Beginning with the End in Mind
The Connection Between Product Labeling and Promotion

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Begin with the end in mind …..

- Proposed Promotional Claims
- Development Plan
- Scientific reports
  - Published/unpublished literature
- Labeling
“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

- Truthful and not misleading
- Consistent with approved labeling
- Balanced (safety and efficacy)
- Reveal all material facts
- Supported by evidence
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 FFDCA 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

- Proposed Promotional Claims
- Labeling
- Development Plan
- Scientific reports
  - Published/unpublished literature
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.”

- Poor health literacy is “a stronger predictor of a person’s health than age, income, employment status, education level & race.”
- Only 12% of American adults have proficient health literacy.

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

Low Health Literacy: Who’s at Risk?

• Health literacy can affect people of all ages, races, incomes, and education levels\textsuperscript{1}

• Some population groups are particularly vulnerable to health literacy challenges\textsuperscript{2}:
  • The elderly (age 65+)
  • Recent immigrants who do not speak English
  • Minorities
  • Low income

Health literacy depends on the context.
Even people with advanced education and reading skills can face health literacy challenges

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.”

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

Patient Health Behaviors and Outcomes Linked to Low Health Literacy

Preventive Services
- 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 advanced

Knowledge & Treatment
- Tend to have less knowledge of their chronic conditions and of their optimal management
- Less likely to ask questions of the provider

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

Adherence
- Often do not understand why they need to take medications
- Difficulty affording medications is often not discussed during physician-patient interactions

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 reform

**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 States

**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 use

**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 2010

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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
“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.”

Thank you!

QUESTIONS?