



Regulatory Education for Industry (REdI):

PRESCRIPTION DRUG LABELING - CHALLENGES AND ISSUES

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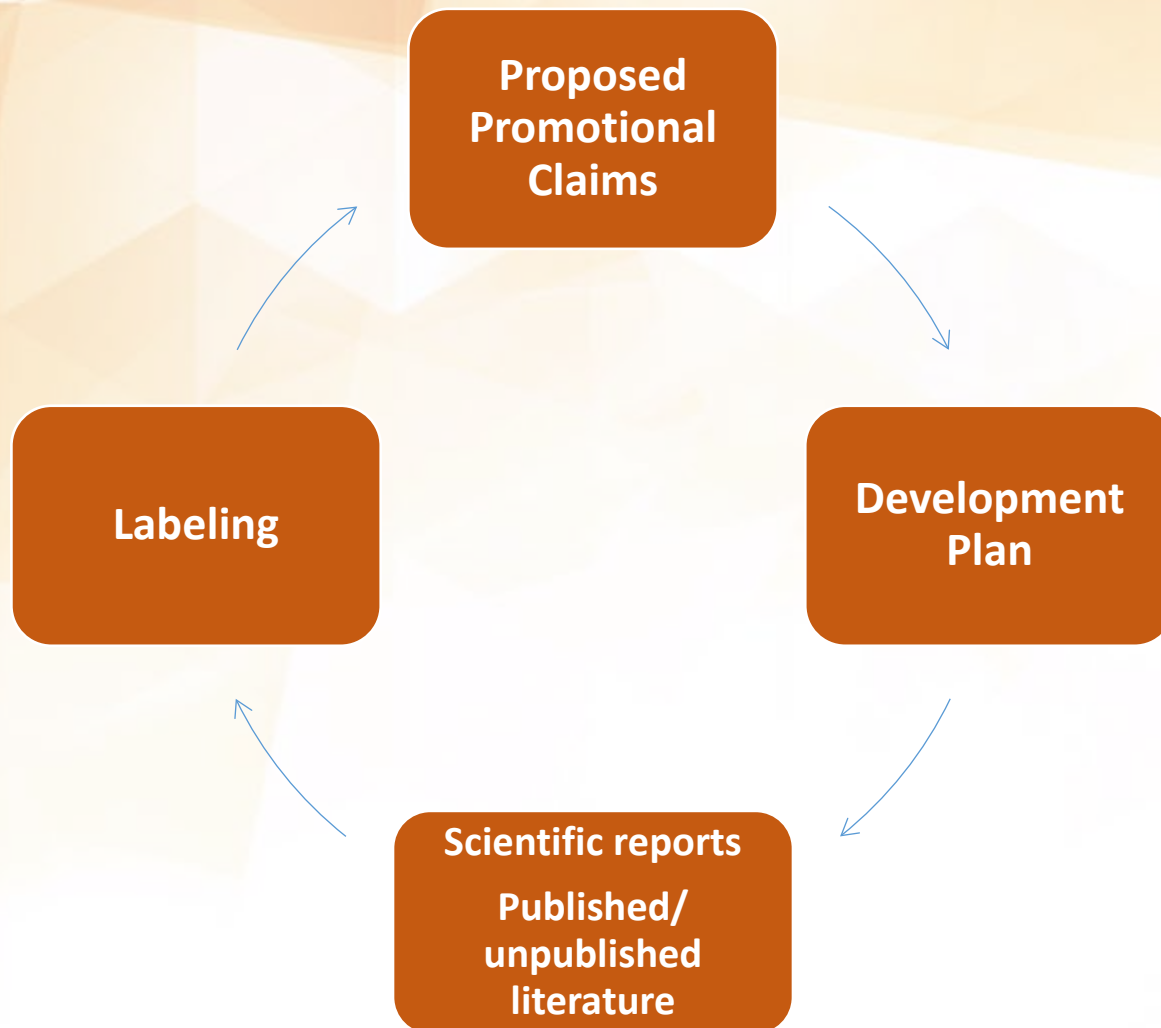
Beginning with the End in Mind

The Connection Between Product Labeling and Promotion

Dolores Shank-Samiec
Merck & Co., Inc.



Begin with the end in mind





The Label....

“The label is the most important product that a company’s research arm produces...”

**Essence of
Licensure**

**Conveys the
Use of the
Product**

**Describes
Efficacy and
Safety of the
Product**

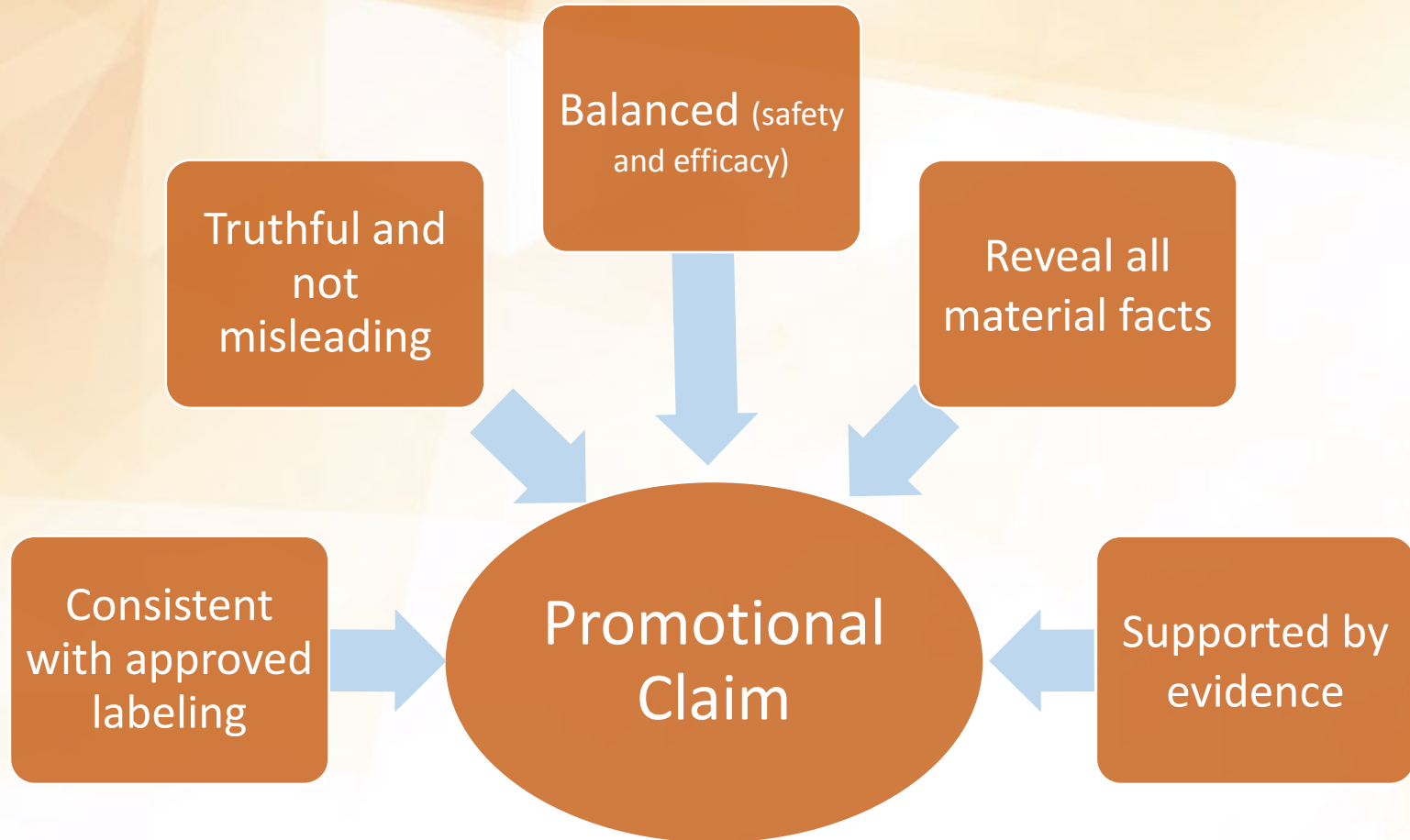


Target Product Profile (TPP): What Is It?

- FDA published draft *Guidance for Industry and Review Staff: Target product Profile—A Strategic Development Process Tool*, in March 2007
- A voluntary planning tool intended to provide a format for discussions between a sponsor and the FDA
 - ...can be used throughout the drug development process
- In a TPP, the sponsor specifies the labeling concepts that are the goals of the drug development program, documents the specific studies intended to support the labeling concepts, and then uses the TPP to assist in a constructive dialogue with the FDA.
- Ideal version of what the sponsor would like to claim in labeling
 - Guides the design, conduct, and analysis of clinical trials to maximize the efficiency of the development program.



The TPP Integrates General Principles of Promotion into Clinical Development Plan





Evidence for Promotional Claims

Different levels of evidence are required to support different promotional claims for prescription drugs

Substantial evidence*

Substantial clinical experience

Adequate evidence

***Section 505(d) of the FDCA describes substantial evidence consisting of adequate and well-controlled investigations...conducted by qualified experts...on the basis of which it could be concluded that the drug will have the effect it is represented to have under the conditions of the use proposed in labeling.**



Evidence for Promotional Claims

Promotional Claims

Claims of Treatment Benefit

Effect of treatment on how a patient
“survives, feels, or functions” in daily
life

Used interchangeably with “clinical
benefit”

Measured directly or indirectly

Includes reported assessments (PROs,
ClinROs, ObsROs)

Non-clinical Claims

No suggestion of treatment benefit,
e.g.,

Certain claims of
convenience/ease of use

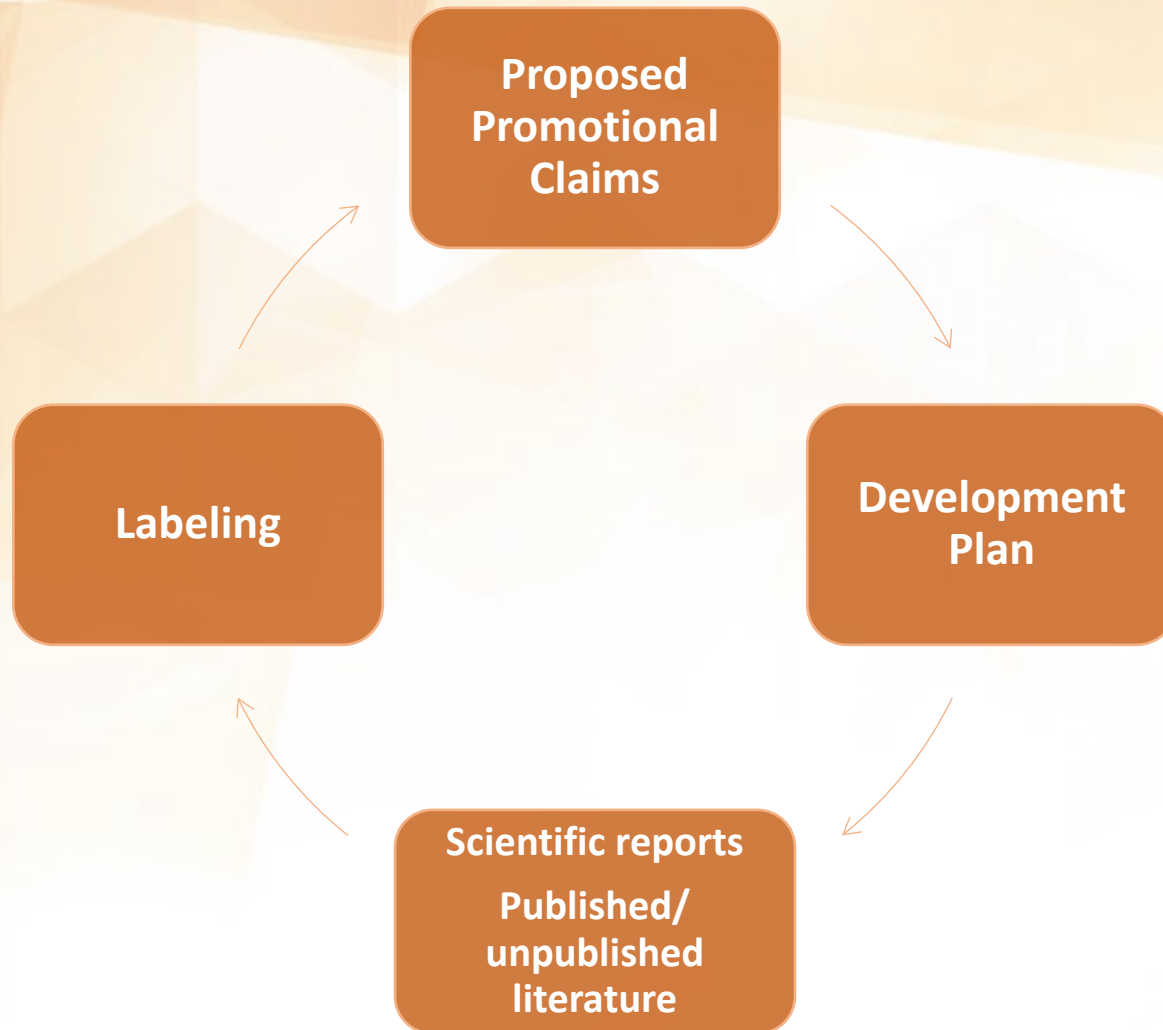
Drug utilization

Substantial Evidence

Adequate Evidence



Begin with the End in Mind: The Case for Building Health Literacy into Patient Labeling



What is Health Literacy?

Definition: “The degree to which individuals have the **capacity to obtain, process and understand basic health information** and services needed to make appropriate health decisions.”¹

- Poor health literacy is “a **stronger predictor** of a person’s health than age, income, employment status, education level & race.”²

- **Only 12%** of American adults have proficient health literacy.³



“That’s not quite the stool sample we had in mind, Mr. O’Donnell.”

1. US Dept Health & Human Services. *Healthy People 2010*. Washington, DC: US Govt Printing Office. 2000.
2. Parker R et al. Library outreach: overcoming health literacy challenges. *J Med Libr Assoc*. 2005 October; 93(4 Suppl): S81-S85.
3. US Dept Health & Human Services, Office of Disease Prevention & Health Promotion. <http://www.health.gov/communication/literacy/issuebrief/>. Accessed on 11/12/13



Low Health Literacy: Who's at Risk?

- Health literacy can affect people of all ages, races, incomes, and education levels¹
- Some population groups are particularly vulnerable to health literacy challenges²:
 - The elderly (age 65+)
 - Recent immigrants who do not speak English
 - Minorities
 - Low income



1. U.S. Department of Health and Human Services (HHS). Office of Disease Prevention and Health Promotion. *National Action Plan to Improve Health Literacy*. Washington, DC: Author. 2010.

2. Weiss BD. *Health Literacy and Patient Safety: Help People Understand*. American Medical Association Foundation and American Medical Association. May 2007.



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Health literacy depends on the context.

Even people with advanced education and reading skills can face health literacy challenges

1. U.S. Department of Health and Human Services (HHS). Office of Disease Prevention and Health Promotion. *National Action Plan to Improve Health Literacy*. Washington, DC: Author. 2010.
2. Weiss BD. *Health Literacy and Patient Safety: Help People Understand*. American Medical Association Foundation and American Medical Association. May 2007.



Health Literacy May Impact a Person's Ability to Self-Manage their Health

“It is neither just, nor fair, to expect a patient to make appropriate health decisions and safely manage his/her care without first understanding the information needed to do so.”²

Comprehension

- Understand and navigate the healthcare system

Communication

- Talk to providers about health information

Performance

- Use numeracy skills

Behaviors

- Adopt healthy lifestyles

Decision-making

- Act on health-related news and public health alerts

1. U.S. Department of Health and Human Services (HHS). Quick Guide to Health Literacy. Fact Sheet. Available at health.gov/communication/literacy/quickguide/. Accessed May 5, 2013.

2. Reducing the Risk by Designing a Safer, Shame-Free Health Care Environment. AMA, 2007

•AHRQ Pub. No. 10-0046-EF



Patient Health Behaviors and Outcomes Linked to Low Health Literacy

Preventive Services¹

- Tend to make less use of preventive care and screenings, such as mammograms and flu shots
- Tend to enter healthcare system later when symptoms and/or disease is more advanced¹

Knowledge & Treatment

- Tend to have less knowledge of their chronic conditions and of their optimal management
- Less likely to ask questions of the provider¹

Utilization

- Generally have more hospital admissions that were potentially preventable, as well as more Emergency Department visits¹

Adherence

- Often do not understand why they need to take medications^{1,2}
- Difficulty affording medications is often not discussed during physician-patient interactions³

1. Nielsen-Bohman, L., Panzer, A. M., & Kindig, D. A. (Eds.). (2004). *Health literacy: A prescription to end confusion*. Washington, DC: National Academies Press.
2. Weiss BD. *Health Literacy: Health literacy and patient safety: Help patients understand*. The American Medical Association (AMA) Foundation and the AMA. May 2007.
3. Wilson IR, et al. "Physician-Patient Communication About Prescription Medication Nonadherence: A 50-State Study of America's Seniors." *JGIM*. January 2007;22(1):6-12.



Major Health Policy Initiatives Promoting Health Literacy

Affordable Care Act

Signed into law in March 2010

- Health literacy provisions are included in the ACA; improving health literacy is an integral part of health care reform¹

The National Action Plan to Improve Health Literacy

Launched by HHS Secretary Sebelius in May 2010

- Includes seven key goals to improve health literacy in the United States²

The Plain Writing Act

Signed by President Obama in October 2010

- To improve the effectiveness and accountability of federal agencies to the public by promoting clear government communication that the public can understand and use¹

•Healthy People 2020

Launched in December 2010

- Healthy People 2020 objectives lend public health policy support to the ACA, the National Action Plan, and the Plain Writing Act of 2010¹

1. IOM (The Institute of Medicine). *Health Literacy Implications for Health Care Reform: A Workshop Summary*. Washington, DC: The National Academies Press. 2011.
2. U.S. Department of Health and Human Services (HHS). Office of Disease Prevention and Health Promotion. *National Action Plan to Improve Health Literacy*. Washington, DC: Author. 2010.



Key Learnings from a Market Research Study

- **Patient Labeling Research:**
 - **Must include a broad range of respondents across all health literacy levels**
 - **Must be an iterative process that incorporates patient feedback at each step**
- **Partnership between academia and industry is key to developing patient centric communications.**
- **It is possible to achieve patient labeling that is well understood by individuals of all health literacy levels.**



Relevance to Other Companies

- **This approach may be viewed as a model that could be adapted by the FDA, other pharmaceutical companies, other industries in healthcare (i.e. health insurers, medical device makers), and health systems that generate patient-facing communications.**
- **Besides patient labeling, this new approach to the application of health literacy principles may be used:**
 - **To aid enrollment of underrepresented populations in clinical trials**
 - **Patient education**
 - **Packaging of medicines**



FDA and Sponsor Companies Collaborate on Patient Labeling

Clear, concise, informative patient labeling is critical to healthcare consumer promotion

**Patient
Product
Information**

**Medication
Guide**

**Instructions for
Use**



Closing Thought

“It will take everyone working together in a linked and coordinated manner to improve access to accurate and actionable health information and usable health services.”

U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion.
(2010). National Action Plan to Improve Health Literacy. Washington, DC.



Thank you!

QUESTIONS?