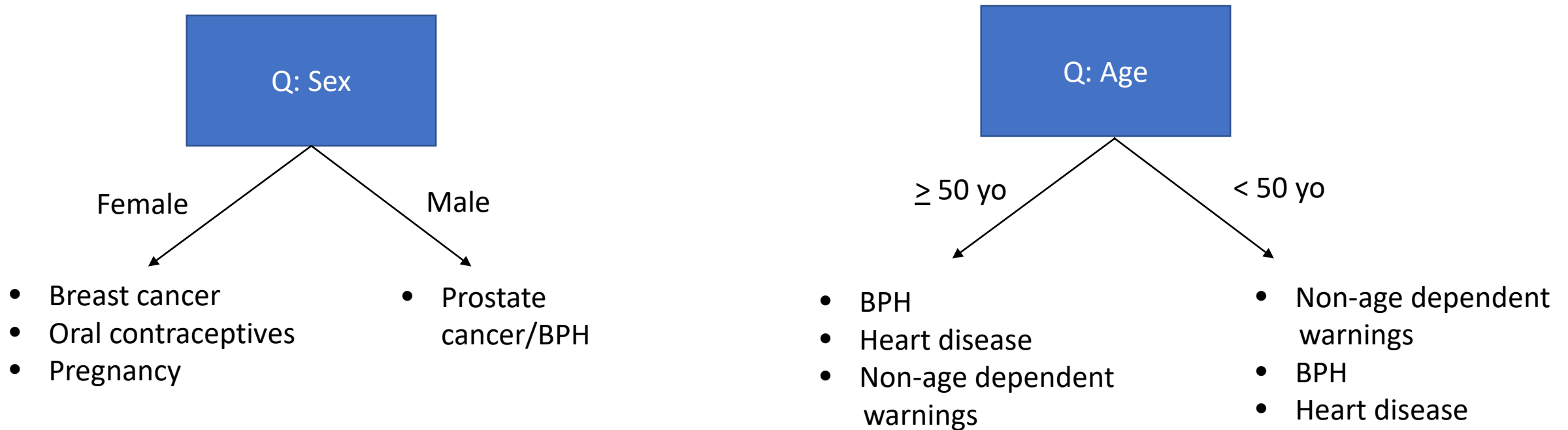
Using technology as an adjunct to the DFL

- Design to mitigate barriers to a specific DFL's effectiveness
 - Communicate *more messages* effectively to consumers
 - Present discrete messages uncluttered and sequentially
 - Adaptive presentation: Only those messages relevant to individual consumer
 - Varieties of strategies to utilize: Smartphone app (QR code linked), Point-of-purchase tablet, etc.
 - Communicate messages effectively to *more consumers*
 - Personalize presentation and other strategies to increase engagement
 - Use of pictures and video
 - Present alternative syntax for different consumers based on literacy, etc.
 - Language translation capabilities
 - Post-purchase assistance, reinforcement of messages
 - NSURE initiative opens the door for innovation, even as detailed regulations pending

Adaptive presentation: Prioritizing important messages and eliminating the irrelevant



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Adaptive presentation may result in an individual consumer seeing fewer messages and better communication of those that are seen

Ellume COVID-19 Home Test Kit – Technology Applications in Nonprescription Setting

- Received Emergency Use Authorization December 2020
- “Authorized Labeling” included:
 - Box labeling, Quick start guide
 - Animated instruction video
 - Ellume COVID-19 Home Test App
 - *Not adjunctive but integral to product use*



Ellume COVID-19 Home Test Kit – Technology Applications in Nonprescription Setting

- Allows result sharing with, for example, personal physician, health care authorities, employers
- Facilitate access to relevant healthcare educational materials
- Sophistication and need for smartphone means will not be usable by all consumers

Heretical proposal #3: Inability of some consumers to use the product should not be a barrier to approval

- An innovative product may have a highly favorable benefit-risk for consumers, but only for those who are able to use the product correctly
- What about consumers who can't use the product due to reasons of technology requirements or complexity?
 - For consumers unable to use is there a risk of harm if they attempt to use, or will they simply not select to use the product?
 - Can the consumer determine their ability to use the product prior to purchase?
- Should some consumers be denied benefits of product that other consumers are unable to use?
 - Both individual and public health benefits may still be substantial for such products
 - Industry with incentives to maximize number of consumers able to use

An underutilized adjunctive technology



- How to ensure provides value-added for all stakeholders?
- NOT require to do clerical, non-professional level tasks
- NOT a default BTC classification
- Implement and interpret facile tools designed to ascertain information critical to selection decision or deselection with repurchase
- Vaccine administration example of expanding role

Need to ensure future “improvements” evidence-based: Missed opportunities for research in marketplace ‘experiments’

- Evolutions in the world-wide marketplace allow for research to inform future regulatory decisions. For example,
 - What is the impact of pharmacists in markets with a BTC class?
 - How do consumers respond in markets when a product is down-classified (for example, diclofenac in UK)? Do they use alternatives that increase risk?
 - How do consumers use other healthcare products with adjunctive tools?
 - Do consumer-healthcare provider interactions change after an Rx-OTC switch? Is there harm from a decrease in other healthcare services?

Summary

- Going forward, DFL should be viewed as starting point for consumer communications
- OK if information on DFL *necessary* but not *sufficient*
- Adjunctive tools can be used to enhance decision making:
 - Purchase decision
 - Use decision
 - Ensuring proper use
 - Deselection decision
- Decisions on messaging strategies should be evidence-based with focus on product-specific, clinically important outcomes

Thank you for
your attention