Marketing and Advertising in Drug Development

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Presentation Overview

• Mission

• Advice within FDA

• Advice to Industry

• Surveillance and Enforcement
OPDP’s Mission

• Protect the public health by ensuring prescription drug information is truthful, balanced, and accurately communicated

• To guard against false and misleading advertising and promotion through comprehensive surveillance, enforcement, and educational programs
Advice within FDA

• Professional Labeling
  – Prescribing Information
  – Package labeling
  – Tradename Review
    (Proprietary Name)

• Patient Labeling
  – Patient Package Insert
  – Medication Guide
  – Instructions for Use
### Patient Labeling – Medication Guide

#### Medication Guide

**TECENTRIQ** (te-SEN-trik) (atezolizumab) Injection

**What is the most important information I should know about TECENTRIQ?**
TECENTRIQ is a medicine that may treat your bladder cancer or lung cancer by working with your immune system. TECENTRIQ can cause your immune system to attack normal organs and tissues in many areas of your body and can affect the way they work. These problems can sometimes become serious or life-threatening and can lead to death. Call or see your healthcare provider right away if you get any symptoms of the following problems or these symptoms get worse:

**Lung problems (pneumonitis).** Signs and symptoms of pneumonitis may include:
- New or worsening cough
- Shortness of breath
- Chest pain

**Liver problems (hepatitis).** Signs and symptoms of hepatitis may include:
- Yellowing of your skin or the whites of your eyes
- Severe nausea or vomiting
- Pain on the right side of your stomach area (abdomen)
- Drowsiness

**Intestinal problems (colitis).** Signs and symptoms of colitis may include:
- Diarrhea (loose stools) or more bowel movements than usual
- Blood in your stools or dark, tarry, sticky stools
- Severe stomach area (abdomen) pain or tenderness

**Hormone gland problems (especially the pituitary, thyroid, adrenal glands, and pancreas).** Signs and symptoms that your hormone glands are not working properly may include:
- Feeling cold
- Constipation
- Your voice gets deeper
- Urinating more often than usual
- Nausea or vomiting
- Feeling less hungry than usual
- Feeling more hungry or thirsty than usual
- Hair loss
- Changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

**Nervous system problems (neuropathy, meningitis, encephalitis).** Signs and symptoms of nervous system problems may include:
- Severe muscle weakness
- Sensation of pins and needles in hands or feet
- Fever
- Confusion
- Changes in mood or behavior
- Extreme sensitivity to light
- Neck stiffness

**Inflammation of the eyes.** Signs and symptoms may include:
- Eye pain or redness

**Severe infections.** Signs and symptoms of infection may include:
- Fever
- Cough
- Frequent urination
- Flu-like symptoms
- Pain when urinating

**Severe infusion reactions.** Signs and symptoms of infusion reactions may include:
- Chills or shaking
- Tingling or rash
- Flushing
- Shortness of breath or wheezing
- Swelling of your face or lips
- Nausea or vomiting
- Feeling like passing out
- Back or neck pain

Getting medical treatment right away may help keep these problems from becoming more serious.

Your healthcare provider will check you for these problems during your treatment with TECENTRIQ. Your healthcare provider may treat you with corticosteroids or hormone replacement medicines. Your healthcare provider may delay or completely stop treatment with TECENTRIQ if you have severe side effects.
Advice to Industry

• Promotional materials
  – Professional audience
    • Press releases, sales aids and journal ads
    • Professional presentations
    • Websites and other electronic media
  – Patient audience
    • Patient brochures and journal ads
    • Television and radio advertisements
    • Websites and social media
THE STRUGGLE IS REAL.

AND SO AM I.

For HR+ (ER+ and/or PR+), HER2- Metastatic Breast Cancer

I have metastatic breast cancer.
It doesn’t have me.

For more information, visit www.kisqali.com.
Review of Promotional Materials

• Common Promotional Problems
  – Omitting or downplaying risk information
  – Overstating the effectiveness
  – Promoting unapproved uses
  – Misleading drug comparisons
Surveillance of Industry

• Review materials submitted to OPDP at the time of initial dissemination

• Conferences

• Complaints
  – Healthcare professionals
  – Consumers
  – Competitors
Limitations of Surveillance

• Areas not included in surveillance activities:
  – Physician offices
  – Industry-sponsored dinner and lunch programs

• That is why we developed the Bad Ad Program
  – Goals of the program
    • Increase effectiveness of surveillance program
    • Raise awareness among healthcare professionals about promotional materials that may be false or misleading
  • Anyone can submit a complaint
What will happen if you report misleading promotion to OPDP?

• Enforcement Actions
  – Contribution to ongoing OPDP surveillance activities
  – Untitled letters (Notice of Violation/NOV)
  – Warning letters
  – Injunction/consent decree
  – Seizures
  – Criminal action
OMG. Have you heard about this? As you guys know, my #morningsickness has been pretty bad. I tried changing things about my lifestyle, like my diet, but nothing helped, so I talked to my doctor. He prescribed me #Diclegis, and I felt a lot better and most importantly, it's been studied and there was no increased risk to the baby. I'm so excited and happy with my results that I'm partnering with Duchesnay USA to raise awareness about treating morning sickness. If you have morning sickness, be safe and sure to ask your doctor about the pill with the pregnant woman on it and find out more www.diclegis.com; www.DiclegisImportantSafetyInfo.com

Please note: image of Diclegis bottle will be prominent enough to read established name

2015-0069-01
If You See Something, Say Something!

- e-mail to BadAd@fda.gov or
- calling 855-RX-BADAD (855-792-2323)

- Phone number: (301) 796-1200
- Fax number: (301) 847-8444
Questions?
Back-up Slides
Reminder Ad
Broadcast Advertising

- **“Major Statement”**
  - Information relating to the major side effects and contraindications

- **“Adequate Provision”**
  - Provides for dissemination of the Prescribing Information
  - Recognizes the inability of broadcast advertisements of reasonable length to present and communicate this information effectively
Ibrance TV Ad

https://www.ispot.tv/ad/wITp/ibrance-julies-new-normal
Total 2253 Promotional Pieces by Year

*Mixed = Internet pieces, video news releases and "other" material
** Mixed pieces are listed as either professional or consumer