Enhancing Patient Centricity: Communication and Involvement

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FDLI Advertising and Promotion Conference: For the Drug, Medical Device, and Veterinary Industries
September 26, 2017/Washington, DC
2017 Life Sciences Trends

The year of the patient

“Patient first has become a rallying cry in the pharma industry, but not all companies can live up to that standard. In general, the most successful firms are moving away from a traditional, top-down model of product promotion and toward a flexible, interactive approach that gives patients better tools and more focused information about the drugs they are taking and how to manage their conditions. The insights that drugmakers provide to patients reduce potentially dangerous errors related to taking the drug and minimize the time that patients have to spend managing their disease and navigating the healthcare system.”

Although many patients are sensitive about sharing personal information, a recent survey by PwC’s Health Research Institute (HRI) found that most people are willing to let pharma companies and regulators know about their medical activities if it will lead to better care.

Pharma companies that succeed in patient engagement efforts increase their chances of regulatory and commercial success.

https://www.strategyand.pwc.com/trend/2017-life-sciences-trends
Patient Centricity in Practice – Some Examples

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FDA Consumer-Oriented Advertising and Promotion Guidances – Some Examples

- Consumer-Directed Broadcast Advertisements (1999)
- Consumer-Directed Broadcast Advertisements – Questions and Answers (1999)
- Direct-to-Consumer Television Advertisements -- FDAAA DTC Television Ad Pre-Dissemination Review Program (2012)
- Internet/Social Media Platforms with Character Space Limitations— Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (2014)
- Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (2014)
- Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs (2015)
PhRMA Guiding Principles DTC Advertising

18 PhRMA Guiding Principles

1. DTC advertising of prescription medicines *can benefit the public health* by increasing awareness about diseases,

2. DTC information *should be accurate and not misleading*, should make claims only when supported by substantial evidence, should reflect balance between risks and benefits, and should be consistent with FDA approved labeling.

3. DTC television and print advertising which is designed to market a prescription drug *should also be designed to responsibly educate the consumer* about that medicine.

4. DTC television and print advertising of prescription drugs *should clearly indicate that the medicine is a prescription drug* to distinguish such advertising from other advertising for non-prescription products.

5. DTC television and print advertising *should foster responsible communications between patients and health care professionals* to help patients achieve better health.
FTC Guides Concerning the Use of Endorsements and Testimonials in Advertising

➢ The Guides provide the basis for voluntary compliance with the law by advertisers and endorsers.

➢ Practices inconsistent with these Guides may result in corrective action by the Commission under Section 5 if, after investigation, the Commission has reason to believe that the practices fall within the scope of conduct declared unlawful by the statute.

➢ The Guides set forth the general principles that the Commission will use in evaluating endorsements and testimonials, together with examples illustrating the application of those principles.

➢ Whether a particular endorsement or testimonial is deceptive will depend on the specific factual circumstances of the advertisement at issue.
DTC Advertising: Patient Testimonials

OPDP Warning Letter
Teva Pharmaceuticals Web Page and Exhibit Booth Materials

Misleading or Unsubstantiated Efficacy Claim(s)
Broadening, Misinformation, or Inadequate Communication or Indication, Use or Administration

- “With the help of his doctor, David began COPAXONE® (glatiramer acetate injection) therapy in 2003”

- “After a year and a half of hard work and determination, David was the USA Triathlon National Champion in the physically challenged category.”

- David went on to compete and win numerous national and international triathlons from 2005-2008.

While the statements may be an accurate reflection of these patients’ experiences, the patient testimonials, according to OPDP, misleadingly broaden the indication and overstate the efficacy of Copaxone.
Social Media: Patient Testimonials

The Office of Prescription Drug Promotion (OPDP) issued a Warning Letter on August 7, 2015 to Duchesnay, Inc. for its morning sickness drug, Diclegis (doxylamine succinate and pyridoxine hydrochloride), citing a violative social media post by Kim Kardashian.

As stated in the Warning Letter, the social media post is misleading because it presents various efficacy claims for DICLEGIS, but fails to communicate any risk information.
Patient Ambassador Model

• Numerous surveys have reported on a trust gap that currently exists between pharmaceutical companies and their patient consumers.
• What is the right information to communicate to patients? And what is the best way to communicate this information effectively?
• Examples:
  – Patient Speaker Programs
  – Patient Advocacy Groups

Patient Registries

• May be institution-driven, or initiated by advocacy groups or pharma/device industry

• Potential Issues:
  – Integrity of information
  – Bias/motivation for participation
  – Use of data
  – Consent / privacy issues
PatientsLikeME (Online Patient Network)

- A new report from the National Quality Forum (NQF) highlights the potential of online patient communities to serve as virtual “town squares” where measure developers and other stakeholders can access the patient experience not otherwise available.

- PatientsLikeME, the online patient network and research platform, analyzed data from its multiple sclerosis, chronic obstructive pulmonary disease, and rheumatoid arthritis communities to better understand health-related quality of life and functional outcomes. Members of these communities also provided feedback on specific tools used to collect patient-reported outcomes (PRO) data.

- According to NQF, the guidance from patients indicated that tools available for clinicians to collect PROs do not use language that patients would use to describe common symptoms, presenting an opportunity for “real-world” improvement.

- Researchers identified opportunities to improve tools used to collect PROs. This approach marks the first time that patients’ voices have been captured on such a large scale for the development and refinement of select measures, according to NQF.

The guidance describes how the Food and Drug Administration (FDA) reviews and evaluates existing, modified, or newly created patient-reported outcome (PRO) instruments used to support claims in approved medical product labeling.

A PRO instrument (i.e., a questionnaire plus the information and documentation that support its use) is a means to capture PRO data used to measure treatment benefit or risk in medical product clinical trials.
FDA Patient Network

• Created in 2012, the FDA Patient Network (PN) is part of the Office of Health and Constituent Affairs (OHCA).

• The FDA Patient Network is a comprehensive program that works to expand and sustain communication with patients and their community.

• The FDA Patient Network also helps educate patients, patient advocates, and their healthcare professionals about medical product regulations.
Patient Engagement at the FDA

Learn About Patient Engagement at the FDA

The FDA has a difficult task when it comes to evaluating and approving new and innovative medical products. Individual patients may experience the effects of diseases and therapies differently and each individual patient has a unique perspective about treatments or diagnostic procedures that differ from those perspectives of other patients or of their healthcare provider. The FDA has included the patient perspective in FDA Advisory Committee meetings since 1991. This page summarizes the different opportunities that patient and caregivers can get involved in at the FDA.

- FDA Patient Network
- FDA Patient Representative Program
- Food and Drug Administration Safety and Innovation Act (FDASIA) Section 1137
- FDA and European Medicines Agency Patient Engagement Cluster
- Patient Engagement Initiative
- Patient Reported Outcomes
- Patient Focused Drug Development Initiative
- Device Patient Preference Initiative
- Patient Engagement Advisory Committee
FDA Patient Engagement

The FDA is seeking input from the committee and the public on challenges faced by patients in medical device clinical trials, and recommendations for how patient input and engagement can be used to overcome these challenges. Based on feedback from patient groups and industry, incorporating patient input in the design, conduct and communication of clinical trials is a top priority.
The Voice of the Patient: A Series of Reports from FDA's Patient-Focused Drug Development Initiative

FDA's Patient-Focused Drug Development initiative is a commitment under the fifth authorization of the Prescription Drug User Fee Act (PDUFA V) that aims to more systematically gather patients’ perspectives on their condition and available therapies to treat their condition.

FDA is holding at least 20 public meetings, each focused on a specific disease area.

The Voice of the Patient reports will summarize the input provided by patients and patient representatives at each of these public meetings.
Questions?

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