

**Attachment A**  
**Toll-Free Statement Internet Research - Participant Screener and Questionnaire**

**Toll-Free Statement Internet Research**  
**Participant Screener**  
*Draft*

**Recruitment Criteria**

N = 1600

Sixteen hundred people will be recruited over the Internet to participate in a survey lasting no more than 15 minutes.

Participants will be randomly assigned to 10 conditions.

- Gender:
  - Roughly equal distribution of men and women:
  - At least 40%-60% men in each condition
  
- Age:
  - Must be 21 years or older
  - Spectrum of ages from 20s to 80s
  - No more than 15% under age 25 in each condition
  - At least 40% over age 55 in each condition
  
- Education:
  - Spectrum from high school grad to post grad
  - No more than 30% with advanced degrees
  - At least 15% with high school education or less

## Attachment A

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#### Screener for Toll-Free participants (Please place in appropriate Internet format)

1. What is your date of birth?
  - Under age 21 → eliminate [thank respondent politely]
  - Over age 21 → continue
2. Can you read English?
  - Yes → continue
  - No → eliminate [thank respondent politely]
3. Gender:
  - Male
  - Female
4. What level of education have you reached?
  - Less than high school
  - High school graduate
  - Some college
  - College graduate
  - Advanced degree
5. What is your ethnic background?
  - White, not Hispanic or Latino Origin
  - Black or African American
  - Hispanic or Latino
  - American Indian or Alaska Native
  - Asian
  - Native Hawaiian or Pacific Islander
  - Other [Specify] \_\_\_\_\_
  - Refused

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*We will obtain gender, age, ethnicity, and education from the Synovate screener. Statements will be shown in context (i.e., with other label info).*

Thank you for agreeing to participate today. This study looks at information that comes with prescription drugs or on over-the-counter drug labels. We are interested in what your reactions are to the different types of information you might see there. Your participation will help provide the best information for people all over the country. All of your answers are anonymous and confidential. Please answer the questions honestly. The study should take approximately 15 minutes....{standard instructions for participating in studies from vendor}

*[Ensure a progression bar that allows participants to determine how far through the study they are. Also ensure that they have an option to continue the study at a later time if necessary]*

First, we would like you to look at a [prescription bottle][drug label], one similar to those you may have received or bought at a pharmacy. After you have spent as much time as you like looking at the [bottle][label], please click the “Next” button to answer some questions about it.

[PROGRAMMER: Show [prescription drug container] or [OTC drug label] –randomly assigned]  
[PROGRAMMER—within Rx or OTC condition, randomly assign statements]

Imagine you have taken a drug with this information on the label. Please think about each of the following situations and answer each question as best you can.

**Attachment A**  
**Toll-Free Statement Internet Research - Participant Screener and Questionnaire**

1. a. How likely would you be to do the following things if you had a **mild** side effect of this drug? [RANDOMIZE response options]

	Not at all likely	Somewhat likely	Moderately likely	Very likely	Extremely likely
Call your doctor right away					
Call FDA right away					
Treat with another OTC drug					
Go to the emergency room right away					
Call the poison control center right away					
Call your doctor next day or later					
Call FDA next day or later					
Do nothing					
Do something else					

1. b. Please select the action above that you would do **first** if you had a mild side effect of this drug.

2. a. How likely would you be to do the following things if you had a **severe** side effect of this drug? [RANDOMIZE response options]

	Not at all likely	Somewhat likely	Moderately likely	Very likely	Extremely likely
Call your doctor right away					
Call FDA right away					
Treat with another OTC drug					
Go to the emergency room right away					
Call the poison control center right away					
Call your doctor next day or later					
Call FDA next day or later					
Do nothing					
Do something else					

2. b. Please select the action above that you would do **first** if you had a severe side effect of this drug.

**Attachment A**  
**Toll-Free Statement Internet Research - Participant Screener and Questionnaire**

3. a. How likely would you be to do the following things if you took an accidental **overdose** of this drug? [RANDOMIZE response options]

	Not at all likely	Somewhat likely	Moderately likely	Very likely	Extremely likely
Call your doctor right away					
Call FDA right away					
Treat with another OTC drug					
Go to the emergency room right away					
Call the poison control center right away					
Call your doctor next day or later					
Call FDA next day or later					
Do nothing					
Do something else					

3. b. Please select the action above that you would do **first** if you took an accidental overdose of this drug.

The following questions are about the following statement:

[Insert statement]

[Statement should be visible at top of screen for remainder of study]

Think just about this statement when answering the next few questions.

4. Thinking about the drug information you saw, why would you call your doctor after experiencing a side effect? (please check all that apply) [RANDOMIZE response options]

- To find out if the side effect is serious
- To make an appointment
- To find out if I should go to the emergency room
- To tell my doctor I don't want to take the drug any more
- To find out if I should keep taking this drug
- So that my doctor can warn other patients about the side effect

**Attachment A**  
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5. Thinking about the bottle you saw, why would you call FDA after experiencing a side effect?  
(please check all that apply) [RANDOMIZE response options]

- To find out if the side effect is serious
- To tell them about the side effect I have/had
- To find out if I should go to the emergency room
- To find out if I should keep taking this drug
- To warn others about my side effect
- To ask FDA to call my doctor
- To get medical advice

6. How likely are you to call FDA if you have a side effect?

- Very likely
- Somewhat likely
- Neither likely nor unlikely
- Somewhat unlikely
- Very unlikely

7. When you call this number, who do you think you will talk to? (please select one)  
[RANDOMIZE response options]

- A trained medical professional who will answer my questions
- A clerk who will record my answers for someone else
- An answering machine where I can leave my report
- An answering machine that tells me how to get a form to mail in to FDA

**Attachment A**  
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8. How likely would you be to report the following types of side effects to the FDA?

	Not at all likely	Somewhat likely	Moderately likely	Very likely	Extremely likely
Side effects that bothered me for a few days					
Side effects that did not go away					
Side effects that made me miserable					
Side effects that sent me to my doctor					
Side effects that sent me to the emergency room					
Side effects that killed someone I know					
Side effects not listed on the label					
All side effects I had					

9. Which of the following side effects would you report? (please check all that apply)

- Nausea
- Headache
- Liver failure
- Ruptured spleen
- Appendicitis
- Dry mouth
- Itchiness
- Loss of toe
- Fainting
- Trouble breathing
- Sore throat
- Chest pain
- None

**Attachment A**  
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10. Which of the following best describes what “serious side effect” means to you? (please select one)

- Any effect other than the one that treats my condition
- A side effect that I notice
- A side effect that really impacts my activities for a few days
- A side effect that requires a visit to the doctor
- A side effect that requires a trip to the emergency room
- A side effect that requires surgery

11. When you contact the FDA about side effects, what do you think will happen to the information you give? (please check all that apply) [RANDOMIZE response options]

- My information will be added to information from other people who had side effects
- My information will be used to trace me
- My information will be used to make drugs safer
- My information will be stored

12. Why wouldn't you call the FDA? (please check all that apply) [RANDOMIZE response options]

- Privacy issues
- Don't expect a satisfactory response
- Don't trust the government
- Can't be bothered
- Side effect is already written on the container
- Side effect is minor
- I never have any side effects

13. How understandable or confusing is the statement at the top of your screen? (please select one)

- Very understandable
- Somewhat understandable
- Neither understandable nor confusing
- Somewhat confusing
- Very confusing



**Attachment A**  
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14. How clear is this statement? (please select one)

- Very clear
- Somewhat clear
- Neither clear nor unclear
- Somewhat unclear
- Very unclear

15. If you were given the website, how likely would you be to use it? (please select one) [ASK ONLY of those who *do not* have website in their statement]

- Very likely
- Somewhat likely
- Neither likely nor unlikely
- Somewhat unlikely
- Very unlikely

16. Out of the following choices, which would you be most likely to do if you wanted to report a side effect? (please select one) [ASK ONLY of those who *do* have website in their statement]

- Call the 1-800 number
- Go to the website
- Write to FDA
- Call my doctor

17. How important do you think reporting side effects to the FDA is? (please select one)

- Very important
- Somewhat important
- Neither important nor unimportant
- Somewhat unimportant
- Very unimportant

18. a. Have you ever experienced a reaction or side effect from a prescription drug?

- Yes
- No (skip to 19)

**Attachment A**  
**Toll-Free Statement Internet Research - Participant Screener and Questionnaire**

18. b. What did you do after you had that side effect? (please select one)

- Did nothing
- Called my doctor for advice
- Called my doctor for an appointment
- Went to ER
- Took another medication to counteract side effect
- Other

19. a. Have you ever experienced a reaction or side effect from an over-the-counter drug?

- Yes
- No (skip to 20)

19. b. What did you do after you had that side effect? (please select one)

- Did nothing
- Called my doctor for advice
- Called my doctor for an appointment
- Went to ER
- Took another medication to counteract side effect
- Other

20. a. Are you currently taking any prescription drugs?

- Yes
- No (skip to 21)

20. b. How many? (type in number)

21. a. Are you currently taking any over-the-counter drugs?

- Yes
- No (skip to 22)

**Attachment A**  
**Toll-Free Statement Internet Research - Participant Screener and Questionnaire**

21. b. How many? (type in number).

\_\_\_\_\_

22. Are you:

- Hispanic or Latino
- Not Hispanic or Latino

23. Which of these best represents your ethnic group? You may choose one or more. Would you say that you are:

- American Indian or Alaska Native
- Asian
- Black or African-American
- Native Hawaiian or Other Pacific Islander
- White

24. What is the last grade of school that you completed? Was it: (may not need this if in screener)

- Grade school or less
- Some high school
- Completed high school
- Some college
- Completed college
- Graduate school or more
- Other beyond high school  
(business, technical, etc.)