***Phase 1 High Cholesterol***

***FDA Online Study*
*Survey Instrument***

**SCREENING / INTRODUCTION**

Thank you for agreeing to participate in this study today. Make sure you are comfortable and can read the screen from where you sit. The survey will include some audio, so please make sure the sound is on and the speaker volume is turned up.

This study will take about 25 minutes to complete. We ask you to please complete the study in one sitting (without taking any breaks) in order to avoid distractions.

First, we will ask you a few health-related questions. Next, we will let you explore a Web site about a new medicine. Finally, we will ask you some questions about the medicine.

**S1. [Illness Diagnosis #1]**

Have you ever been diagnosed by a health professional with any of the following conditions? (Check all that apply)

 Arthritis

 Sleep Apnea

 High Cholesterol🡺 [Continue]

 Crohn’s Disease

 Diabetes

 None of the above

**S2. [Illness Diagnosis #2]**

Do you still have high cholesterol?

 Yes 🡺 [Skip to Web Site Instructions]

 No 🡺 [Continue to S3]

**S3. [Illness Diagnosis #3]**

Have you taken any medication for high cholesterol in the past 12 months?

 Yes 🡺 [Continue]

 No 🡺 [Terminate]

**WEB SITE INSTRUCTIONS**

On the next screen, you will see a Web site for a new product. The Web site will open in a new window. Please turn up your speakers and review the site carefully.

Once you finish, please close the Web site window and click *Next* to continue with the study.

 **[DIRECT PARTICIPANTS TO APPROPRIATE WEB SITE]**

**SURVEY INSTRUCTIONS**

Please answer the following questions based on the Web site you visited.

**Q1. [Web Site Viewing]**

**Were you able to view and explore the Web site for PEXACOR?**

 Yes

 No 🡺 [Terminate]

**Q2. [Drug Knowledge (indication, illness)]**

**What condition does PEXACOR treat?**

High Cholesterol

High Blood Pressure

Anemia (Low Red Blood Cells)

Congestive Heart Failure

**Q3. [Risk Info Exposure]**

**PEXACOR.com had information about PEXACOR’s benefits and risks. How much of the risk information did you read?**

All of it (100%)

Most of it (50-99%)
Some of it (1-49%)
None of it (0%)

**P-RB4. [Risk Information Signal Awareness]**

**Which of the following statements appeared on the PEXACOR.com home page?**

“Please see Important Safety Information below.”

“Please see Important Safety Information by visiting this link.”

“Please see your local pharmacist for Important Safety Information.”

“Please contact KAJ Pharmaceuticals at 1-800-692-2557 for Important Safety Information.”

None of the above statements appeared on the Web site.

**[PHASE 1: ASK Q8-11 BEFORE Q4-7]**

**Q8. [Risk Recall]**

**What are the side effects and negative outcomes of PEXACOR?**

(open ended)

**[DISPLAY Q9 AND Q10 ON THE SAME SCREEN]**

When considering a new medicine, most people ask two questions:

1. Will this medicine cause any side effects?
2. If it does cause side effects, how serious will the side effects be?

The questions below ask about these two ideas.

**Q9. [Perceived Risk - Likelihood of Risk]**

**In your opinion…If 100 people take PEXACOR, how many will have any side effects or negative outcomes? Please enter a number in the box below.**

\_\_\_ people

**Q10. [Perceived Risk - Magnitude of Risk]**

**In your opinion…If PEXACOR did cause a person to have side effects or negative outcomes, how serious would they be?**

1 2 3 4 5 6

Not at all Very

serious serious

**Q11. [Risk Recall – Closed]**

**Please check which of the following were mentioned on the Web site as warnings, side effects, or negative outcomes of taking PEXACOR. Even if you think a statement is true, please select it only if it was mentioned on the site.**

|  |  |  |
| --- | --- | --- |
| **[RANDOMIZE ORDER]** | **Mentioned on Web Site** | **Not Mentioned on Web Site** |
| a. PEXACOR cannot be taken by people who have liver problems. | x |  |
| b. PEXACOR can cause thrombotic thrombocytopenic purpura (TTP). | x |  |
| c. A side effect of PEXACOR is diarrhea. | x |  |
| d. Patients taking PEXACOR may be at higher risk for internal bleeding.  |  | x |
| e. PEXACOR can cause birth defects. | x |  |
| f. A side effect of PEXACOR is difficulty concentrating. |  | x |
| g. Side effects of PEXACOR usually occur within one month of starting therapy. |  | x |
| h. People who are taking other cholesterol medications cannot take PEXACOR. |  | x |

**Q4. [Benefit Recall]**

**What are the benefits of PEXACOR?**

(open ended)

**[DISPLAY Q5 AND Q6 ON SAME SCREEN]**

When considering a new medicine, most people ask two questions:

1. Will this medicine work?
2. If it does work, will it help a little or help a lot?

The questions below ask about these two ideas.

**Q5. [Perceived Efficacy - Likelihood of Benefit]**

**In your opinion…If 100 people take PEXACOR, for how many will the drug work? Please enter a number in the box below.**

\_\_\_ people

**Q6. [Perceived Efficacy - Magnitude of Benefit]**

**In your opinion…If PEXACOR did help a person’s high cholesterol, how effective would PEXACOR be?**

1 2 3 4 5 6

Would help high cholesterol very little Would help high cholesterol a lot

**Q7. [Benefit Recall – Closed] [Benefit Knowledge]**

**Please check which of the following were mentioned on the Web site as benefits of taking PEXACOR. Even if you think a statement is true, please select it only if it was mentioned on the site.**

|  |  |  |
| --- | --- | --- |
| **[RANDOMIZE ORDER]** | **Mentioned on Web Site** | **Not Mentioned on Web Site** |
| a.  PEXACOR can lower levels of LDL cholesterol (bad cholesterol). | x |  |
| b.  PEXACOR can lower levels of fats (triglycerides) in the blood. | x |  |
| c.  PEXACOR can raise levels of HDL cholesterol (good cholesterol). | x |  |
| d.  PEXACOR can raise the number of red blood cells (RBCs). |  | x |
| e.  PEXACOR contains an enzyme that helps people lose weight. |  | x |
| f.  PEXACOR has been proven to reverse heart disease. |  | x |
| g.  PEXACOR is a type of statin. | x |  |
| h.  PEXACOR can lower blood pressure.  |  | x |

The next few questions ask about PEXACOR’s risk and benefits. By risks, we mean the drug’s possible side effects and negative outcomes. By benefits, we mean the drug’s ability to improve symptoms of high cholesterol.

**Q12. [Drug Balance of Risks / Benefits]**

**Thinking about all its risks and benefits, how would you rate PEXACOR:**

1 2 3 4 5 6 7

Risks outweigh benefits Benefits outweigh risks

**Q18. [Perceived Clarity / Understanding of Site]**

**Please rate your agreement or disagreement with each of the following statements.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **[RANDOMIZE ORDER]** | **Strongly disagree** | **Somewhat disagree** | **Neither agree nor disagree** | **Somewhat agree** | **Strongly agree** |
| 1. The Web site clearly communicated the *benefits* of PEXACOR.
 |  |  |  |  |  |
| 1. The Web site clearly communicated the *risks* of PEXACOR.
 |  |  |  |  |  |

**Q13. [Web Site Balance of Risks / Benefits]**

**Please think about how the risks and benefits of PEXACOR were presented on the Web site. Did the site place more emphasis on risks or more emphasis on benefits?**

1 2 3 4 5 6 7

More emphasis on risks More emphasis on benefits

**Q14. [Behavioral Intentions (seek drug info, talk to doc, etc.)]**

**Based on what you learned, please rate how likely or unlikely you are to do each of the following behaviors.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| [RANDOMIZE ORDER] | Very Unlikely | Somewhat Unlikely | Neither Likely nor Unlikely | Somewhat Likely | Very Likely |
| a. Talk to your doctor about PEXACOR |  |  |  |  |  |
| b. Ask your doctor about getting a sample of PEXACOR |  |  |  |  |  |
| c. Ask your doctor to prescribe PEXACOR |  |  |  |  |  |
| e. Join an online community or support group *for people with high cholesterol* |  |  |  |  |  |
| f. Join an online community or support group *sponsored by PEXACOR* |  |  |  |  |  |

**Q15. [Behavioral Intentions (seek drug info, talk to doc, etc.)]**

**Based on what you learned, please rate how likely or unlikely you are to do each of the following behaviors.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **[RANDOMIZE ORDER]** | **Very Unlikely** | **Somewhat Unlikely** | **Neither Likely nor Unlikely** | **Somewhat Likely** | **Very Likely** |
| a. Look for information online about other people’s experience with PEXACOR |  |  |  |  |  |
| b. Look for information *about PEXACOR* on medical Web sites |  |  |  |  |  |
| c. Look for information *about high cholesterol* on medical Web sites |  |  |  |  |  |
| d. Print information from PEXACOR.com to discuss with your doctor |  |  |  |  |  |

**Q16. [Attitudes Toward Drug]**

**Based on what you learned, please rate PEXACOR. [RANDOMIZE ORDER OF ROWS]**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **1** | **2** | **3** | **4** | **5** | **6** | **7** |  |
| **Bad product** |  |  |  |  |  |  |  | **Good product** |
| **Disliked a lot** |  |  |  |  |  |  |  | **Liked a lot** |
| **Unpleasant** |  |  |  |  |  |  |  | **Pleasant** |
| **Poor quality** |  |  |  |  |  |  |  | **Good quality** |

**Q19. [Site Skepticism]**

**How likely or unlikely is it that the information about PEXACOR presented on this Web site is true?**

1 2 3 4 5 6 7

Extremely Extremely

Unlikely Likely

**Q20. [Site Skepticism]**

**How skeptical or not skeptical are you about the information about PEXACOR presented on this Web site?**

1 2 3 4 5 6 7

Not at all Extremely

Skeptical Skeptical

**Q22. [Illness Information Seeking (Knowledge Proxy)]**

**In the past 12 months, how often did you use the Internet to look for health or medical information about high cholesterol or treatments for high cholesterol?**

Once a week

Once a month

Every few months

Less often

Never

**Q24. [Web Navigation Skills]**

**We would like to know more about your Internet skills. For each statement below, please tell us to what extent you agree or disagree with the statement.**

[Q24A.] I am extremely skilled at using the Web.

1 2 3 4 5 6 7

Strongly Strongly

Disagree Agree

[Q24B.] I consider myself knowledgeable about good search techniques on the Web.

1 2 3 4 5 6 7

Strongly Strongly

Disagree Agree

[Q24C.] I know less about using the Web than most users.

1 2 3 4 5 6 7

Strongly Strongly

Disagree Agree

[Q24D.] I know how to find what I am looking for on the Web.

1 2 3 4 5 6 7

Strongly Strongly

Disagree Agree

**Q25. [Trust in Online Information (HMTS)]**

**In general, how much do you or would you trust information about prescription drugs from each of the following sources?**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **[RANDOMIZE ORDER]** | **Not at all** | **A little** | **Some** | **A lot** |
| Drug Web sites (example: Pexacor.com) |  |  |  |  |
| Medical Web sites (example: WebMD.com) |  |  |  |  |
|  |  |  |  |  |
| Family and friends |  |  |  |  |
| Doctors, nurses, and healthcare providers |  |  |  |  |
| Food and Drug Administration (FDA) |  |  |  |  |
| Pharmaceutical companies |  |  |  |  |
|  |  |  |  |  |

**Q. [Illness Knowledge – Subjective]**

**In general, how much do you know about seasonal allergies? Would you say you know:**

Nothing at all

Only a slight amount

Some

A good bit

A lot

**Q26. [Current Prescription Drug Use]**

**Are you currently taking, or have you ever taken, any prescription drugs for high cholesterol?**

Currently taking

Have taken in the past but not currently taking

Have never taken

**Q27. [History of Side Effects]**

**Have you ever had a SERIOUS side effect from a prescription drug?**

Yes

No

Don’t Know

**Q28. [Time Since Diagnosis]**

**When did a healthcare professional first tell you that you had high cholesterol?**

Six months ago or less

More than six months ago but less than a year ago

A year ago or more but less than 5 years

Five years ago or longer

**Q29. [Severity of Illness – Subjective]**

**In general, how severe is your high cholesterol? Would you describe it as:**

* Very mild
* Mild
* Moderate
* Serious
* Severe

**Q31. [Health Literacy – Assistance (Leaflet Study)]**

**How often do you have someone (like a family member or friend) help you read instructions, pamphlets, or other written material from your doctor or pharmacy?**

* Never
* Occasionally
* Sometimes
* Often
* Always

**Q32. [Health Literacy – Self Efficacy (Leaflet Study)]**

**How confident are you filling out medical forms by yourself?**

* Not at all
* A little bit
* Somewhat
* Quite a bit
* Extremely

**Q33. [Survey Device]**

**What did you use to complete today’s survey?**

* Laptop computer / Netbook computer
* Desktop computer
* Handheld phone (iPhone, Blackberry, Droid)
* Handheld device other than a phone (iPod Touch, Palm Pilot, iPad)
* Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**CLOSING**

The purpose of this study is to learn about how individuals use information from medical Web sites. In order to get a real-life reaction, we used a pretend product in this study.

PEXACOR is not a real product and is not available for sale. Please see your healthcare provider for questions about high cholesterol.

You have been very helpful. Thank you very much for your participation!