Case Study

LOMAIRA™

(phentermine hydrochloride USP) tablets, CIV

Bad Ad Case Study

Lomaira™ (phentermine hydrochloride USP) tablets, CIV

Facilitator Guide

Approximate Time: 30 minutes

Exercise prerequisite:

Students should view the Bad Ad e-learning course located at www.fda.gov/BadAd prior to completing this exercise.

Student Materials:

Before the exercise:

- Lomaira exhibit panel
- Prescribing Information (PI) for Lomaira

After the exercise:

- FDA Warning Letter for Lomaira

Facilitator Materials:

- Facilitator guide (includes a detailed answer key for the case study)

Facilitator instructions:

1. Distribute the Lomaira exhibit panel along with the PI for Lomaira.
2. Present the Background and Case Study Instructions shown below.
3. Allow students approximately 10 minutes to review the Lomaira exhibit panel.
4. Use the discussion questions in this guide to assist students in identifying prescription drug promotion issues of concern, including false or misleading statements.
5. After discussing the issues of concern, distribute the FDA Warning Letter for Lomaira.

Background and Case Study Instructions[1]:

This promotional piece is an exhibit panel for Lomaira that appeared in the main exhibit hall at the Endocrine Society's 99th Annual Meeting and Expo and the American College of Cardiology's 66th Annual Scientific Session and Expo during 2017. Below are the indication and summary of the most serious and most common risks associated with the use of Lomaira. According to the PI:

> LOMAIRA™ tablets are indicated as a short-term (a few weeks) adjunct in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity in patients with an initial body mass index greater than or equal to 30 kg/m^2, or greater than or equal to 27 kg/m^2 in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia). . . .
>
> The limited usefulness of agents of this class, including phentermine . . . ., should be measured against possible risk factors inherent in their use . . . .

Lomaira is contraindicated in patients with a history of cardiovascular disease; during or within 14 days following the administration of monoamine oxidase inhibitors; in patients with hyperthyroidism, glaucoma, agitated states, or history of drug abuse; in pregnant or nursing patients; and in patients with a known hypersensitivity, or idiosyncrasy to the sympathomimetic amines. The PI for Lomaira contains warnings regarding coadministration with other drug products for weight loss, primary pulmonary hypertension, valvular heart disease, development of tolerance and discontinuation, effect on the ability to engage in potentially hazardous tasks, risk of abuse and dependence, usage with alcohol, use in patients with hypertension, and use in patients on insulin or oral hypoglycemic medications for diabetes mellitus. Adverse events have been reported in the cardiovascular, central nervous, gastrointestinal, allergic, and endocrine systems.

Using the PI as a reference, identify the issues of concern in the exhibit panel. (Approximately 10 minutes)

[1] When FDA reviews a promotional piece, it determines whether the relevant legal and regulatory requirements are met, including whether the piece is truthful and not misleading, in light of the information available at that time.

Discussion Questions:

General

1. What are the key promotional messages for Lomaira on the exhibit panel?

2. Based on your knowledge and information from the PI, which claims, if any, do you think are false or misleading?

Specific

1. Does the exhibit panel adequately communicate adverse events and other risks associated with Lomaira?

   (See Detailed Answer Key #1 – False or Misleading Risk Presentation)

2. Is there adequate context provided in the following claims (emphasis original)?

   - "**THE POWER OF THREE**"
     "**Diet**" "**Exercise**" "**Lomaira™**"

   - "**Consider adding Lomaira™ to your patients' weight-management plan**"

   (See Detailed Answer Key #2 – Omission of Material Facts)

Detailed Answer Key

1. False or Misleading Risk Presentation

The exhibit panel is misleading because it makes representations and/or suggestions about the benefits of Lomaira; however, it fails to communicate any risk information. By omitting the risks associated with Lomaira, including serious and potentially fatal risks, the panel fails to provide material information about the consequences that may result from the use of the drug and creates a misleading impression about the drug's safety.

2. Omission of Material Facts

The exhibit panel makes several representations and/or suggestions about the benefits of Lomaira such as the following (emphasis original):

- "**THE POWER OF THREE**"
  "**Diet**" "**Exercise**" "**Lomaira™**"

- "**Consider adding Lomaira™ to your patients' weight-management plan**"

However, the panel is misleading because it fails to communicate material information regarding the FDA-approved indication for Lomaira. Specifically, it omits the following material information from the INDICATIONS AND USAGE section of the PI (underlined emphasis added):

> LOMAIRA™ tablets are indicated <u>as a short-term (a few weeks)</u> adjunct in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity <u>in patients with an initial body mass index greater than or equal to 30 kg/m^2, or greater than or equal to 27 kg/m$_2$ in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia).</u>
>
> <u>The limited usefulness of agents of this class, including phentermine should be measured against possible risk factors inherent in their use</u> . . . .

By omitting this information, the panel creates a misleading impression about the FDA approved indication for Lomaira. These omissions are particularly concerning from a public health perspective due to the serious health risks associated with Lomaira.

Discussion and Outcome

The FDA issued a Warning Letter for this Lomaira exhibit panel on December 19, 2017. As a result, the manufacturer for Lomaira stopped using the exhibit panel and distributed a “Dear Health Care Provider Letter” to correct the violative messages cited in the Warning Letter. In addition, the manufacturer for Lomaira stopped using other promotional pieces for Lomaira that contained similar claims and presentations.