OPDP Update on Oversight of Prescription Drug Promotion

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Topics

- Operations and Reorganization Update
- Policy and Guidance Development
- Enforcement Analysis and Examples

Office of Prescription Drug Promotion (OPDP)

- Formerly known as the Division of Drug Marketing, Advertising, and Communications (DDMAC)
- September 2011 - DDMAC was reorganized and elevated to an office structure (OPDP) which consists of:
  - Immediate Office
  - Division of Professional Drug Promotion (DPDP)
  - Division of Consumer Drug Promotion (DCDP)
- OPDP alignment based on functional areas
  - Review functions
  - Policy and support functions

Office of Prescription Drug Promotion

- Immediate Office
  - Office Director (Thomas Abrams)
  - Associate Office Director (Mark Askine)
    - Review Functions
      - Division of Professional Drug Promotion
      - Division of Consumer Drug Promotion
  - Associate Office Director (Marci Kiester)
    - Policy and Support Functions
      - Regulatory Counsel Team
      - Social Science Research Team
      - Project Management Team

Office of Prescription Drug Promotion

- Divisions
  - Division of Professional Drug Promotion
    - Division Director (Andrew Haffer)
      - 4 Review Teams and Team Leaders
  - Division of Consumer Drug Promotion
    - Division Director (Robert Dean)
      - 4 Review Teams and Team Leaders

Top Priorities of OPDP

- Policy and guidance development
- Labeling reviews
- Core launch reviews and TV ad reviews
- Enforcement
- Training and communications

Note all are top priorities and not in any rank order

Guidance Issued Since Last Year's Conference

- Draft Guidances
  - *DTC Television Advertisements – FDAAA DTC Television Ad Pre-Dissemination Review Program*
  - *Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices*
- Final Guidance
  - *Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling*

Guidance Development Plans

- Revising current draft guidances
  - *Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements*
  - *Presenting Risk Information in Prescription Drug and Medical Device Promotion*
- Exploring and discussing other areas of interest
  - Health care economic information/formularies
  - Medical practice guidelines
  - Comparative claims
  - Scientific exchange
    - FR Notice seeking comments
- Working on Internet/social media promotion

Voluntary Compliance

- Overall promotional materials appear to be improving
- Certain promotional proposals and suggestions are also concerning
- Other promotional materials and activities are violative

Enforcement

Surveillance

- Disseminated materials submitted to FDA
  - Post-marketing reporting requirements (Form FDA 2253)
- Conference attendance
- Complaints
- Broad surveillance of materials
- Healthcare Professional Outreach Initiative
  - Bad Ad Program

The Bad Ad Program

- FDA-sponsored outreach program designed to increase awareness of healthcare professionals (HCPs) about the role they can play in helping FDA ensure that prescription drug advertising and promotion is truthful and not misleading
- When HCPs recognize misleading drug promotion, they can help put a stop to it by reporting it to FDA:
  - Call
    - **855-RX-BadAd**
  - E-mail
    - **BadAd@fda.gov**

The Bad Ad Program Highlights

- Developed educational brochure, video, and reminder magnet
- Staffed exhibits at medical conferences
- Presented at U.S. teaching hospitals
- Participated in webcast for FDA's Expert Commentary Series on Medscape
- Hosted live Bad Ad webinar for medical and pharmacy professionals
- Running journal ad campaign
- Developing web-based continuing education program for the nation's healthcare professionals
- Pursuing opportunities to enhance student education (medical/pharmacy/nursing)

Risk-Based Enforcement Approach

- Focus on the impact on public health including:
  - Newly approved products
  - Products with significant risks
  - Products cited for violations in the past
  - Products cited in complaints
  - Products promoted with far reaching campaigns

Most Common Violations January 2011 – September 2012

- Omission and minimization of risk information
- Misleading efficacy claims
- Misleading superiority claims
- Promotion of unapproved uses of drugs (includes broadening of the indication)

Copaxone Warning Letter

- Medical convention exhibit panels and DTC websites
- Violations included
  - Overstatement of efficacy
  - Broadening of indication
- Indication
  - Reduction of the frequency of relapses in patients with Relapsing-Remitting Multiple Sclerosis (RRMS), including patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis

Copaxone Warning Letter

"David Kyle" webpage: "**Running, Swimming and Biking Against Multiple Sclerosis**"

Before Copaxone

- "It's hard to believe that just a few years ago, this energetic and dynamic athlete had to use a cane for mobility and often could barely muster enough energy to work half a day. This was the case for David, who was diagnosed with multiple sclerosis (MS) in 2002. David awoke one morning experiencing numbness in his toes."

- "Over the course of a few weeks, the numbness moved up his body and he eventually became partially paralyzed from the chest down. The symptoms subsided briefly only to return just six months later, this time advancing to his entire right side."

Copaxone Warning Letter

After Copaxone

- "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.

Copaxone Warning Letter

Overstatement of Efficacy/Broadening of Indication

- Claims imply that Copaxone reverses patients' disability and enables them to lead an active lifestyle, return to work, and/or accomplish great athletic feats.

- Broadens indication by implying that Copaxone is approved to treat **all** types of MS.

- Start date of therapy (2003) implies effectiveness beyond three years of data included in the PI.

EpiPen Warning Letter

- DTC television advertisement
- Overstatement of efficacy
- Indication
  - Indicated in the emergency treatment of allergic reactions (Type 1) including anaphylaxis to stinging insects… biting insects… foods… drugs….
  - Intended for immediate administration in patients, who are determined to be at increased risk for anaphylaxis….
  - Intended for immediate self-administration as emergency supportive therapy only and are not a substitute for immediate medical care
- Most important information section of Patient Labeling
  - When you have an allergic reaction (anaphylaxis) use the EpiPen … right away and immediately go to your doctor or emergency room for more medical treatment

EpiPen Warning Letter

- TV ad included the following:
  - Mother: “Excited for Max’s birthday? Should be pretty awesome.”
  - Son: “Yeah!”
  - Mother: “Even with your peanut allergy and a cake made of who-knows what.”
  - Mother: “Because we’re prepared, right Jake?”
  - Son: “Yup!”
  - Mother: “With EpiPen.”
- Supers (over visual)
  - EpiPen (epinedrine) Auto-Injector can’t eliminate the risk of analphylaxis

OPDP Web Resources

- OPDP home page
  - http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090142.htm
- OPDP organization listing
  - http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm154886.htm
- OPDP guidances
  - http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm109905.htm#Guidances
- Warning and untitled letters
  - www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/default.htm

OPDP Contact Information

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